CBA 27th Annual Conference–Maryland

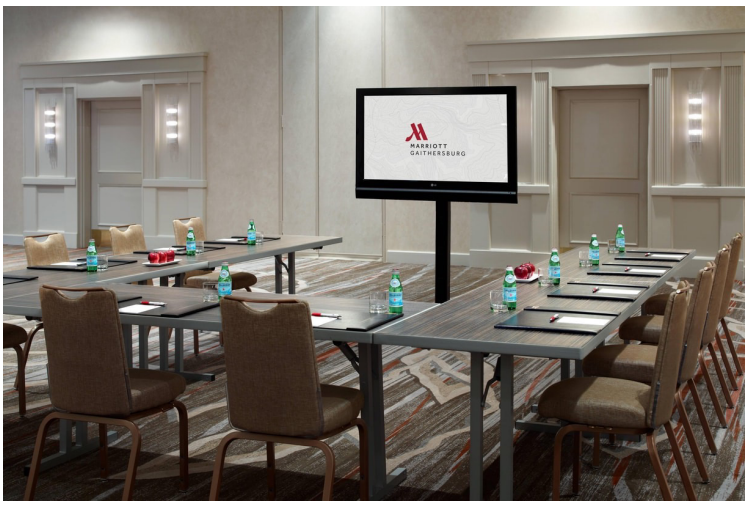
Empowering Healthcare with Cutting–Edge Biopharma Technologies and Leading Global Partnerships

The 27th Annual Conference

Chinese Biopharmaceutical Association

The Bridge Between
US and China Biopharmaceuticals

December 17th, 2022
Marriott Washingtonian Center, Maryland, USA



Washingtonian Ballroom & Lakeside Ballroom, 9751 Washingtonian Blvd, Gaithersburg, MD 20878

Welcome Letter from the CBA President

Dear CBA Members and Friends,

It is my great pleasure to warmly welcome you to the 27th Annual Conference of the Chinese Bio–pharmaceutical Association in the US (CBA–USA). This year, the CBA conference is an onsite–online hybrid event, and it is being held on Dec 17 2022 in Maryland, USA.

CBA was established by a group of then young Chinese–American biopharmaceutical professionals in 1995 with a vision to provide a platform for collaboration in the life sciences and biopharmaceuti–cal industry. Over the past twenty–seven years, CBA has gone through a robust growth phase wit–nessing the early days of biotech and its booming into the biopharmaceutical industry. The CBA annual conference serves to reinforce and expand CBA's commitment to cater to changing needs by fostering cutting–edge technologies, stimulating greater global collaboration and partnerships between US and China in the biotech and pharmaceutical arenas.

Looking back in the past year, the pandemics is still raging on, however, with our super dedicated volunteers and strong partners, CBA has successfully hosted multiple momentous events, such as career fair, appreciation dinners, summer picnics, scientific symposiums, and numerous ad–hoc virtual events and webinars. Throughout the whole year, CBA has truly provided a bridge for biotech companies, scientists, entrepreneurs and researchers in both US and China to communicate and interact with each other, to develop their careers and build their companies.

It is my honor to serve as the chair of the 27th Annual Conference Organizing Committee. The theme of the annual conference for this year is "Empowering Healthcare with Cutting–Edge Biopharma Technologies and Leading Global Partnerships". We are very fortunate and honored to have more than 30 distinguished speakers who will present on several hot topics arranged into eight sessions. The conference promises to share insights of the world's elite minds on the latest progress in global biopharmaceutical and healthcare development.

The event is co–sponsored by the Maryland Department of Commerce, with support from CBA–Canada and CBA–Boston chapters. This year, CBA has received generous support from our sponsors, including pharmaceutical companies, contract research organizations (CROs), and medi–cal device companies operating in the US and China. On behalf of CBA, I sincerely thank all of our sponsors and partners for their support and contribution to the success of this conference.

As the chair of the conference organizing committee, I owe the greatest debt to all the committee members, volunteers and CBA friends who have worked diligently to organize every detail of the conference. I am very grateful for your dedication to this conference and other CBA events. I truly hope that every one of you, whether onsite or online, will enjoy the event.

Sincerely,

Song Wu, PhD

CBA President and the 27th CBA Annual Conference Chair

Head of Translational Oncology, Hansoh Bio/Hansoh Pharm

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1995–2022 CBA History and Accomplishments

The Chinese Biopharmaceutical Association–USA (CBA–USA, www.cba–usa.org) is one of the largest Chinese American professional associations in the US. CBA was founded in 1995 by a group of Chinese American biopharmaceutical professionals as a non–political and non–profit organization, headquartered in the Washington DC area. Over the past 27 years, through the persistent efforts of CBA's strong leader–ship, devoted members and volunteers, and sponsors and supporters, CBA has become a well–recognized and influential professional organization with more than 8,000 members scattered in the US, China, and the rest of the world.

The mission of CBA is to foster communication and collaboration among biopharmaceutical and life science professionals and to foster business collaborations among countries and regions, especially between the US and China.

CBA has earned an excellent reputation both in China and the US for developing and fostering friendship and collaboration in the biopharmaceutical and life sciences industries by bringing science, policy, and investment opportunities together. Our efforts have been applauded over the years by industry executives and prominent leaders from both the US and China. Numerous Nobel laureates, members of the US National Academies of Science, Engineering, and Medicines, top US and China government officials have attended the CBA events in the past. Of special mention, China's former Minister of Health, Dr. Zhu Chen, former CFO of US Department of Labor, Samuel Tingsing Mok, former Chinese Ambassadors to the US, Wenzhong Zhou and Daoyu Li, have attended and spoken at CBA's Annual Conferences or sponsored events. Several prestigious scientific journals, including Nature, Science, and Bioprocess International, have reported on CBA's events and its members.

Since its establishment, CBA has stayed true to its mission of bridging the biopharmaceutical industry within and between the US and China. Its signature event, the CBA Annual Conferences, have been suc–cessfully held in the US or in China for 27 consecutive years As an effective platform, the CBA Annual Conferences continue to bring together elite scientific minds, successful entrepreneurs, and investors from both the private and government sectors to these events. Some of the key topics at past CBA annual conferences include:

- Cutting edge sciences and technologies in drug development
- Commercialization and globalization of biopharmaceuticals through partnerships
- Regulatory perspectives of drug development
- Startups, mentoring and entrepreneurships

In addition to the CBA Annual Conferences, CBA has hosted and co–hosted many workshops and semi–nars focusing on local and international hot topics in cutting–edge science and technologies. Some of the most recent events despite of the COVID–19 pandemic include:

- 2022 CBA Career Fair and Scientific Symposium, Maryland, US
- 2022 CBA Appreciation Dinner, Maryland, US
- 2022 CBA Annual Conference,Guangzhou, China
- 2021 BioInnovation Summit and CBA Annual Conference, Hangzhou, China
- 2021 Bio Partnering APAC, Shanghai, China

- 2020 An Overview of FDA COVID-19 Guidance (Virtual)
- 2020 How Will the US-China Relationship Affect the Biotech Industry? (Virtual)
- 2020 Biomap Forum on COVID-19 Vaccines and Therapeutic Antibodies Development
- 2020 IGC Forum on Immunotherapy, Cell Therapy and Gene Therapy, Shanghai, China
- 2020 AI and Machine Learning in Medicine and Beyond (Virtual)
- 2019 Spring Workshop on Genomic Editing-Opportunities and Challenges, Maryland, US
- 2019 CBA Scientific Forum, Maryland, US
- 2019 CBA Annual Conference, Guangzhou, China

In the past 27 years, CBA also has served as an incubator for talents and entrepreneurs, and a place for professional networking and career development. Serving as good examples, many former CBA presidents and board members have advanced their professional leadership skills and become established industry leaders in the US and China.

Starting in 2016, CBA has started and continued to regular workshops and webinars to provide more opportunities for seasoned professionals to share their experiences and expertise with wider audiences... Each of these events attracted hundreds of medical, clinical, and pharmaceutical students and professionals who were seeking new or advanced career opportunities.

In 2018, CBA launched an initiative to form multiple small study groups for members to discuss innovative trends in the biopharma industry, exchanging their expertise and deepening their knowledge. They are the Clinical Translational Medicine Study Group and the Clinical and Regulatory Affairs Study Group. Other study groups that cover the latest trends in additional interest areas in drug development are under conception.

Lastly, CBA is also a place for Chinese American pharmaceutical professionals to get together and celebrate. Over these years, the CBA Chinese New Year Gala and summer/fall picnics provided a relaxing and fun social setting for CBA members to connect and celebrate with friends and families.

Looking back, CBA's success is largely attributed to the active involvement of its members around North America and China who strongly believe in its mission. As the global biopharmaceutical and healthcare industry continues to evolve and grow, particularly in China and the Asia Pacific area. CBA members are looking forward to continuing the legacy of this great organization and rising to the challenges ahead.

CBA PRESIDENTS

Song Wu, Ph.D.

President of Chinese Biopharmaceutical association (CBA)

Dr. Song Wu is the current President of the Chinese Biopharmaceutical Association (CBA) and a member of the Board of Directors. Dr.Wu joined Hansoh Bio/Pharma in August 2021 as head of translational oncology. His leadership focuses on clinical strategy development of all clinical oncology programs and translational strategy of preclinical projects. Prior to joining Hansoh, Dr. Wu worked for Oncology translational medicine in AstraZeneca from 2015 to 2021. He made critical contributions to early and late phase development of multiple IO assets, including Imfinzi, Imjudo and Oleclumab etc.. Dr.Wu worked for Eli–Lilly from 2005 to 2015. He held a few positions at Lilly, including bioinformatics scientist in Lilly Singapore research center and translational science lead in Lilly Oncology. He focused on leading biomarker development of oncology assets involving RTK/epigenetics inhibitors and bispecific Mabs, such as Abemaciclib. Dr. Wu obtained his PhD degree from National University of Singapore. Dr.Wu has broad research experience in oncology translational science. His key research interest is studying resistant mechanism for therapies in lung cancer.

Hang Lu, M.D.

Immediate Past President of Chinese Biopharmaceutical association (CBA)

Dr. Hang Lu is the Immediate Past President of the Chinese Biopharmaceutical Association (CBA) and a member of the Board of Directors. Dr. Lu obtained his medical degree from Zhejiang University. He completed post–doctoral research training at the University of British Columbia with a sponsorship from the Canadian Institutes of Health Research. Dr. Lu has extensive experience in biologics development as well as CDMO after working at Emergent BioSolutions and Merck for over twenty years. Dr. Lu contributed to the development of several traditional and new generation vaccines from the preclinical, phase 1, phase 3 to post approval submissions leading to regulatory approvals in the USA. Dr. Hang Lu is the founder and CEO of NexTranslate Biopharmaceutical Co.. Previously he served as a director of Development Services, CDMO at Emergent BioSolutions, a NYSE–listed public global life sciences company seeking to protect and enhance life by focusing on providing specialty products for civilian and military populations.

Jingyu (Julia) Luan, Ph.D., RAC

President–Elect of Chinese Biopharmaceutical association (CBA)

Dr. Jingyu (Julia) Luan is the President–Elect of the Chinese Biopharmaceutical Association (CBA) and a member of the Board of Directors. Dr. Luan is currently a Senior Director of Global Regulatory Affairs in AstraZeneca, leading global drug development, regulatory strategies and regulatory execution for multiple top priority products. Dr. Luan is a frequent speaker, organizer and chair for international conferences, workshops, and forums. Prior to AstraZeneca, Dr. Luan worked at the US FDA for more than 13 years and held various positions of increasing responsibilities, including Statistical Reviewer, Team Leader, and Acting Deputy Division Director. She received more than ten FDA honor awards. Before the FDA, she was a member of the research faculty at Johns Hopkins University and a Statistical Consultant at the University of Kentucky Medical Center. Dr. Luan is a board member and committee co–chair of FDA Alumni Association (FDAAA).

The 27th Annual Conference Chinese Biopharmaceutical Association

The Bridge of US–China Biopharmaceuticals

Saturday, December 17, 2022

08:30 am — 5:30 pm

Washingtonian Ballroom & Lakeside Ballroom, 9751 Washingtonian Blvd, Gaithersburg, MD 20878

08:30 – 08:40 Opening Remarks — Washingtonian Ballroom

Song Wu, PhD, CBA President, 2022–2023, Head of Translational Oncology, Hansoh Bio/Hansoh Pharm

08:40 – 10:40 Plenary Keynote Session 1: The Future of Global Drug Development

Session Moderators:
Jingyu (Julia) Luan, PhD, Angela Yuxin Men, MD, PhD — Washingtonian Ballroom

08:40 – 09:05 Taking Gene Therapy to the Next Level

Peter Marks, MD, PhD, Director, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA)
Member of the National Academy of Medicine

09:05 – 09:30 Clinical Trial Diversity/Global Multi–Regional Clinical Trials (MRCT)

Peter Stein, MD, Director, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)

09:30 – 9:55 Multi–Regional Trials: Opportunities and Challenges

Patricia Keegan MD, CMO and SVP, Shanghai Junshi Biosciences and TopAlliance Biosciences

9:55 – 10:30 Q&A and Panel Discussion:

Panelist: Peter Stein, MD
Peter Marks, MD, PhD
Patricia Keegan MD
Sunil Verma, MD
Mark Lanasa, MD, PhD

10:30 – 10:50 Coffee Break and Group Photos

10:50 – 12:20

Plenary Keynote Session 2: From the Discovery of Novel Science to Epic Molecule Development

Session Moderators:
Angela Zeng, MD, PhD, Yingxi Chen, MD, PhD

Washingtonian Ballroom

10:50 – 11:15 **HIF Inhibitors for Cancer Therapy**
Gregg Semenza, MD, PhD, Professor, Johns Hopkins University School of Medicine, 2019 Nobel Laureate in Physiology or Medicine

11:15 – 11:40 **Establishing a New Pillar in Cancer Care: The Emergence of Antibody Drug Conjugates (ADCs)**
Sunil Verma, MD, MSEd, FRCPC, SVP, Global Head of Oncology, Medical, AstraZeneca

11:40 – 12:05 **New Generation of Global Biotech**
Mark Lanasa, MD, PhD, SVP, Chief Medical Officer, Solid Tumors, BeiGene

12:05 – 12:20 **Q&A**

12:20 – 12:30 **Lucky Draw Session**

Washingtonian Ballroom

12:30 – 13:30 **Parallel Lunch Sessions**

Lunch Session A

Washingtonian Ballroom

Session Moderator: Xuyang Song, PhD, MBA

12: 40 – 13:00 **SMART PLATFORM STRATEGIES: Accelerate Molecule to Market**
Min Park, Chief Business Officer, Aton Biotech

13: 00 – 13:30 CBA and Partners' Show

Lunch Session B

Lakeside Ballroom

Session Moderator: Jack Yang, MSc

12: 40 – 13:00 **IP Strategies for Valuable and Enforceable Patents**
Yieyie Yang, PhD, JD, Associate, Finnegan, Henderson, Farabow, Garrett & Dunner LLP

13: 00 – 13:30 CBA and Partners' Show

13:30 – 14:50 **Parallel Sessions 3A and 3B**

Parallel Session 3A: Clinical Development in Novel Checkpoint Inhibitors

Washingtonian Ballroom

Session Moderators: Helen Fu, PhD, Tongqing Zhou, PhD

13:30 – 13:50 **Preserving Immune Tolerance Checkpoints for Safer and More Effective Immunotherapy**
Yang Liu, PhD., Founder, Chairman, CEO and Chief Scientific Officer, OncoC4

13:50 – 14:10 **Perspectives for Cancer Cell Therapy**
Ke Liu, MD, PhD, Chief Development Officer, Marengo Therapeutics

14:10 – 14:30 **Immunogenicity Assessment in the Age of New Drug Modalities**
Rafiq Islam, Vice President, Amador Bioscience

14:30 – 14:50 Q&A

Parallel Session 3B:
CMC and Emerging Bioprocess Technologies

Lakeside Ballroom

Session Moderators: Xu-Rong Jiang, MD, PhD, Hao Li, PhD

13:30 – 13:50 **The Evolving Landscape of Anti-PD-1/PD-L1 Antibody Development**
Baolin Zhang, PhD, SBRBPAS Expert, FDA/CDER/OBP

13:50 – 14:10 **Next Generation Biologics: Moving beyond mAbs**
Raghavan Venkat, PhD, Senior Vice President, Head of Biopharmaceutical Development, AstraZeneca

14:10 – 14:30 **Overcoming the Challenges of CMC in Cell and Gene Therapy**
Xu-Rong Jiang, MD, PhD, Senior Vice President, Cellular Biomedicine Group

14:30 – 14:50 Q&A

14:50 – 15:10 **Coffee Break and Group Photos**

15:10 – 16:30 **Parallel Sessions 4A and 4B**

Parallel Session 4A:
Recent Advances in Innovative Therapeutic Modalities: siRNA and ADC

Washingtonian Ballroom

Session Moderators: Qing Li, PhD, Chunhong Liu, PhD

15:10 – 15:30 **Advancing RNAi Therapeutics for Cancer Treatment**
Patrick Lu, PhD, President, and CEO, Sirnaomics

15:30 – 15:50 **Antibody Glycosylation and Site-Specific Antibody-Drug Conjugation**
Lai-Xi Wang, PhD, Professor of Chemistry and Biochemistry, University of Maryland

15:50 – 16:10 **An Anti-HER2/Trop-2 Bispecific Antibody-Drug Conjugate with a New DNA Topoisomerase Inhibitor Exerts Potent and Broad Antitumor Activity in Preclinical Tumor Models**
Helen Zhong, PhD, Senior Vice President, Preclinical Research, BiOneCure

16:10 – 16:30 Q&A

Parallel Session 4B:
Drug Development in the Era of Precision Medicine

Lakeside Ballroom

Session Moderators: You Li, PhD, Hongjun Yang, PhD

15:10 – 15:30 **Reimagining Clinical Trials: New Path, New Possibilities for Early Phase Clinical Development from China to Global**
Jane Fang, MD, CEO & Founder, Polaris Strategic Partners

15:30 – 15:50 **Affinity-Tuning and Tracking CAR T Cells for Solid Tumors**
Matt Britz, COO, AffyImmune Therapeutics

15:50 – 16:10 **Bringing the Promise of Precision Medicine for Cancer Care within Reach for All**
Rami Zahr, Sr. Director of Product Strategy, Personal Genome Diagnostics, Labcorp

16:10 – 16:30 Q&A

16:30 – 17:15

Parallel Session 5A:
Round Table Discussion: Challenges and Opportunities in the New Era of Biotech Investment

Lakeside Ballroom

Session Moderators: Frank Li, PhD, Fiona Yu, MBA

Panelist: Fiona Yu, MBA, Founder and CEO, Unogen Biotech
Frank Li, PhD, Founder and Senior Consultant, BLA Regulatory, Past CBA President
Changshou Gao, PhD, SVP & CTO, Innovent Biologics Inc
Nektarios (Aris) Oraiopoulos, PhD, Professor, University of Cambridge
Ting Feng, PhD, Partner, Sirona Capital
Catherine Pan, Partner, Co–Chair of US–China Practice Group, DORSEY & WHITNEY LLP

16:30 – 17:15

Parallel Session 5B:
Round Table Discussion: 27–Years of Bridging Innovations and Entrepreneurship Between US and China

Washingtonian Ballroom

Session Moderator: Richard Y. Zhao, PhD

Panelist: Richard Y. Zhao, PhD, Professor & Div Head, Mol Path, Director, Mol Diagnostics, Fellow, American Academy Microbiology, Univ. Maryland Med Ctr, Past CBA President
Patrick Lu, PhD, President, and CEO, Sirnaomics, Past CBA President
Yifan Zhai, MD, PhD, CMO, Ascentage Pharma, Past CBA President
Lin Sun–Hoffman, JD, PhD, Founding Partner, Ambiz Law Group, Past CBA President

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17:15 – 17:25

Lucky Draw Session

Washingtonian Ballroom

17:25 – 17:30

Conclusion Remarks and Group Photos

Jingyu (Julia) Luan, PhD, CBA President–Elect (2023–2024)

Washingtonian Ballroom

18:00 – 20:30

CBA Annual Conference Dinner

New Fortune, 16515 S Frederick Ave., Gaithersburg

Hosts: Angela Yuxin Men, MD, PhD, Xuyang Song, PhD, MBA

Dinner tickets are not included in the general registration for the conference, and it should be purchased separately in advance.
Dinner tickets are required to attend the CBA Annual Conference Dinner

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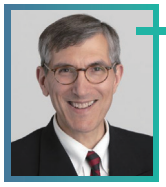
CBA 27th Annual Conference – Maryland

Empowering Healthcare with Cutting-Edge and Leading Global Partnerships

Plenary Keynote Session 1

The Future of Global Drug Development



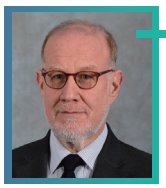
Peter Marks, MD, PhD

Director, Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Peter Marks received his graduate degree in cell and molecular biology and his medical degree at New York University and completed Internal Medicine residency and Hematology/Medical Oncology training at Brigham and Women's Hospital in Boston. He has worked in academic settings teaching and caring for patients and in industry on drug development. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in 2016.

Title of Speech <FDA's Perspective on the Future of Cell and Gene Therapy>

Gene therapy offers tremendous promise for the treatment of both rare and common diseases. Despite initial successes, particularly in the area of genetically-modified cellular therapies such as CAR-T cells, growth of the field has been slower than predicted. By leveraging product characteristics in common when possible, by focusing on advancing manufacturing, and by maximally employing expedited development pathways, FDA hopes to accelerate the pace of bringing advances to the benefit of patients.



Peter Stein, MD

Director, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Peter Stein, M.D., is the Director of CDER's Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters.

A nationally-recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late stage development, diabetes, and endocrinology at Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience.

Dr. Stein holds a bachelor's degree in history from the University of Rochester in New York and a medical degree from University of Pennsylvania. He trained at Yale University and Yale–New Haven Hospital in internal medicine and in endocrinology and metabolism.

Title of Speech <Clinical Trial Diversity/Global Multi–Regional Clinical Trials (MRCT)>

Patricia Keegan, MD

CMO and SVP and Senior Vice President for Medical Science
Shanghai Junshi Biosciences and TopAlliance Biosciences, Inc., a subsidiary of Shanghai Junshi Biosciences.

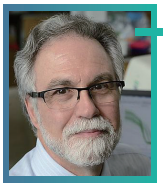
Dr. Patricia Keegan, is the Chief Medical Officer and Senior Vice President for Medical Science at Shanghai Junshi Biosciences and TopAlliance Biosciences, Inc., a subsidiary of Shanghai Junshi Biosciences. Junshi Biosciences is an innovation–driven biopharmaceutical company which is dedicated to the discovery and development of innovative drugs and their clinical research and commercialization on a global scale. Junshi Biosciences was the first Chinese pharmaceutical company that obtained marketing approval for anti–PD–1 monoclonal antibody in China. With enrichment of our product pipelines and exploration of drug combination therapies, Junshi Biosciences has expanded its innovation to the R&D of more types of drugs, including small molecule drugs and antibody drug conjugates (or ADCs), as well as to the exploration of the next–generation innovative therapies for cancer and autoimmune diseases. Prior to joining TopAlliance Biosciences, Inc. since August 2020. Prior to joining TopAlliance, Dr. Keegan held multiple positions at the U.S. Food and Drug Administration for nearly 30 years. Her most recent position was Acting Associate Director of Medical Policy Oncology Center for Excellence (OCE), Office of the commissioner; as well as 16 years as the Division Director of Oncology Products; 4 years as Deputy Director Division of Clinical Trial Design and Analysis; and 8 years as Chief and Medical officer at Oncology Branch, with regulatory oversight of thousands of investigational drug programs. Prior to joining FDA, Dr. Keegan was a Clinical Assistant Professor of Medicine in Hematology and Medical Oncology at University of North Carolina at Chapel Hill. Dr. Keegan received her Bachelor of Science in Biology from University of Illinois Champaign–Urbana. She earned her medical degree from Loyola University Stritch School of Medicine, where she also completed a residency in internal medicine and completed a fellowship in medical oncology at Roswell Park Memorial Institute, Buffalo, New York.

Title of Speech <Multi–Regional Trials: Opportunities and Challenges>

For several decades, regulatory agencies across countries/regions have grappled with the relevance of clinical trial data with few or no patients studied in that country/region. Common standards for clinical trial design and conduct supported by scientific justification for extrapolation of results to regions not included in the clinical trial form the bases of prior drug approvals. The recognized international standards for clinical trial conduct were established by the International Conference on Harmonisation, which now includes 16 member countries/regions, and guidelines for the conduct of multi–regional clinical trials (MRCT) are summarized in ICH E17, supplemented by ICH E5, ICH E6, E8, E9, E10, and E18. ICH E17 also discusses settings where an MRCT may not be appropriate. The opportunities with MRCTs include more rapid accrual leading to earlier drug approval across region and earlier patient access to effective drugs. MRCTs may also identify potential regional differences in drug treatment effects, if such differences exist. However, challenges include: 1) slow accrual based on different regional requirements for initiation of trials that may delay start–up; 2) lack of agreement across regions regarding key trial design elements, such as primary endpoint and comparator arms; and 3) fixed requirements for patient enrollment by region leading to very large sample sizes. Such challenges may preclude inclusion of certain regions in MRCTs.

Plenary Keynote Session 2

From the Discovery of Novel Science to Epic Molecule Development



Gregg Semenza, MD, PhD

Professor, Johns Hopkins University School of Medicine
2019 Nobel Laureate in Physiology or Medicine

Dr. Semenza is the C. Michael Armstrong professor of genetic medicine, with appointments in pediatrics, radiation oncology, biological chemistry, medicine, and oncology at the Johns Hopkins University School of Medicine. He serves as founding director of the Vascular Program at the Johns Hopkins Institute for Cell Engineering and founding director of the Armstrong Oxygen Biology Research Center. Dr. Semenza received an A.B. (in Biology) from Harvard University and M.D. and Ph.D. (in Genetics) degrees from the University of Pennsylvania. He completed pediatrics residency training at Duke University Medical Center and postdoctoral training in medical genetics at Johns Hopkins. He has been a member of the Johns Hopkins faculty since 1990.

Dr. Semenza's lab discovered hypoxia–inducible factor 1 (HIF–1), a transcription factor that controls the expression of thousands of genes in response to changes in oxygen availability, for which he was awarded the 2019 Nobel Prize in Physiology or Medicine. Dr. Semenza has also received the Albert Lasker Basic Medical Research Award (2016), Lefoulon–Delalande Grand Prize from the Institut de France (2012), and the Canada Gairdner International Award (2010). He has authored more than 450 research articles and book chapters, and his work has been cited more than 180,000 times according to Google Scholar.

Dr. Semenza's current research interests include investigating the molecular mechanisms of oxygen homeostasis, the role of HIF–1 in cancer progression, and the development of HIF inhibitors for cancer therapy.

Title of Speech <HIF Inhibitors for Cancer Therapy>

Hypoxia–inducible factors (HIFs) are transcriptional activators that balance O_2 supply and demand by regulating the expression of genes that control the delivery and consumption of O_2 , respectively. We purified HIF–1 and found that it was a heterodimer composed of an O_2 –regulated HIF–1a subunit and a constitutively–expressed HIF–1b subunit. In the presence of O_2 , HIF–1a is subject to hydroxylation on two proline residues by prolyl hydroxylase domain proteins. Hydroxylated HIF–1a is bound by the von Hippel–Lindau protein (VHL), which recruits a ubiquitin–protein ligase, leading to the ubiquitination and proteasomal degradation of HIF–1a under normoxic conditions. Under hypoxic conditions, the hydroxylation reaction is inhibited and HIF–1a rapidly accumulates, dimerizes with HIF–1b, binds to target genes and activates their transcription. HIF–2a is also O_2 –regulated and dimerizes with HIF–1b, but unlike the ubiquitous expression of HIF–1a, HIF–2a is only expressed in a limited number of cell types. HIF–1a is highly expressed in cancer cells and increased HIF–1a in the diagnostic tumor biopsy is associated with an increased risk of patient mortality. Patients with the VHL syndrome are at risk of renal cell carcinoma (RCC) and other tumors due to a germline mutation in the VHL gene. Inactivation of the second allele in kidney cells leads to dysregulated HIF–1a and HIF–2a expression, and tumor formation. In 2021, the FDA approved Belzutifan, a selective HIF–2a antagonist, for treatment of RCC and VHL syndrome–associated tumors. We performed a cell–based screening assay for HIF inhibitors in Hep3B hepatocellular carcinoma (HCC) cells and identified 32–134D, which causes the degradation of HIF–1a and HIF–2a. Administration of 32–134D to immunodeficient mice bearing Hep3B tumor xenografts blocked tumor growth and vascularization. Administration of 32–134D to immunocompetent mice bearing Hepa1–6 mouse HCC cells led to tumor eradication in 33% of the mice. Administration of anti–PD1 antibody caused tumor eradication in 25% of treated mice, whereas combination therapy with 32–134D improved the tumor eradication rate to 67%.

32–134D treatment switched the tumor immune

microenvironment from one favoring immunosuppression due to predominance of tumor–associated macrophages and myeloid–derived suppressor cells to one favoring anti–tumor immunity due to the presence of CD8 + T cells and natural killer cells.

Sunil Verma, MD, MSEd, FRCPC

SVP, Global Head of Oncology, Medical, AstraZeneca

Sunil Verma, MD, MSEd, FRCPC is Global Head of Oncology, Medical in AstraZeneca, helping to drive the vision to redefine cancer care. His leadership is focused on advancing the practice of cancer care through robust clinical studies, evidence generation, scientific partnerships and helping to reimagine the future cancer care paradigm.

Prior to his current role, Sunil was Vice President, Head of Breast Cancer strategy and Global Clinical Head for Breast Cancer Program, leading AstraZeneca's global research and development in breast cancer. As part of that work, he led the development and execution of breast cancer strategy, establishing the tumour council model, and designed and established our industry leading clinical development program in Breast Cancer.

Before joining AstraZeneca in August 2019, Dr. Verma as a Medical Oncologist, provided clinical care and expertise with a focus in breast and lung cancer and held several pivotal leadership and research roles in academic medicine over 15 years. He served as Professor and Head of the Department of Oncology at the University of Calgary and the Medical Director of the Tom Baker Cancer Centre from 2015–2019. During this term he led the growth of the Department and launched the build of the New Calgary Cancer Centre, the largest comprehensive cancer care facility in Canada. He also served on faculty at University of Toronto as Associate Professor and Medical Director of the Breast Cancer Centre at Sunnybrook, Toronto.

He completed his medical degree and postgraduate training in Internal Medicine and Medical Oncology at the University of Alberta in Canada. In addition, Dr. Verma completed a fellowship in breast cancer at the University of Toronto with a Masters' degree in Medical Education at the University of Southern California.

Dr. Verma is internationally recognized for his research and education leadership in breast cancer. His research interests include developing novel therapies for breast cancer, reducing toxicities associated with systemic treatment and medical education. He was the principal investigator for many pivotal trials in breast cancer including a number of practice–changing Phase III trials. His work has been published in the New England Journal of Medicine, The Lancet, Journal of Clinical Oncology and Cancer. He has led and created numerous innovative educational projects in oncology and has won several teaching and mentoring awards.

Title of Speech <Establishing a New Pillar in Cancer Care: The Emergence of Antibody Drug Conjugates (ADCs)>

Cancer care traditionally has been based on three important therapeutic pillars: chemotherapy, radiation therapy and surgery. While chemotherapy has significantly helped many lives, there are significant limitations primarily related to acute and long–term toxicity, limited duration of response, and at times rapid resistance due to multiple pathways. The quest to deliver chemotherapy right to cancer cells and thereby improve the therapeutic index led to the advent of Antibody drug conjugates (ADCs) with a focus on replacing and displacing chemotherapy. Over the past decade, we have now seen a rapid increase in a number of novel ADCs across key tumor areas and we will have an opportunity to focus on breast cancer and share lessons learned as we have integrated ADCs in clinical care and also the opportunity to refine the next generation of ADCs.

Mark Lanasa, MD, PhD

SVP, Chief Medical Officer, Solid Tumors
BeiGene

Mark Lanasa, M.D., Ph.D., joined BeiGene in February 2022 as Senior Vice President, Chief Medical Officer for Solid Tumors. In this role he leads clinical development of all solid tumor programs and all assets through their regulatory approval. Prior to joining BeiGene, Dr. Lanasa most recently served as Vice President and Global Clinical Head, Late Development Oncology at AstraZeneca from 2019 to 2022. He held a number of positions at AstraZeneca, including development leadership roles for Enhertu (trastuzumab-deruxtecan) and Imfinzi (durvalumab). Dr. Lanasa also worked as Senior Director of Clinical Development at Immunocore, where he contributed to the late-phase development of T-cell engager Kimmtrak (tebentafusp).

Dr. Lanasa earned his B.S. in chemistry from Pennsylvania State University, and both his Ph.D. in biochemistry and molecular genetics and M.D. in the Medical Scientist Training Program at the University of Pittsburgh School of Medicine. He completed his residency and was a post-graduate fellow at the Duke University Medical Center, where was subsequently on the faculty in hematologic malignancies.

Title of Speech <New Generation of Global Biotech>

Parallel Sessions 3A and 3B

Parallel Session 3A

Clinical Development in Novel Check Point Inhibitors

Yang Liu, PhD

Founder, Chairman, CEO and Chief Scientific Officer
OncoC4

Dr. Liu co-founded OncoImmune and OncoC4 after OncoImmune was acquired by Merck in 2020. Dr. Liu is recognized internationally for his research on immune recognition of cancer and activation of lymphocytes, the main immune defender against cancer. Under his leadership, OncoC4 has received fast track designation for its leading clinical candidate ONC-392 for metastatic non-small cell lung cancer that is resistant to PD-(L)-1 treatment. He has received multiple lifetime awards for his outstanding research career, including the Markey Scholar Award (1992), the Sears Scholar Award (1993), Snyder Award for Cancer Research (2015) and was inducted as the Fellow of the American Association for Advancement of Science (AAAS) in 2004 for his pioneering contribution to innate immunity, T cell costimulation and cancer immunology.

Dr. Liu received his Ph.D. from the Australian National University, and postdoctoral fellowship from Yale University. Prior to serving full-time as OncoC4 CEO, Dr. Liu was a faculty in multiple academic institutions, including New York University, the Ohio State University, the Children's National Medical Center, and Institute of Human Virology at University of Maryland School of Medicine.

Title of Speech <Preserving immune tolerance checkpoints for safer and more effective immuno–therapy>

CTLA–4 targeting agent was the first approved immuno–oncology drug, but it has met with an enormous chal–lenge in the market because of its high toxicity, which also prevents patients from receiving effective dosing. Dr. Liu and his team's decades of dedicated work on ligand recognition and biology of CTLA–4 has led to OncoC4's nextgen anti–CTLA–4 antibodies that differentiate from other CTLA–4 antibody products in that they selectively eliminate the evasive immune function of CTLA–4 by killing the high CTLA–4– expressing immune–suppressor cells (called regulatory T cells) reside in the tumors but preserve immune tolerance function of CTLA–4 in the normal tissues.

OncoC4 is currently developing ONC–392 for the treatment of patients with solid tumors including NSCLC in Phase I/II clinical trials. The product is being tested as monotherapy and combination therapy with pembroli–zumab. Recent data from the ONC–392–001 study as well as other preclinical novel checkpoint inhibitors will be presented.

Ke Liu, MD, PhD

Chief Development Officer
Marengo Therapeutics

Ke Liu, MD, PhD, is Chief Development Officer of Marengo Therapeutics. Ke has over 20 years of experience in the field of oncology, immuno–oncology, and cell and gene therapy, most recently serving as Senior Vice President and led the key regulatory activities at *Sana Biotechnology*. Prior to Sana, he spent more than 17 years working at the *U.S. Food and Drug Administration* (FDA) where he held leadership roles at the *Center for Biologics Evaluation and Research* (CBER), *Center for Drug Evaluation and Research* (CDER), and the Oncology Center of Excel–lence (OCE). Ke has made major contributions to the field of Oncology and led the clinical evaluations and approvals of key first–in–class cancer therapeutics over the past decade, including checkpoint inhibitors, chimeric antigen receptor (CAR) T cells, T cell receptor (TCR) modified T cells, genome–edited products, neo–antigen–based therapies, adoptive T cell therapies, oncolytic viral therapy, dendritic cell therapy, and combina–tions of these immune–oncologic therapeutics with checkpoint inhibitors and other agents.

Ke received his M.D. from *Henan Medical University* in China and his Ph.D. in molecular biology from *Cornell Univer-sity*. He completed his internal medicine internship and residency at *Albert Einstein College of Medicine*, his medical oncology fellowship at the *National Cancer Institute* (NCI), and additional cancer immunotherapy training at the *NCI's Surgery Branch*. Ke is an internist and medical oncologist certified by the *American Board of Internal Medicine.*

Title of Speech <Perspectives for Cancer Cell Therapy>

Rafiq Islam

VP
Amador Bioscience

Rafiq Islam is the Vice President at Amador Bioscience responsible for scientific and operational leadership of Bioanalysis and Biomarker Services operation in Germantown, MD. Prior to joining Amador, he was the VP of Pharmaceutical Development Services Division at Smithers.

Previously, he served as the Executive Director at Celerion Inc, and a Scientific Director for Biopharma Services at EMD Millipore (MO, USA). He held similar positions as the head of a bioanalytical department at Covance Inc. (AZ, USA) and Huntingdon Life Sciences (NJ, USA). He also held several positions of increasing responsibility with Curagen Corporation. He has over 20 years of biotechnology and CRO industry experience. He has authored and contributed to more than 50 articles, industry whitepapers, and numerous posters on the topic of regulated bioanalysis.

Title of Speech <Immunogenicity Assessment in the Age of New Drug Modalities>

As the diversity and complexity of therapeutic modalities increases, our bioanalytical toolbox for the assessment of immunogenicity needs to be expanded.? This presentation focuses on the challenges and solutions associated with complex drug modalities such as nucleic acid–based therapies, multi–domain therapies, cell and gene thera–pies, etc. Case studies outlining best practices for method selection and validation are presented as well as a future perspective to address challenges associated with immunogenicity assessment.

Parallel Session 3B

CMC and Emerging Bioprocess Technologies

Baolin Zhang, PhD

SBRBPAS Expert
FDA/CDER/OBP

Dr. Baolin Zhang is a regulatory–affairs professional with 20 years of FDA regulatory review, translational research and leadership experience. Dr. Zhang currently serves as FDA Senior Biomedical Research and Biomedical Product Assessment Service (SBRBPAS) Expert. Dr. Zhang leads the regulatory review of INDs and BLAs for numerous biotechnology products and biosimilars, with a focus on Chemistry, Manufacturing and Con–trol (CMC). Dr. Zhang has contributed to the FDA policy and guidance for industry regarding drug quality assessment and surrogate biomarkers for accelerated approval. Dr. Zhang also directs translational research programs to support regulatory decision making, with special expertise in bioassays, biomarkers and disease models for cancer drug development. Dr. Zhang has authored more than 120 peer–reviewed articles and book chapters, also given over 100 invited presentations. Dr. Zhang received numerous awards for his scientific achievements and exceptional regulatory efforts.?Prior to joining FDA, Dr. Zhang worked as Deputy Director and Professor at the Beijing Center for Biologics Research and Development, and a Senior Scientist at the University of Tennessee School of Medicine. He received his B.S. and M.Sc. in Chemistry from Lanzhou University, his Ph.D. in Chemistry from Peking University, and a postdoctoral fellowship at Nanjing University.

Title of Speech <The Evolving Landscape of Anti–PD–1/PD–L1 Antibody Development>

The Food and Drug Administration (FDA) has approved 7 monoclonal antibodies against PD–1 or PD–L1 for more than 85 oncology indications, still with nearly 5000 active clinical trials testing at least 33 new candidates. The hotly commercial competition in the PD–1/PD–L1 space calls for collaboration and coordination between stakeholders to harmonize regulatory submissions and multinational clinical trial design (Beaver & Pazdur, NEJM

2022). There is also an urgent need to standardize the biomarkers and companion diagnostics (CDx) for patient selection across different products and cancer types. This talk will provide an update on FDA approvals of anti–PD–1/PD–L1 monoclonal antibodies and associated CDx?along with an overview of the regulatory path–ways for incorporating biomarkers into drug development programs. The information will be further discussed with potential strategies to optimize biomarkers and CDx to guide the clinical use of anti–PD–1/PD–L1 therapy.

Raghavan Venkat, PhD

Vice President, Biopharmaceutical Development
AstraZeneca

Raghavan Venkat (Venkat in short) obtained his M.S. and Ph.D. degrees in Chemical Engineering at The Ohio State University and a Certificate in Business from the Wharton School at University of Pennsylvania. Venkat joined MedImmune / AstraZeneca in 2006 and has worked in the biopharmaceutical industry for almost 26 years across many roles at GSK, Lilly and AZ. Over his career, Venkat has led teams or directly contributed to the commercialization of more than 10 biologics medicines, including Vaxzevria and Evusheld developed in response to the COVID pandemic. Venkat has a strong expertise in pharmaceutical process and product development, especially in biologics process development and manufacturing, with keen interest and strength in novel modali–ties. At AstraZeneca, he currently leads the Biopharmaceutical Development function responsible for end to end CMC development of all biologics within the AZ pipeline.

Title of Speech <Next Generation Biologics: Moving beyond mAbs>

Xu–Rong Jiang, MD, PhD

Senior Vice President
Cellular Biomedicine Group Inc.

Xu–Rong Jiang, MD, PhD, currently serves as Senior VP of Tech Ops in Cellular Biomedicine Group Ltd. (CBMG). Prior to that, he had worked at AstraZeneca for 14 years, most recently as a Senior Director of Quality and Technical in Global Quality Biologics and BioVentures of AstraZeneca. In addition, he also served as the Head of Quality for Centus Biotherapeutics Ltd, a joint venture between AstraZeneca and Fujifilm Kyowa Kirin Biolog–ics, and successfully obtained EMA approval of biosimilar bevacizumab, Equidacent. During 2008–2014, he led the analytical & biological function and served as a CMC Team Leader for FluMab. His group in Analytical Sciences at MedImmune was responsible for biologics analytical method development, IND filing, GMP testing, technology transfer, process development, PPQ and BLA. In 2002 to 2008, he was a Principal Scientist in Pro–cess & Analytical Sciences at Amgen responsible for development, qualification, validation of potency assays for biologics development. In 1998–2002, he was a Senior Scientist at Geron Corporation specialized on gene and cell therapy, drug discovery, and regenerative medicine with embryonic stem cells. Xu–Rong received his Ph.D. in molecular cell biology, University of London, and his M.D. in hematology from China Medical University. He has served at various scientific and professional organizations and committees: an Associate Director for CASSS, an International Separation Science Society, and a member of Scientific Organizing Committee for CASSS Bioassays since 2011. He was the President and Chairman of the Board of Directors in the Chinese Biopharmaceutical Association–USA 2016–2017.

Title of Speech <Overcoming the Challenges of CMC in Cell and Gene Therapy>

Cell and Gene Therapies (CGT) are transforming not just how humans treat genetic and intractable diseases but are altering the entire pharmaceutical ecosystem. CGT are rapidly becoming established as the new wave of biological therapeutics. Whether using autologous or allogeneic engineered cells as the active therapeutic (Cell Therapy), or the gene delivery system (Gene Therapy; e.g., LNP's, AAV's, etc.), CGT is in the process of becoming a mainstream approach. Around 990 companies are engaged in R&D and commercialization of next-generation CGT. Resultingly, CGT is now in the process of transitioning from the 'Wild West' of a novel therapeutic to the emerging requirements of being a fully realized biotherapeutic. The chemistry, manufacturing and controls (CMC) processes are key to ensuring at every stage that a drug is safe and effective. But given the novelty and variability of cell and gene therapies, the challenges CMC faces in this field, and the strategies to overcome these challenges will be discussed in the presentation.?

Min Park

Chief Business Officer
Aton Biotech

Min Park is the Chief Business Officer at Aton Biotech — A Henlius Company, responsible for establishing long-term growth strategy for the company. He has over 20 years of domestic and international experience in developing, implementing, and managing global commercial operations in the life science industry. He successfully launched several CDMOs from Biologics to Cell and Gene Therapy with aggressive targets. Prior, he has served at WuXi AppTec – WuXi Advanced Therapies, Abzena, Catalent, Samsung Biologics, and several other CDMO holding several global leadership roles. He is also a Vice Chairman of the Board with National Association of Asian American Professionals (NAAAP) which is the largest and fastest growing 501(c)(3) inclusive organization. He holds a Bachelor of Science (B.S.), Business Administration in Marketing from Montclair State University and now studying at Louisiana State University for an MBA. He is bilingual in English and Korean.

Title of Speech <SMART PLATFORM STRATEGIES: Accelerate Molecule to Market>

In our industry, it is widely known the slow moving companies give their nimbler competition an advantage to dominate the marker even if their product is not superior. Fast movers are flexible and adaptive to rapidly changing dynamic business environment. Those that can capitalize on opportunities and better navigate risks and challenges with quicker adaptability will triumph from competition.

At Aton (A Henlius Company), we have established SMART PLATFORM STRATEGIES that enabled acceleration of pipelines to market through experience including 500 commercial batch productions, 100+ Tox & clinical batches, 30+ molecules, 50+ IND approved, and 100% tech transfer success rate. What we have learned from all our experience, is PLATFORM APPROACH that enable us to successfully accelerate molecules to market. Our platform strategy allows us to shorten timeline efficiently by integrating all aspects of production of drug substance and drug product. In this presentation, Aton will share how to deploy smart platform approach strategies to accelerate molecule to market.

Yieyie Yang, JD, PhD

Associate
Finnegan, Henderson, Farabow, Garrett & Dunner LLP

Yieyie Yang, PhD, JD, focuses on complex patent litigation before U.S. district courts and post–grant proceedings in the chemical, pharmaceutical, and biotechnological fields. She has experience representing biopharmaceutical patent holders in Hatch–Waxman and biosimilars litigations and appeals before the U.S. Court of Appeals for the Federal Circuit. Yieyie also has been leading due diligence projects in the biotech field for licensing, acquisition, freedom–to–operate, and startup fundraising, which involve technologies such as gene sequencing, vaccines, antibody drugs, CAR–T therapies, gene editing technologies, and gene therapies. With unique insight from her extensive experience in litigation and due diligence, Yieyie is also managing patent prosecution for multiple Chinese biotech companies. Yieyie was named by the U.S. News – Best Lawyers journal as the "Ones to Watch" in 2023 for excellence in Patent Law.

Title of Speech <IP Strategies for Valuable and Enforceable Patents>

Strategic patenting can help a biopharmaceutical company build strong portfolios to protect its innovative technology. Well–planned health checks and due diligence can be used to further cement competitive advantages. Understanding the values and strength of IP is also critical in dealing with patent challenges before the PTAB, litigation, and negotiations. In her talk, Dr. Yang will explain IP strategies that are crucial for the success of biopharmaceutical companies and provide tips on best practices.

Parallel Sessions 4A and 4B

Parallel Session 4A

Recent Advances in Innovative Drug Modalities: siRNA and ADC

Patrick Lu, PhD

President and CEO
Sirnaomics

Dr. Patrick Lu is the founder, the chairman of Sirnaomics Board, Executive Director, the president, the Chief Executive Officer. Dr. Lu has led the Company from an early discovery effort to an siRNA therapeutics product company, with multiple programs currently at clinical stage.

Prior to establishing Sirnaomics, Patrick held positions as a scientist in BioReliance, a lab head at Genetic Therapy, Inc., a Novartis Company and a senior scientist and project leader at Digene Corporation. Dr. Lu co–founded Intradigm and served as the executive vice president. After Sirnaomics inception in the US, Dr. Lu established Sirnaomics Suzhou (2008) and Sirbaomics Guangzhou (2012), to conduct research and development for RNAi based therapeutics and to conduct formulation and manufacture of its novel RNAi therapeutic product. Dr. Lu has led the company to raise more than US$340 million funding from venture capital groups and to conduct a successful initial public offering (IPO) in Hong Kong Stock Exchanges. Dr. Lu has authored/co–authored 55 scientific publications including a senior author for a research article in "Nature Medicine" and is the inventor/–

co-inventor of 78 patents. Patrick obtained a bachelor's degree, a master's degree and a doctoral degree from Sun Yat-sen University in China and conducted his postdoctoral training at the University of Maryland at College Park and Georgetown University Medical School in the U.S.

Title of Speech <Advancing RNAi Therapeutics for Cancer Treatment>

Sirnaomics is discovering and developing innovative RNA therapeutics with small interfering RNA (siRNA) as novel therapeutic modalities. There are two technology platforms within the company: Polypeptide Nanoparticle Delivery and GalNAc-based Conjugation Delivery. We have two teams working specifically for development of siRNA drug products with their specialized technology platforms at a R&D stage, while when the drug candidates are reaching to the "Early Selected Compound" stage, the CMC, Pharm/Tox, Regulatory and Clinical teams are working in concert to send the products successfully for Clinical Testing. As a biopharmaceutical company specializing in RNA therapeutics, Sirnaomics has embraced two major achievements: (1) having the first clinical successes of its two Phase II studies for treatment of various types of cancer, which not only validated its technology but also demonstrated an enriched product pipeline; (2) having raised more than USD$340 million fundings with a successful initial public offering. Sirnaomics has two well-established delivery platforms for RNA drug administration. The Polypeptide Nanoparticle (PNP) formulation is well-suite for tumor and exhepatic tissue delivery, while the GalNAc-based (Galahead, PDoV) formulation is for liver hepatocyte specific delivery. Two PNP-based siRNA drug candidates, STP705 and STP707, have already been tested in multiple clinical trials at Phase I and Phase II stages for treatment of BCC, isSCC, Liver Cancer, Melanoma, Pancreatic Cancer and Colorectal Cancer. The GalNAc-based STP122G is going to be in the clinical study soon.

Lai-Xi Wang, PhD

Professor of Chemistry and Biochemistry
University of Maryland

Lai-Xi Wang is Professor of Chemistry and Biochemistry at the University of Maryland, College Park. He received his PhD from Shanghai Institute of Organic Chemistry, Chinese Academy of Sciences. After postdoctoral studies in glycobiology and molecular biology at Johns Hopkins University and MIT, respectively, he joined the faculty of University of Maryland as an assistant professor in 2000 and was promoted to full professor in 2009. His research is centered on protein glycosylation, including the development of new chemoenzymatic methods for glycoprotein synthesis, antibody glycoengineering, and carbohydrate-based HIV-1 vaccine design. His group has developed a site-specific antibody glycan remodeling method that enables a quick access to various homogeneous antibody glycoforms for immunological studies. More recently, his team has developed a general and efficient chemoenzymatic approach for site-specific antibody labeling and bioconjugation. It provides a platform technology for producing homogeneous antibody-drug conjugates and antibody-ligand conjugates for immunological studies and for therapeutic development. Dr. Wang has received numerous recognition and honors for his research, teaching, and service, including the Young Investigator Award (2004) in Carbohydrate Chemistry and the Melville L. Wolfrom Award (2014) (Both from the American Chemical Society); the Dean's Award of Excellence in Teaching (2020, the College of Computer, Mathematical, and Natural Sciences (CMNS), and the Norma M. Allewell Prize in Entrepreneurship (2021, University of Maryland College Park). Dr. Wang was elected as an AAAS Fellow in 2014 and an ACS Fellow in 2019.

Title of Speech <Antibody Glycosylation and Site-Specific Antibody-Drug Conjugation>

All human IgG type antibodies have a conserved N-glycan at the Asn-297 site in the Fc domain. The Fc glycans

play an important role in modulating an antibody's effector functions such as the antibody-dependent cellular cytotoxicity (ADCC). We report in this lecture a general chemoenzymatic method for Fc glycan remodeling of intact antibodies, which involves deglycosylation with a wild-type endoglycosidase and subsequent glycosylation with a structurally well-defined glycan using a glycosynthase mutant. This method permits a quick access to homogeneous antibody glycoforms for structural and functional studies. Recently, we have extended this chemoenzymatic method to site-specific bioconjugation of antibodies with cytotoxic drugs to make homogeneous antibody-drug conjugates (ADCs). We found that the glycosynthase mutants of the endoglycosidase from Streptococcus pyogenes (Endo-S and Endo-S2) could efficiently transfer azide-modified glycans to antibodies, which allows subsequent click reaction with a payload to make ADCs with varied drug/antibody ratios (DAR 2-12). Moreover, we further discovered that the wild-type endoglycosidase (Endo-S2) could perform deglycosylation and simultaneous glycosylation with a series of synthetic azide-tagged disaccharide oxazolines as the substrates without product hydrolysis, enabling a single enzyme, one-pot, and site-specific modification of antibodies. In addition to ADC production, this chemoenzymatic Fc glycan remodeling strategy was also applied for site-specific one-pot conjugation of high-affinity ligands of cellular receptors to antibodies, enabling the construction of homogeneous lysosome-targeting chimeras (LYTACs) for targeted degradation of extracellular proteins.

Helen Zhong, PhD

Senior Vice President

Preclinical Research, BiOneCure

Over 20 years of drug discovery and development experience in both large pharma and small biotech companies including AstraZeneca and Curagen with demonstrated success of leading preclinical drug discovery and clinical development programs. Led or contributed to the discovery and progression into clinic of a number of drug candidates and drug approvals with a focus on antibody and ADC drugs. Postdoc in the department of Immunobiology at Yale University School of Medicine, PhD in Biological Sciences from Dartmouth College.

Title of Speech <An anti-HER2/Trop-2 bispecific antibody-drug conjugate with a new DNA topoisomerase I inhibitor exerts potent and broad antitumor activity in preclinical tumor models>

Bispecific antibody-drug conjugate represents a fast-growing class of next generation ADC due to its potentials in enhancing specificity, improving efficacy and reducing toxicity. Additionally, targeting more than one molecule can be useful to avoid resistance to treatment and broaden the patient population. Here, we describe a novel bispecific ADC (BIO-201) co-targeting HER2 and Trop-2 which are the two clinically validated tumor-associated antigens that are expressed on a wide variety of tumors. BIO-201 is consisted of a novel bispecific anti-HER2/Trop-2 antibody conjugated with a proprietary new DNA topoisomerase I inhibitor via a cleavable linker. This bispecific antibody showed comparable or increased cell binding and internalization compared with the parental antibodies in various tumor cells that express different surface levels of HER2 and Trop-2. BIO-201 demonstrated potent bystander killing effect. In the in vitro cytotoxicity assay, the bispecific ADC BIO-201 effectively killed cancer cells with IC50 in the sub nM range with BIO-201 being most potent against cancer cells that co-express HER2 and Trop-2. The anti-tumor activity of BIO-201 was further demonstrated in vivo in a number of tumor xenograft models. Treatment of BIO-201 induced significant tumor regression. Taken together, these findings suggest that anti-HER2/Trop-2 bispecific ADC has potential as an effective therapy for a variety of cancers that co-express HER2/Trop-2 or express either of the targets, and a broad patient population my benefit from this new class of bispecific ADC.

Parallel Session 4B

Drug development in the Era of Precision Medicine

Jane Fang, PhD

CEO & Founder
Polaris Strategic Partners

Dr. Jane Fang has 25 years of unique across discipline experiences in medical practice, life science research, global biopharmaceutical clinical drug development and clinical trial innovations.

With extensive medical and clinical research training from one of the most prestigious medical universities in China, and healthcare management training from University of Pittsburg, Dr. Fang has broad international experience across US and China with comprehensive expertise of drug development from translational research to clinical trial design, strategic planning, study management, data analytics, and regulatory standards.

As Founder and CEO of Polaris Strategic Partners, Dr. Fang is creating an innovative accelerator of clinical trial development and leading the company to partner with emerging biotech companies, especially those innovative companies conducting US and China clinical and commercial development, to explore new therapies to address unmet medical needs and cure diseases. She has extensive global experience in oncology, autoimmune and respiratory diseases, metabolic and cardiovascular diseases, infectious diseases and vaccine. She had contributed to AstraZeneca/MedImmune's Durvalumb, Benralizumab, Fasenra and FluMist development.

Prior to founding Polaris Strategic Partners, Dr. Fang had worked at the leading global biopharmaceutical companies such as AstraZeneca/MedImmune, Schering-Plough/Merck and the top academic medical center and teaching hospital in US and China.

Title of Speech <Reimagining clinical trials: new path, new possibilities for early phase clinical development from China to Global>

US and China, the world's No. 1 and 2 largest economy and pharmaceutical markets, are facing the challenges of healthcare equity and affordability. Both countries are putting pressure on drug prices and deepening reimbursement reforms. This trend has demanded biopharma companies to have more cost effective and smarter approaches to conduct new drug clinical development and commercialization than ever before.

Precision medicine driven drug discovery has to be closed connected and guided by medical evidence for unmet healthcare needs. As a result, clinical trial development and operations have to be changed and innovated through smarter and better solutions, especially for emerging biotech companies moving from pre-clinical to early clinical stage development.

Reflecting on 2020 and 2021, COVD pandemic challenges have called for global collaborations and innovations across different countries, governments, industries and individual citizens for more effective and rapid new therapy development.

Considering the above main drivers in the global environment, drug developers and investors have to strategically position their organizations and teams and adapt to these changes by learning new paths of drug clinical development and execution. This talk will highlight the key areas and considerations from scientific research, clinical trial development, to medical and standard of cares, and regulatory and health insurance impact. Innovative clinical drug development case examples from global biopharma industry will be illustrated.

A new era of US-China biotech development has emerged and we have to reimagine how to conduct early phase clinical trials through new path with smarter, faster, better and more affordable approaches.

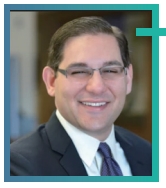
Matt Britz, BS, MBA

COO
Affyimmune

Matt Britz is the Chief Operating Officer of AffyImmune Therapeutics, based in Natick, Massachusetts. After graduating with degrees in Chemical Engineering and Biology from MIT, Matt began his career in process development and clinical manufacturing at Merck in Rahway, NJ and later at Pfizer, in St. Louis. After obtaining a Master's degree in Biology and an MBA from Washington University, Matt begin working in consulting and business development, consulting at Equinox Group and Health Advances, and leading business development efforts at Envoy Therapeutics, including an M&A with Takeda for over 17.5 times funds raised. Prior to AffyImmune, Matt was SVP of Business Development at Minerva Biotechnologies, where we took a cancer specific antibody and turned into a CAR T against breast cancers. At Minerva, where he had significant roles in CMC, regulatory, and clinical operations in addition to business and corporate development. Originally hired at AffyImmune to be SVP of Business Development, Matt took over operations of the entire company and the COO role in January 2022.

Title of Speech <Affinity–tuning and tracking CAR T cells for solid tumors>

It is well known that CAR T cells directed at solid tumors have not had the same success as has been seen in the hematological tumors. These challenges in solid tumors include but are not limited to, on–target, off–tumor toxicities, tumor heterogeneity, T cell exhaustion, and the immunosuppressive tumor microenvironment. AffyImmune is using its "Tune & Track" platform to tackle these challenges. As with many other cancer targets, the ideal target is differentially expressed: there is order of magnitudes more expression on cancer cell than on normal cells. The interaction between the CAR T cells and the target cancer antigen is systematically affinity tuned in a way that the CAR T cells recognize the higher expression on cancer cells, but do not recognize the lower levels of antigens on normal cells. Affinity tuning also reduces the interaction between CAR T cells and cancer cells to level that is more in line with the natural affinity of T cells when they kill. This affinity tuning results in lower on–target, off–tumor toxicities, better serial killing, and less T cell exhaustion. The "track" part of the platform allows for real time tracking of CAR T cells in vivo. The CAR T cells are engineered to also express a membrane protein on their CAR T cells that interacts with FDA approved DOTATATE, which can be used to image the CAR T cells in vivo in real time via PET scan. AffyImmune is currently in a phase I trial in refractory thyroid cancers expressing ICAM–1.



Rami Zahr, MS

Sr. Director of Product Strategy
Personal Genome Diagnostics (PGDx)
Labcorp

Rami Zahr is the Head of Product Strategy at Personal Genome Diagnostics (PGDx), now part of Labcorp. PGDx is empowering the fight against cancer by unlocking actionable information from the genome by working to bring novel diagnostic approaches to patients with cancer. Rami leads the product and project management teams to develop a pipeline of products and services that provide critical information to cancer patients globally. Prior to PGDx, Rami managed single–cell sequencing products at BD and nanoliter–scale automation instruments bringing cutting–edge products to the cancer research market. Rami also managed IDT's NGS portfolio, introducing best–in–class products to NGS labs around the world.

Title of Speech <Bringing the promise of precision medicine for cancer care within reach for all>

Labcorp is committed to elevating cancer care globally by setting a new standard where precision oncology testing is used for every patient. Labcorp is achieving this by providing the critical insights needed at every step of a cancer patient journey by offering a wide array of tests. To ensure that all patients have precision medicine within their reach, Labcorp offers decentralized or kitted solutions alongside centralized testing run within Labcorp labs. Pharma partners can leverage these kitted solutions for global clinical trials for when testing needs to be run locally. Labcorp is also able to support pharma needs at all stages — from research & discovery support for the identification of biomarkers for drug response to registrational clinical trials for a companion diagnostic (CDx).

Parallel Session 5A

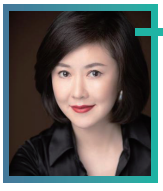
Round Table Discussion: Challenges and Opportunities in the New Era of Biotech Investment

Frank Li, PhD

Founder and Senior Consultant
BLA Regulatory, LLC
Past CBA President

Dr. Li is the Founder of BLA Regulatory based in Maryland, USA. He is an expert in Clinical and Regulatory Affairs. Dr. Li has been working in the Biopharmaceutical industry for more than 16 years such as in AstraZeneca, MedImmune, AZ BioVenture, Acentage, and SNBL. Dr. Li contributed significantly as the Regulatory Project Lead to the development of FASENRA (Benralizumab, an anti-IL5R antibody for Asthma) from Ph-2 to Worldwide Marketing applications and approvals including US, EU, Switzerland, Canada, Australia, Japan, and Brazil. Dr. Li also was the US and Canadian Regulatory lead for a biosimilar BLA filled with the FDA and NDS with Health Canada and got review approval. Dr. Li has had many successful INDs and CTAs preparation and approvals worldwide for clients including from Asian and pacific regions as a regulatory professional. Dr. Li obtained his PhD degree in Molecular Medicine from Kyoto University, School of Medicine, Japan. Dr. Li did a medical residency in surgical departments followed by clinical research training for his master's degree in China-Japan Friendship Hospital and Peking Union Medical College in Beijing, China. Dr. Li studied/contributed to clinical studies of Adoptive Immunotherapy using T lymphocytes and Dendritic cells for the treatment of Breast cancer and Melanoma patients. Dr. Li also conducted cytokine signal transduction research as a post-doctoral fellow in the US. Dr. Li obtained his Regulatory Affairs Certificate (RAC) from the Regulatory Affairs Professionals Society (RAPS) in 2005.

Dr. Li is the 23rd President of Chinese Biopharmaceutical association. As the Chairman of CBA organizing committee, Dr. Li successfully organized the 23rd Annual Conference in June 2018 with more than 800 attendees and famous Keynote Speakers from academia, regulatory authority, and industry including Drs. Lieping Chen (Yale University, Professor), Richard Pazdur (FDA, Center Director), Yongjun Liu (Sanofi, Global R&D Head), and Laurence Cooper (ZioPharm CEO).



Fiona Yu, MBA

CEO
Unogen Biotech Ltd.

Ms. Fiona Yu (Ao Yu) is the founder and CEO of Unogenbio. Before founding this company, Ms. Fiona Yu has over 20 years of corporate executive experience. She focuses on pharmaceutical strategy research and has accumulated extensive experience in the biopharmaceutical field in both China and the United States. Ms. Yu has written a book of strategic analysis "The Success Code of Pharmaceutical Giant", which is generally considered to be of great reference and thinking value by senior people in the industry.

Changshou Gao, PhD

SVP & CTO
Innovent Biologics Inc

Dr. Changshou Gao is the senior vice president and Chief Technology Officer of Innovent, and is chiefly responsible for Innovent Academy and global research center. Dr. Gao received his master's degree from the Shanghai Institute of Biochemistry, Chinese Academy of Sciences, and a Ph.D. degree in Chemistry and Molecular Biology from the Scripps Research Institute (La Jolla, California).

Dr. Gao is a well–recognized scientist and innovator with about 20 years of experience in biopharmaceutical research and drug development, and a luminous track record in lead antibody discovery and early drug development. Prior to joining Innovent, Dr. Gao was Senior Director of the Antibody Discovery & Protein Engineering Department of MedImmune/AstraZeneca. Dr. Gao has a breadth of experience that covers antibody discovery–/engineering, protein scaffolds, bispecific antibodies, antibody drug conjugates, large scale antibody transient expression, targeted nanoparticles, PROTAC, AAV mediated gene therapy, new technology development for the next generation of biologics and more. He has advanced more than 20 therapeutic antibodies to clinical trials, including antibody drug conjugates and bispecific antibodies, covering oncology, immunology, infectious diseases, cardiovascular, renal, and metabolic diseases.

Dr. Gao also has 30 years of academic excellence with publications in major journals (h–index=32, over 3300 citations) and invention of 38 issued patents or patent applications.

Nektarios (Aris) Oraiopoulos, PhD

Professor
University of Cambridge

Dr. Nektarios Oraiopoulos is a professor in Operations and Technology Management at the Judge Business School, University of Cambridge. His research has been invited for presentation in numerous academic conferences, has won multiple awards, and has been published in the flagships journals of the field. He has also co–authored the book "From Breakthrough to Blockbuster: the Business of Biotechnology" (Oxford University Press, 2022). In addition to his academic work, Nektarios has worked closely on research projects with numerous executives from the biopharmaceutical industry, both in large pharmaceutical organizations and small biotech companies. He received his B.S. degree in electrical and computer engineering from the National Technical University of Athens, and his PhD degree in operations management from the Georgia Institute of Technology.

Catherine Pan

Partner, Corporate Group Head of New York Office, Co-Chair of US-China Practice Group, Management Committee Member
DORSEY & WHITNEY LLP

Ms. Catherine X. Pan-Giordano is a Partner and Corporate Group Head of the East Coast offices of Dorsey & Whitney, a national law firm with 19 offices in the U.S. and around the globe. Ms. Pan also chairs the firm's industry recognized U.S.-China Practice.

As a highly skilled attorney and trusted advisor, and one of the most prominent Chinese-speaking business lawyers in New York, Ms. Pan is relied on by our clients to handle their strategic corporate transactions and to solve complex legal problems for their business. Ms. Pan has a strong client following among some of the world's largest corporations, financial institutions and business leaders. The strategic corporate transactions that Ms. Pan handles include mergers, acquisitions, joint ventures, equity and debt financings, and other cross-border corporate transactions.

Parallel Session 5B

Round Table Discussion: 27-Years of Bridging Innovations and Entrepreneurship Between US and China

Richard Y. Zhao, PhD

Professor and Division Head of Molecular Pathology, University of Maryland School of Medicine
Fellow, American Academy of Microbiology

Dr. Zhao is a tenured Professor of Pathology, Microbiology-Immunology, Human Virology and Global Health, Division Head of Molecular Pathology, Founding Director of Translational Genome Laboratory at University of Maryland School of Medicine. He is also the Director of Molecular Diagnostics Laboratory at University of Maryland Medical Center. Dr. Zhao obtained his B.S. from China Oceanography University, M.S. and Ph.D. from Oregon State University. His postdoctoral training was at College of Physicians and Surgeons of Columbia University, where he later served as a Research Associate Scientist/Research Assistant Professor. He started his independent research laboratory in the early 90's at Northwestern University Feinberg School of Medicine where he received an Endowed Chair as a "Bernard L. Mirkin PhD/MD Research Scholar". Dr. Zhao's research interest is HIV/AIDS, Zika virus, and SARS-CoV-2/COVID-19 in the areas of virus-host interaction, viral pathogenesis, and new antiviral drug discovery. He published over 150 scientific papers, serves/served on numerous editorial boards of scientific journals, chaired/served on NIH grant review panels, reviewed scientific grant applications for funding agencies of over ten different countries. Dr. Zhao's clinical expertise is in molecular pathology. He founded several CLIA/CAP accredited Molecular Diagnostic Laboratories and co-founded a Translational Genomics Laboratory since the early 90's. He has been invited to give scientific and clinical lectures world-wide. Dr. Zhao is a past President of CBA.

Yifan Zhai, MD, PhD

Chief Medical Officer
Ascentage Pharma

Yifan Zhai, MD, PhD, is Chief Medical Officer of Ascentage Pharma, CEO at Guangzhou Healthquest Pharma. She has worked in new drug development for nearly 30 years in NCI/NIH, GSK, Bayer, Exelixis and others, including small molecules, antibody and vaccine based therapeutics. Under the leadership of Dr. Zhai, Ascentage Pharma has built a pipeline of eight clinical drug candidates, the company is conducting nearly 50 clinical trials in the US, Australia, Europe, and China, she is responsible for NDA submission of Olverembatinib in 2020 in China. Dr. Zhai has exceptional expertise and experience in pathology, pharmacology, toxicology and clinical research. She is one of the inventors and manufacturers of the world's first tumor vaccines, Ad2MART1 and Ad2GP100, and jointly developed Sorafenib (NEXAVAR®) as the patent co–inventors while working at Bayer.

Dr. Zhai more than 50 publications and have more than 80 patent applications. She was selected as the Leading Talent of Guangzhou Science and Technology Innovation in 2012, the Leading Talent of Guangdong Science and Technology Innovation Team in 2013, and she named in "2020 Women in Tech" by Forbes China. Dr. Zhai was also the 12th President (2009–2010) of Chinese Biopharmaceutical Association, USA (CBA).

Lin Sun–Hoffman, PhD, JD

Founding Partner
Ambiz Law Group (Liu, Chen & Hoffman LLP)

A founding partner in Ambiz Law Group (Liu, Chen & Hoffman LLP), Dr. Lin Sun–Hoffman is a patent attorney with more than 20–year experience focused on innovative life sciences. Lin has deep knowledge in all aspects of patent practices, ranging from patent preparation and prosecution, due diligence, opinion work, through licensing and technology transfer negotiation.

Lin's diverse background has prepared her to tackle the toughest challenges facing innovative life sciences companies today, starting with her time as a patent examiner at the United States Patent and Trademark Office (USPTO). She left USPTO to serve as managing patent counsel at Celera Genomics before joining the Life Technologies Corporation (formerly Applied Biosystems, now ThermoFisher). She is a frequent speaker in China, the US, and Europe, including participation at the invitation of USPTO to speak at many conferences.

Lin also has over ten years of biomedical research experience including several years as a postdoctoral research fellow with several publications at the National Cancer Institute (NCI) of National Institutes of Health (NIH) in Maryland. Lin currently serves N California Bay Area Chapter head for the BayHelix Group, Board member of Chinese Health Initiative, advisor for California Life Science Association and Stanford University SPARKs program. Lin was President of the Chinese Bioscience Association in Silicon Valley in 2013, and President of the Chinese Biopharmaceutical Association (CBA) 2008–2009. Lin also served as Chief Advisor for Asia at the Gro–cery Manufacturers Association (GMA) during 2011–2015, and Chief Advisor for Asia at Biotechnology Innova–tion Organization's (BIO) during 2009–2011.

Lin holds PhD from University of Nevada, Reno and JD from University of Maryland and is licensed to practice in Maryland and USPTO.

The Organizing Committee of CBA 27th Annual Conference

Chairmen: Song Wu & Jingyu (Julia) Luan

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sirnaomics

Advancing RNAi Therapeutics

Who We Are

Sirnaomics is the first biopharmaceutical company to achieve positive Phase IIa clinical outcomes in oncology clinical-stage RNA therapeutics, with a strong presence in the world that is discovering and developing innovative drugs for indications with significant unmet medical needs and large market opportunities. The company became a public company in Hong Kong market in 2021.

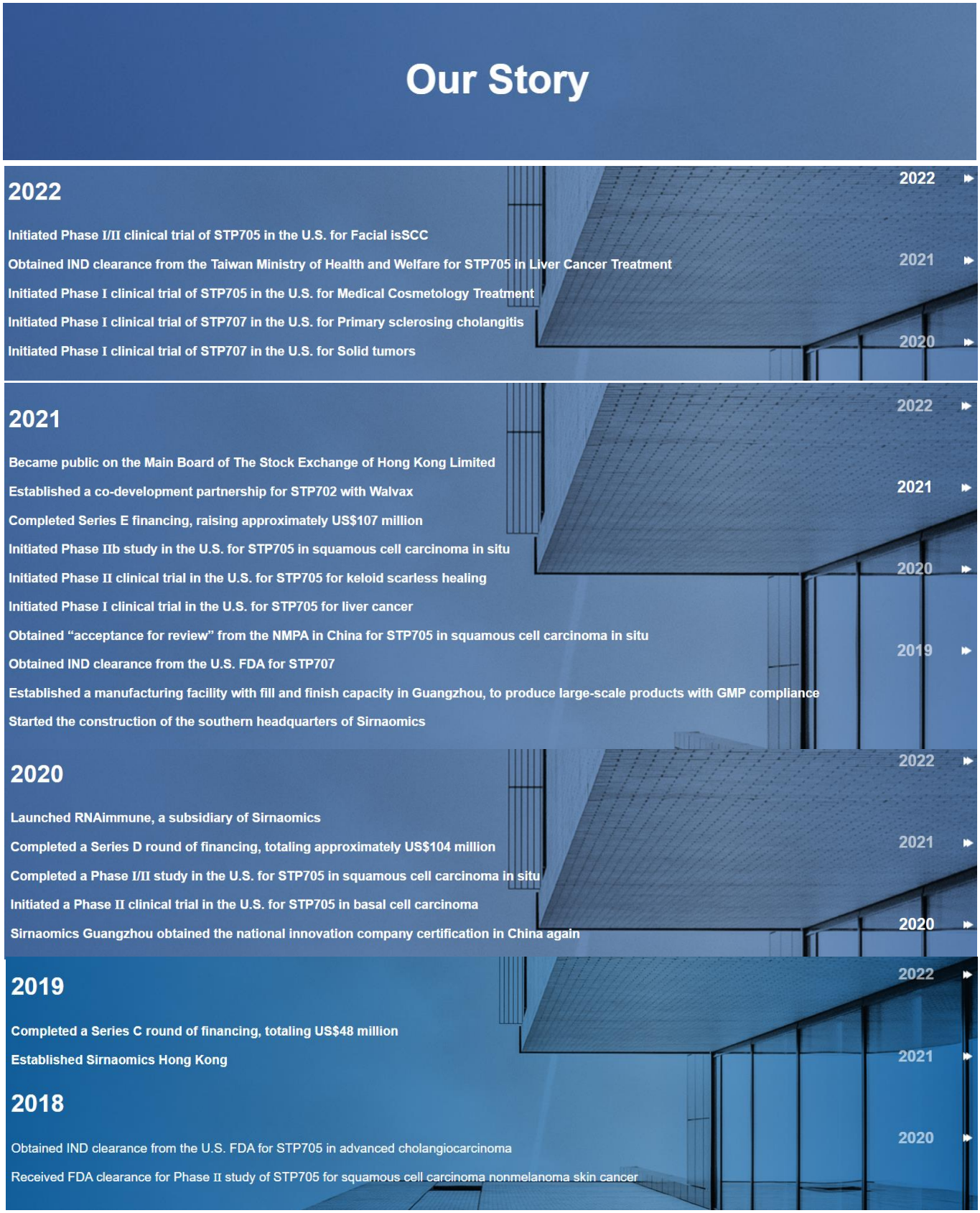
Sirnaomics' proprietary delivery platforms for RNA-based therapeutics are the foundation of our product pipeline. Our polypeptide nanoparticle delivery platform (PNP) is primarily used to administer mRNA vaccines and therapeutics. Our GalNAc delivery platform provides systemic administration for liver-targeting RNAi therapeutics.

Sirnaomics, Inc., located in Maryland USA since 2007 as Sirnaomics Group's global headquarters, is the base for R&D discovery, clinical, production, and general operation with more than 80 local employees. The entity has recently moved to Seneca Meadows Parkway, Germantown, MD to meet its fast growth needs.

Awards & Recognitions

2017	2020	2021	2021	2022
National New and Advanced Technology Enterprise National Office of Leading Group for Administration of Hi-tech Enterprise Recognition	National New and Advanced Technology Enterprise National Office of Leading Group for Administration of Hi-tech Enterprise Recognition	Top 10 RNA-Based Biopharmas Genetic Engineering and Biotechnology News	Top 3 finalists of Skin Health Innovation Competition Gore Range Capital	The Listed Enterprise Excellence Awards 2021 Capital Magazine

www.sirnaomics.com * 20511 Seneca meadows pkwy, Germantown, md 20876



www.sirnaomics.com * 20511 Seneca meadows pkwy, Germantown, md 20876

AAVnerGene
Together We Find The Cures

AAVnerGene Inc. is an innovative company developing new technologies to make AAV based gene therapy possible and more accessible.

AAVnerGene's Tissue–specific, Highly–transductive and Expressive New AAVs (ATHENA) screening platform has high complexity to find the best AAV for each specific disease therapy, so to increase productivity, efficiency and specificity while decrease manufacture pressure, side effects, immunity and price. We have about 1000 different AAV serotypes that can be used to screen a better AAV for any specific cell, and we are working on different animal models to get an atlas of cells and AAVs. Based on the screened data, we can further design and create new efficient AAV serotype to reduce AAV gene therapy's dose, side effects and price.

AAVnerGene's new patent technology, mini–pHelper system, makes AAV packaging more efficient and less costly. The derived dual–plasmids transfection and one–plasmid trans–fection system have significant advantages over the current tri–plasmids transfection for AAV production, and will revolutionize the AAV production system and make the AAV gene therapy more accessable.

With 20 years of AAV gene therapy front line expertise, AAVnerGene provides you cutting edge ideas, designs, high quality AAV packaging, products, library construction and screening services. Collaboration is welcome to promote the advance of the thriving area and bring hopes to patients. Together, we find the cures.

We are expanding quickly and we welcome all kinds of talents join us. Our address is 9620 Medical Center Dr, Rockville, MD 20850.

Please refer to WWW.AAVnerGene.com for more information and send your questions to daozhan.yu@aavnergene.com.

BioValley
佰 傲 谷
生物医药知识聚合社区

1 COMPANY

BioValley is born in 2016，a rapidly growing biopharma and biotechnology focused knowledgement community，headquartered in Shanghai. In the spirit of Expertise & Originality, BioValley is committed to providing the high-value knowledge, holistic consulting services, and precision marketing solutions to the entire biopharmaceutical industry.

A biopharma and biotechnology focused knowledgement community

BioValley has an omnichannel media matrix - "Biovalley" , "Biotitude" , "Immunology Chat" ,etc., with totally 300,000+ subscribers on Tiktok, TouTiao.com, Zhihu, etc. On this basis, we provide a complete knowledge service system and precise marketing solutions for the entire bio chain. BioValley has been recognized as a platform with "attitude, altitude, warmth" , a close liaison for all stakeholders on the value chain of this industry.

"Biovalley"　"Biotitude"　"Immunology Chat"

2 COMPANY

甲贝医药 Shell BioTech

Shell BioTech A Leading CDMO in China

Shell BioTech is a leading Contract Development and Manufacturing Organization (CDMO) in China, which providing one-stop "From DNA to IND filing" solutions that enable our partners to discovery, develop and manufacture novel biologics (including recombined protein, antibody, mRNA, etc).

Shanghai, China

R&D innovation center (includes 45,000 square foots laboratories)

Ningbo, Zhejiang

2 pilot production bases with 250L, 500L & 1000L cGMP capacity which meets FDA, EMA and NMPA regulatory requirements in (includes 80,000 square foots facility).

Customer first & Innovation-driven

Contact

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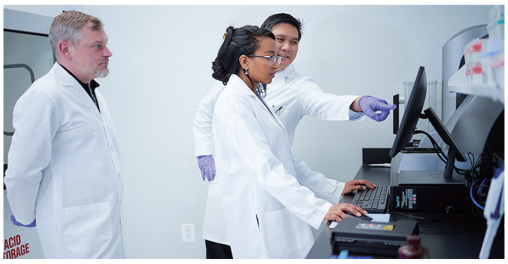
xiaolang.jiang@biovalleyclub.com
www.biovalleyclub.com
Building 6，Xunhao Technology Industrial Park，NO.258 Jinglian Rd., Minhang District, Shanghai

Amador Bioscience

Global leading translational & clinical research CRO

As a leading partner for successful innovative drug R&D, Amador Bioscience provides the whole chain of services for new drug development in CN, US and EU, including translational science, quantitative pharmacology, regulatory submission and clinical development in accordance with international standards, including clinical development strategy and execution from pre-clinical to NDA/BLA. We scientifically "choose dose, choose target, choose patient," and utilize global implementation of quality standards to enhance the success rate of new drugs.

Accelerated New Drug Development
Flexible solutions all under one roof



- Translational and Clinical Pharmacology
- Bioanalysis and Biomarkers
- Regulatory Affairs
- Clinical Research
- Phase I Units

CN China
Shanghai, Hangzhou,Beijing
GxP Lab: Hangzhou

EU Europe
Limburg Province, Belgium

US United States
California, Maryland, Michigan, Virginia
GxP Labs: California, Maryland

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See our facilities

Haichang Biotech

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Zhejiang Haichang Biotech Co., Ltd. (Haichang) is located in Hangzhou Pharmaceutical Port, China. Haichang is a National High-tech Enterprise Focusing on Innovative Biopharmaceutical Technology Development, with Independent Innovation Capability and Global Intellectual Property Rights. Haichang closely revolves around the core values of "Shared Ambition, Real Solutions". With full-scale R&D and manufacturing capabilities and global intellectual property rights, the company focuses on the Development and Industrialization of Drug Delivery Systems, nucleic acid medicine, such as mRNA vaccines, small nucleic acid medicine, and complex injectables. Our pipeline covers various therapeutic areas, including Infectious Disease Prevention, Tumor Immunotherapy, Anti-tumor, Analgesia and Other Fields. The newly established Nucleic Acid Medicine Innovation Center (NAMIC) focuses exclusively on the R&D and clinical transformation of nucleic acid drugs such as ASO, siRNA, miRNA and mRNA. Haichang is a global company at the cutting edge of an increasingly interconnected world. It is our ultimate goal to contribute the wellness of all mankind and grow into an international pharmaceutical company integrating R&D, manufacturing and commercialization.

全球化布局

Globalization

The WhiteOak Group, Inc. (WGI)
- New drug development center/platform
- Project Management
- US FDA regulatory registration and correspondence (IND, ANDA)
- Clinical Trial development
- Technology transfer
- US and EU partnership and market development

WhiteOak Pharmaceutical B.V.
- EU EMA regulatory registration and correspondence
- EU regional partnership and market development

Zhejiang Haichang Biotech Co. Ltd. HQ
- mRNA vaccine, nucleic acid drug delivery development
- LNP and nanotechnology development center
- Process scaling (pilot scale-up), technology transfer
- China NMPA regulatory registration and correspondence
- Investment and Public Listing HQ
- Asia regional partnership and market development

Zhejiang Hahekang Biopharmaceutical Co., Ltd
- Process scaling (pilot scale-up)
- Commercialized production
- Sales & Marketing

Beijing WhiteOak Pharm Co., Ltd.
- Regulatory registration and correspondence

HongKong WhiteOak Pharm Co., Ltd.
- Capital/Financing Center
- Investment hub
- Market and Business Development

技术平台

Technology Platform

合成生物学平台
核酸药物设计、合成和修饰
质粒构建
核酸原液制备

核酸递送系统平台
以QTsome™为基础进行优化

特色递送材料平台
脂质材料合成、筛选和优化

商业化生产平台
核酸药物的转化和商业化生产

中美两地研究院提供持续、丰富的源头创新

The WhiteOak Group, Inc. (Washington, DC)
核酸药物
序列设计、递送技术优化应用

核酸创新研究院 (杭州)
mRNA疗法
小核酸药物
序列设计及优化、递送材料研究、递送平台优化升级、工艺放大

高端制剂研究中心 (杭州)
复杂注射剂
递送技术
改良型新药（复杂注射剂）开发、递送技术开发

研究方向

Research Area

小核酸药物

ASO
单链DNA或修饰RNA靶核苷酸调节靶RNA功能

siRNA
siRNA可诱导基因沉默

miRNA
miRNA可调节mRNA的翻译过程

saRNA
saRNA可激活基因表达

mRNA

mRNA疫苗
直接翻译含有编码抗原蛋白的mRNA

mRNA药物
可作为蛋白质补充或替代疗法

杭州总部：浙江省杭州市钱塘区下沙街道
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第12层08C号
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美国：7529 Standish Pl., Rockville, MD
(240) 702-0080
邮箱：info@zjhaichang.com
官网：www.zhejianghaichang.com/
www.thewhiteoakgroupinc.com/

Aton Biotech, a wholly-owned subsidiary of Henlius, is a fast-growing **CDMO** committed to enabling new biological drugs for clients with integrated bio-pharmaceutical platform. Our service ranges from cell line development to clinical and end-to-end CDMO commercial manufacturing services, including development of mammalian expressed monoclonal antibodies, fusion proteins, bispecific antibodies, ADC, etc. In addition to the industry-leading manufacturing technology platforms, Aton Biotech has established an international level team, with high-quality talent reserve and robust team structure. The core management team has more than 15 years of senior management and industry experience.

Henlius now have two commerical operated facilities, Xuhui Facility and Songjiang First Plant, with a total capacity of 48,000L. Meanwhile, Henlius started construction of Songjiang Second Plant in 2019. The first phase of the project is planned to have a total capacity of 96,000L, of which 36,000L is expected to be put into commercial operation by the end of 2024.

Henlius will rationally allocate and maximize utilization of capacity and technology. The plan is to allocate **24,000L** of Xuhui Facility to Aton Biotech at the end of 2024, which will further accelerate Aton Biotech' s global GMP standard manufacturing capacity, enable Aton Biotech to realize efficient connection from early clinical to commercial manufacturing, and strive to meet the needs of global customers and improve the project delivery capability with experienced manufacturing and quality team.

100+
Technical staff,experienced management team

30+
Molecules (mAb,BsAb,fusion protein , ADC,etc)

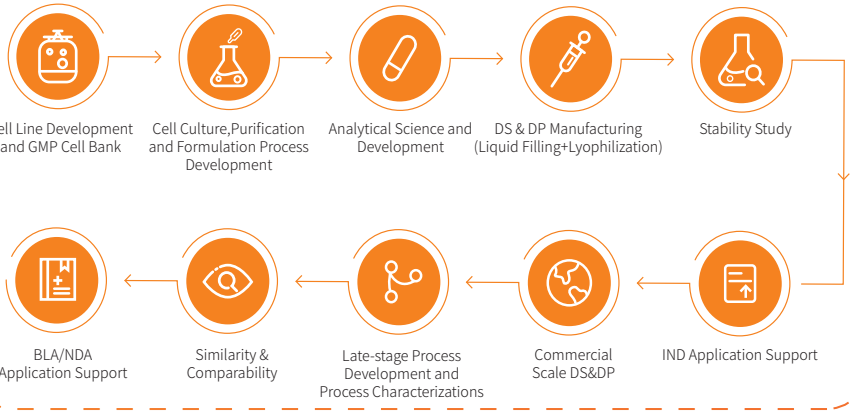
50+
IND approved (China,USA,etc.)

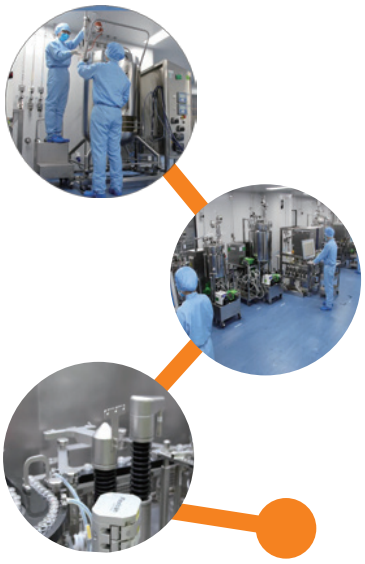
100%
Technology transfer success rate

100+
Tox & clinical batches

450+
Commercial batches

OUR SERVICES





About Henlius

Henlius (2696.HK) is parent company of Aton Biotech, which is a global biopharmaceutical company with the vision to offer high-quality, affordable and innovative biologic medicines for patients worldwide with a focus on oncology, autoimmune diseases and ophthalmic diseases. It has established global innovation centers and Shanghai-based manufacturing facilities in line with global Good Manufacturing Practices (GMPs).

WeChat

Linkedin

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www.atonbio.com
Aton (Shanghai) Biotech Co., Ltd.
1289 Yishan Road, Xuhui District, Shanghai, China

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Dorsey & Whitney LLP is a U.S. law firm with over 108 years of history and 20 offices around the world, including in the U.S., China (Beijing, Shanghai and Hong Kong), Canada and the U.K. Dorsey is consistently ranked as a top law firm by The American Lawyer and Chambers & Partners. Dorsey is also recognized as a "BTI Client Service A–Team".

Dorsey has served clients in the healthcare industry since the 1940s. The firm's Life Science and Healthcare Industry Group consists of about 120 specialized attorneys serving more than 500 clients. We serve clients ranging from companies at the forefront of medical innovation to the largest health care payer in the United States (United Healthcare Group) to one of the world's most recognizable medical practices (Mayo Clinic). Life sciences and healthcare companies rely on Dorsey because our attorneys understand the legal and technical issues crucial to success in this rapidly changing industry. Our wide range of expertise and experi–ence, which includes attorneys with scientific degrees and industry backgrounds, provides a framework for our clients' success — from patent applications, regulatory compliance and licensing agreements to mergers and acquisitions, national security analysis (CFIUS and export control), litigation, private equity and venture capital financings and IPOs.

Dorsey has a dedicated team of Chinese–English bilingual attorneys within its U.S.–China Practice Group assisting Chinese clients, led by prominent international lawyer Catherine Pan–Giordano, a partner based in our New York office. Given their language and culture background, attorneys in our U.S.–China Practice Group can fully understand the needs of Chinese clients and clearly explain U.S. legal matters to these clients.

For more information about Dorsey, please visit:**www.dorsey.com.**

BIOSYSTEMS Acro | *Where Proteins and Innovation Advance Biomedicine*

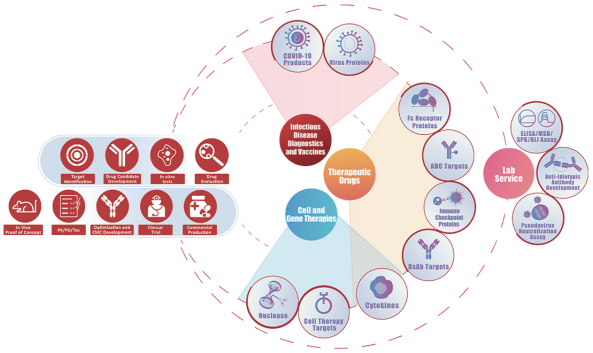
ACROBiosystems Group, founded in 2010 and listed in 2021, is a biotechnology company aimed at being a cornerstone of the global biopharmaceutical and health industries by providing products and business models innovation. The company spans across the globe and maintains offices, R&D centers, and production bases in 12 different cities within the United States, Switzerland, England, Germany, and China. ACROBiosystems Group has establizshed numerous long-term and stable partnerships with the world's top pharmaceutical enterprises, including Pfizer, Novartis, Johnson & Johnson,and numerous well-known academic institutes. The company comprises of several subsidiaries such as **A**CROBiosystems, **b**ioSeedin, **C**ondense Capital, and ACRO**D**iagnostics.

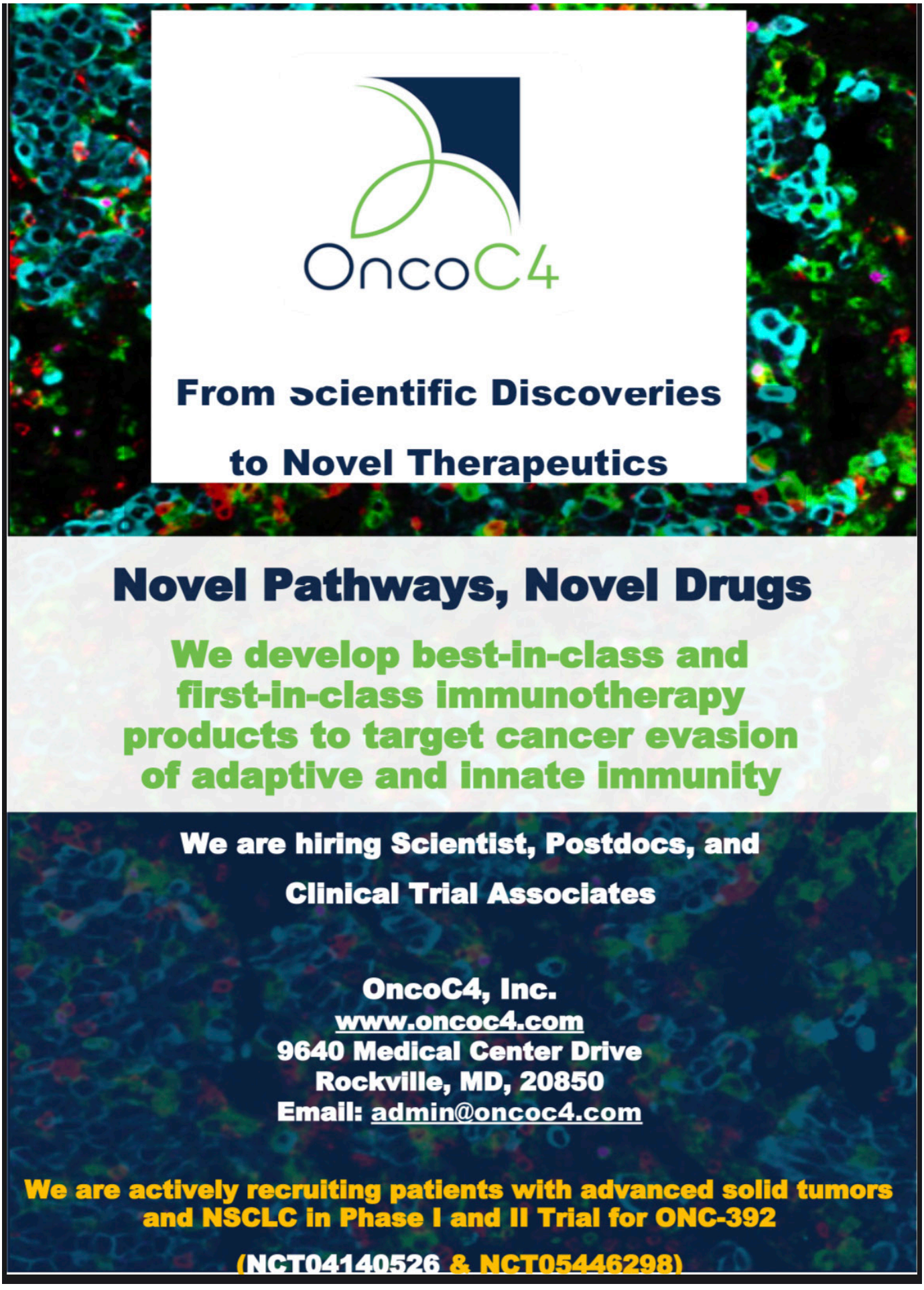
Our Clients

Pharma | Biotech | Diagnostics | Vaccine | CRO | Academia

Products and Services

ACROBiosystems' brands include FLAG, Star Staining, ViruStop, Aneuro, ComboX, GENPower, and many others. Our main products and services are recombinant proteins, kits, antibodies, scientific services, and other related products. ACROBiosystems employs a strict quality control system for its products that are used in biopharmaceutical research and development, production, and clinical application. This includes targeted discovery and validation, candidate drug screening/optimization, CMC development, and pilot production, preclinical research, clinical trials, commercial production, and clinical application companion diagnostics.

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From scientific Discoveries
to Novel Therapeutics
Novel Pathways, Novel Drugs
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products to target cancer evasion
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皓元医药 HaoYuan Chemexpress®

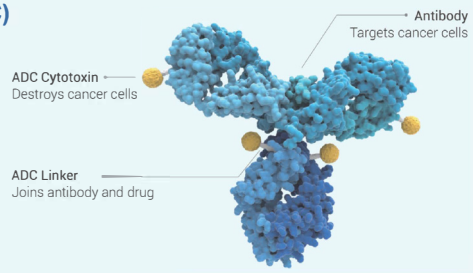
上海皓元医药股份有限公司 成立于 2006 年，位于上海张江生物医药基地，公司是专注于小分子药物研发服务与产业化应用的平台型高新技术企业，主要业务包括小分子药物发现领域的分子砌块和工具化合物的研发，以及小分子药物原料药、中间体的工艺开发和生产技术改进，为全球医药企业和科研机构提供从药物发现到原料药和医药中间体的规模化生产的相关产品和技术服务。

Shanghai Haoyuan Chemexpress Co., Ltd, founded in 2006, is located in the renowned Zhangjiang Biopharmaceutical High-tech base, Shanghai. As a platform-based high-tech enterprise, the company focuses on industrial-scale application as well as supplying products and services to our clients in the field of small molecule drug discovery. The main business includes the R&D of molecular building blocks and reference compounds in the field of small molecule drug discovery, the process development and production technology improvement of Active Pharmaceutical Ingredient (APIs) and pharmaceutical intermediates. Haoyuan Chemexpress is dedicated to provide the related products and services from drug discovery to large-scale production of APIs and pharmaceutical intermediates to global pharmaceutical companies and research institutions.

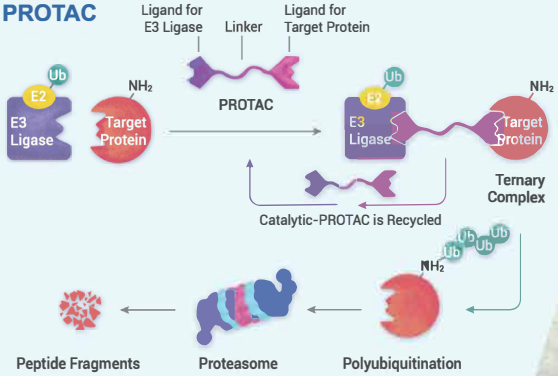
皓元医药：药物研发和产业化服务的一体化技术平台

特色产品

Antibody-Drug Conjugate (ADC)



PROTAC



研发生产能力

- 公司有近 1500 人的技术开发人员，博士和硕士占比为 25%
- 上海研发中心面积约 21,000 m²，其中合成实验室 7,000 m²，分析实验室 2,500 m²；安徽研发中心约 4,900 m²
- 生产基地占地共计 16.6 万平方米，其中安徽 86,000 m²、甘肃 67,000 m²、山东 13,300 m²，拥有 100-5000 L 各种规格的多功能反应釜 230 余台及其配套设施，批量范围百克级到吨级，从科研到商业化生产的不同阶段，均可满足客户对原料药及中间体的需求

生产基地

- 上海 GMP-like 实验室 (Secondary DMF 注册)
- 安徽马鞍山 GMP 高活车间 (DMF 注册)
- 山东淄博合作工厂 (中间体)
- 甘肃白银工厂 (GMP)
- 安徽马鞍山工厂 (cGMP-建设中)

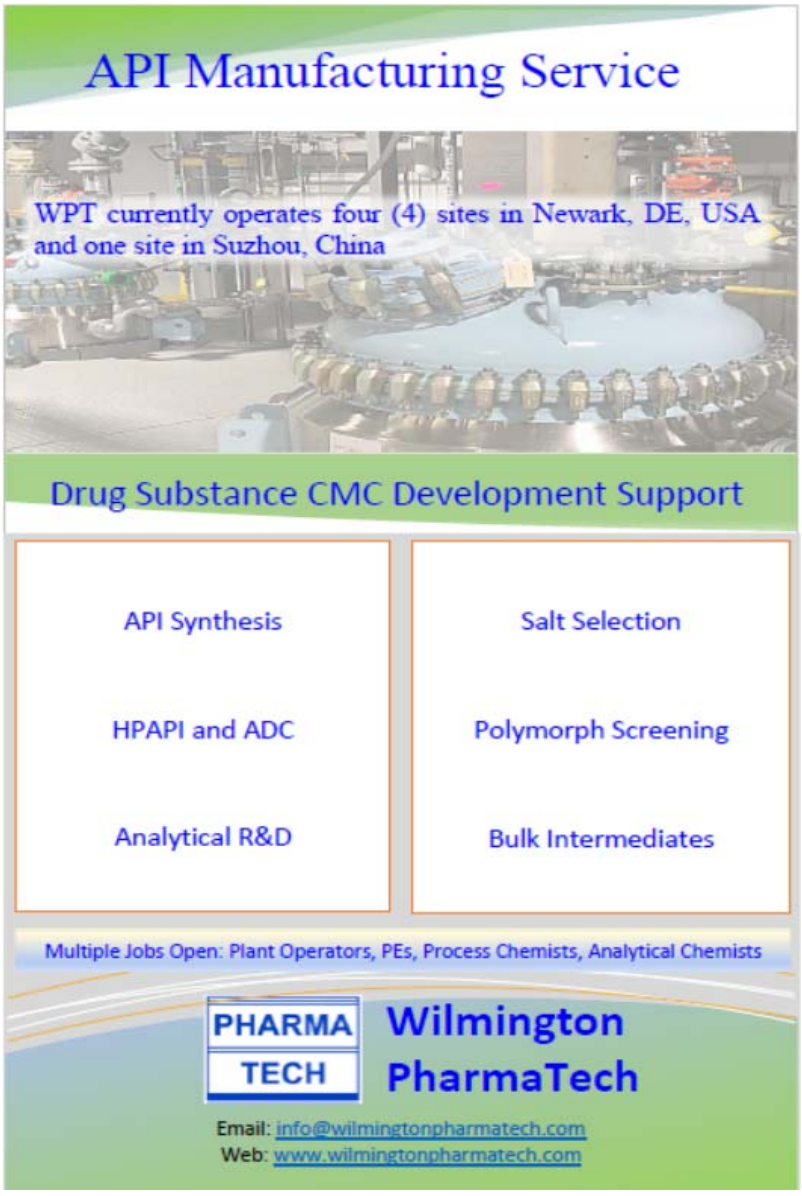
上海皓元医药股份有限公司

Tel (USA): 609-375-6525
Email: jackg.yang@chemexpress.com
Web: www.ChemExpress.com
Address: 1 Deer Park Dr., Monmouth Junction
New Jersey 08852

Wilmington PharmaTech Is Expanding Its Large-Scale API Pharma Manufacturing Capacities

Wilmington PharmaTech Company (WPT) is a leading global contract research organization (CRO) and contract manufacturing organization (CMO) specializing in research and development of large-scale process chemistry for the pharmaceutical and biotechnology industries. Founded in 2003 in Newark, DE, WPT has a track record of providing reliable and quality services for pharmaceutical and biotech companies worldwide with state-of-the-art facilities and operations. Our vision is "Better Science for Better Results". Our mission is to provide creative and practical solutions for complex pharmaceutical projects using high-quality, innovative science.
WPT has several key areas of expertise that enable us to help our customers advance their projects from discovery to development rapidly and efficiently. Based on the established expertise and proprietary technologies, WPT has developed a wide range of capabilities for the research and development of today's medicines. Our capabilities include large scale cGMP synthesis; High Potent API (HPAPI) manufacturing, ADC synthesis, stable isotope labeling; bulk intermediate production; FTE/time-based process and analytical research; salt and polymorph screening; Genotoxic Impurities (GTI's) and trace analysis; analytical GLP/GMP full services; ICH stability studies and sample storage; impurity identification, preparation and qualification: process impurities, stability impurities, and metabolites.

Today, WPT is known as one of the best, fastest and most reliable pharmaceutical API suppliers for pharma and biotech companies.



WPT currently operates four (4) sites in Newark, DE, USA and one site in Suzhou, China. Our new Glasgow (G300) site (https://youtu.be/o0UX2hRSSws) contains two (2) GMP pilot plant manufacturing bays with glass-lined reactors up to 750 gallons, a cGMP high-potency API (HPAPI and ADC) manufacturing facility, cGMP analytical labs, and a CFR facility.

Pilot Plant. There are two state-of-the-art production bays within the WPT pilot plant, with capacities to produce isolated products ranging from 10 to100 kgs in compliance with ICH Q7 guidelines. Each bay is outfitted with reactor vessels up to 750-gallon capacities. Each production bay is associated with a separate, dedicated gowning entrance as well as a dedicated clean room for open-air product handling, such as drying and packaging, to maintain the integrity of the product and prevent cross-contamination.

HPAPI Suites. WPT has a 6000 sqft High Potency API manufacturing suite that was commissioned in 2019, supplying a niche but expanding area of pharmaceutical research and production.

Jet Mill and Mastersizer. A fully enclosed spiral jet mill micronizer inside the HPAPI Suite is used for post-production powder processing to ensure uniform and consistent particle size of the finished material. Micronization is an established technology and manufacturing technique to produce APIs within a 1–10 micron average particle size.

Analytical Capabilities. WPT analytical laboratories have an expansive fleet of GC, GC-MS, HPLC, LC-MS, XRPD, DSC, TGA, and many other instruments to handle full release of APIs.

Storage Capability. WPT has exceptional capabilities for a broad range of storage needs for our clients including ambient, controlled room temperature, refrigerated and frozen conditions.

WPT is eager to dramatically scale our local operations using legacy DuPont Pharma facilities to satisfy significant market and customer demand as well as address an unstable international supply chain situation. These sites are particularly attractive for large-scale production of APIs because of the tremendous chemical production capability and huge waste treatment capacity. With newly developed and advanced technologies, and by redeploying and leveraging this legacy infrastructure, we have a generational opportunity to create a major global hub for manufacturing pharmaceutical active ingredients in the US – fortifying the supply chain challenge. WPT is looking for suggestions, collaborations, and long-term strategic partners who are interested in building reliable pharmaceutical API production capabilities.

康龙化成 PHARMARON

www.pharmaron.com

Pharmaron Clinical Services

Pharmaron Clinical Services (PCS), located in Piscataway, New Jersey, is a full Contract Research Organization (CRO) dedicated to providing high-quality clinical development services globally. With a staff of 3500, we provide full-service platforms in both China and the US. Our team is led by industry veterans with 15-25 years of experience.

Capabilities

- Biometrics
- Regulatory Affairs
- Medical Affairs
- Clinical Operations
- Bioanalytical Lab Testing
- Pharmacovigilance
- Technical Staffing
- Dual Registration

Solutions

- Innovative Drug Development
- Medical Device and Diagnostics
- Functional Service Partnership (FSP)
- Dual Registration
- Early Phase Oncology Product Development

Featured Biometrics Services

- Case Report Form (CRF, eCRF) design
- Randomized trial and drug supply system design
- Database design, build, test and maintain
- Double data entry and comparison of paper-form data
- Data verification and validation management
- Medical coding
- SAE reconciliation
- External data reconciliation
- Sample size calculation
- Protocol development
- Statistical methodology development
- Statistical Analysis Plan (SAP) and mockup shells development
- Randomized schedule development and randomization list generation
- Development of Study Data Tabulation Model (SDTM) datasets
- Development of Analysis Datasets (ADaM)
- Creation of Tables, Listings, and Figures (TLF)
- Interim analysis
- Data Monitoring Committee (DMC) related statistical activities
- Integrated Summaries of Safety and Efficacy (ISS/ISE)
- Annual or periodic safety reporting
- Quality assurance and data management audit

康龙化成 PHARMARON

pcs.bd@pharmaron.com
Phone: +1 240 -326-5418

Pharmaron is a premier R&D service provider for the life sciences industry that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical and clinical development process across multiple therapeutic modalities, including small molecules, biologics and CGT products.

AuHelix Biotech

We are dedicated to providing first-class complement system-based immunoassay services and committed to developing next-generation complement-targeted immunotherapy

Where did our science come from ------ **Complement cascade plays a central role in the immune response. The complement system is activated in almost all antibody-mediated autoimmune diseases. Dysregulation of the complement cascade is a key driver of autoimmune diseases and cancers. Development of complement-targeted therapeutics has become a hot spot in the field of immunotherapy for autoimmune diseases and cancers.**

Problem/Opportunity ------ **A lack of comprehensive drug screening and evaluation platform based on complement system in the R&D of the therapeutics for treating autoimmune diseases and cancers. Current drug development approaches are unable to tackle the issues with complement system involved in.**

Our Solution ------

Unique Advantage of Our Complement-based Innovative Drug Discovery Platform, N.C.B.T:

- ✓ **Covers all pathways and major upstream and downstream factors of the complement system**
- ✓ **A novel pioneer system with the integration of *in vitro* and chip-on-organ techniques**

N.C.B.T Platform

- ✓ **High-throughput engine**
- ✓ **Greatly Reduce drug discovery cost and time**
- ✓ **All-in-one multi-functional platform**

Our Team ----- Experience

Pfizer Takeda NIH FDA U.S. Department of Veterans Affairs HARVARD UNIVERSITY YALE

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Tel: 667-383-9708
Website: www.auhelix.com
WeChat ID: Z-Biz667

TopAlliance Biosciences

君实生物 TopAlliance

TopAlliance Biosciences

Providing patients with treatment options that work better and cost less

About TopAlliance Biosciences

TopAlliance Biosciences is a next-generation biopharmaceutical company dedicated to the discovery and development of innovative drugs towards clinical research and commercialization. We and our parent company, Junshi Biosciences, have leveraged our advanced discovery platforms, research tools and globally integrated R&D processes, and established a diversified R&D pipeline comprising over 50 drug candidates, with five therapeutic focus areas covering cancer, autoimmune, metabolic, neurological, and infectious diseases.

Highlights:

- 1st pharmaceutical company that obtained marketing approval for domestic anti-PD-1 monoclonal antibody in China
- 1st PD-1 checkpoint inhibitor in the world approved for nasopharyngeal carcinoma (NPC), a brand new indication for the entire class of anti-PD-1 drugs
- 1st in the world to be approved for clinical trials by the FDA and NMPA for our first-in-human anti-BTLA monoclonal antibody for the treatment of various cancers

TopAlliance Biosciences: http://www.topalliancebio.com
Junshi Biosciences: http://junshipharma.com

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A highly-educated workforce. Ground-breaking innovation hubs in life sciences, cybersecurity and aerospace. And, a quality of life that makes employees feel right at home. See why businesses are starting up or relocating here, here!

open.maryland.gov/here

For more informatio contact:
Ms Hui-Min Tzeng | hui-min.tzeng@maryland.gov

About Us

Hopstem Bioengineering Co., Ltd. was founded on January 2017 in Hangzhou, by neuroscientists and stem cell biologists from Johns Hopkins University. Hopstem has established world-leading iPSCs platform of neural differentiation and cell engineering. Hopstem has developed several critical patented technologies, as well as CMC platform for iPSC-derived cell therapy products. Hopstem has iPSC reprogramming patent, GMP iPSC line with global licensing rights, iPSC-derived cell product manufacturing and quality system, and a variety of cell therapy products and pipelines, targeting CNS diseases, optical diseases and tumor. Hopstem's first clinical product - neural progenitor cell hNPC01 targets neural injury diseases such as stroke and traumatic brain injury. The company expects to submit IND applications to both NMPA and FDA in 2022. Hopstem is committed to translating the most cutting-edge technologies to provide global patients with safe, efficient and affordable cell therapy products.

Cell Therapy Pipeline

Product	Type	Indication	R&D	CMC	Preclinical	Phase 1
hNPC-01	Human Forebrain Neural Progenitor Cell	Stroke				
		Traumatic Brain Injury				
		Cerebral Palsy				
iCAR-NK-H11 iCAR-NK-H21	CAR-NK	Solid Tumors				
	hypoimmunogenic CAR-NK	Solid Tumors				
hNPC-03	Human Dopaminergic Neural Progenitor Cell	Parkinson's Disease				
		ALS				
hNPC-02	Human Motor Neural Progenitor Cell	Spinal Cord Injury				
hNPC-EX	hNPC Exosome	Autism				
		Alzheimer's Disease				
Ocular Cell	Ocular Cell	Ophthalmic Disorders				

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