

CHINESE BIOSCIENCE ASSOCIATION PRESENTS

NEXT-GENERATION MEDICINE

From Gene, Protein, to Cell Therapy

24th Annual Conference

Oct. 8, 2022
8:30AM - 5:00PM

Crowne Plaza Hotel
1221 Chess Drive
Foster City, CA 94404

www.cbaf.org



CBA MISSION

To Promote Networking

Serve the life science professionals' interest in the Bay Area and facilitate networking between professionals locally and globally

To Promote Awareness

Enhance public awareness of the progress and development of the life science industry

To Update and Educate

Facilitate a better understanding of key trends in life science as well as encouraging scientific innovations to address unmet medical needs

To Foster Collaboration

Establish active collaborations with other organizations in areas of mutual interests

CBA MEMBERSHIP & BENEFITS

- Networking opportunities for success
- Connect with other professionals and share technical interests
- Keep skills and knowledge current and relevant
- Create new partnerships
- Free or discounted admission to seminars and workshops
- Free admission to Annual Summer Picnic
- Discounted admission to Annual Conference
- Access to career resources through job posting portal
- Eligibility to vote or become a board member

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STATE OF THE ASSOCIATION

It is with great pleasure that I begin my term as the president of the CBA from 2022 to 2023. The Chinese Bioscience Association is an organization started by a few Stanford and UCSF students and postdoctoral fellows 25 years ago, and now there are thousands of members in the Bay Area. CBA has been accomplishing its mission to promote educating, networking, mentoring, and community building for biological science professionals. We have experienced an unprecedented pandemic in the past two years, and that has greatly affected all of us. During these difficult times, we were able to witness the magnificent emergence of RNA based vaccines and watch this new technology at the forefront of the battle against COVID-19. Not only was exceptional science applied in vaccinology, the field of immunology too has seen transformative science in cancer, inflammation, and autoimmunity. As an immunologist by training, I would like to see how we will be able to apply basic immunology and cutting-edge technology to other diseases such as metabolic and neurodegenerative diseases that threaten global health.

Our theme for the CBA annual conference this year is “Next Generation Medicine” where we would discuss how researchers combine emerging science and innovative technology, including AI, to identify novel targets and develop revolutionary next generation therapeutics to cure patients with unmet medical needs. Thus, for the first time since the association’s inception, we are honored to invite the 2019 Nobel Laureate, Dr. Gregg Semenza to our annual conference as our keynote speaker. Dr. Semenza is a professor at Johns Hopkins Medical School where he has discovered and published many groundbreaking studies on Hypoxia-induced factors. Arcus Bioscience translated Gregg’s discoveries to develop antibody therapeutics — anti-CD39 and anti-CD73 — that target the hypoxia pathway. Arcus will also be sharing their exciting progress and experiences about targeting this pathway. Additionally, several emerging startups such as Apeximmune Therapeutics and Base Therapeutics will share their cutting-edge technologies and sciences in antibody therapeutics, gene editing, and CART...etc., to combat cancer, inflammation, and neurodegenerative diseases...etc.

We are able to invite several top-notch investors for panel discussion. Our members will get a chance to understand the investment environment under the current financial climate. In addition, there are several reputable contract research companies from model generation, drug screening, and manufacturing. To be able to discuss in person with these experts will be beneficial to speed up drug discovery and development.

Last but not least, I would like to take this opportunity to thank our sponsors, our board members, and all of the participants. This annual conference would not become possible without your sponsorship, your tremendous time, and efforts. I wish you all have a wonderful time at the annual conference.

Sincerely,



Li-Fen Lee, Ph.D.

2022 President of CBA



WELCOME REMARKS

On behalf of the planning committee and the entire CBA family, I am honored and delighted to welcome you to our 24th annual conference at Crowne Plaza in Foster City.

This year's conference is unique because it is the first in-person meeting after two years of disruption by the COVID-19 pandemic. We expect this conference to bring back enjoyable face-to-face communication to our members and friends. And we aim to create opportunities for scientists from academia and industry and investors from the biotechnology and healthcare community to exchange information on scientific innovations, technological advances, regulatory programs, and ideas in entrepreneurship.

The theme of this year's conference is Next Generation Medicine—From Gene, Protein, to Cell Therapy. We endeavor to provide all attendees with a great experience of learning cutting-edge research in life sciences and its applications in clinical practices. In addition to the scientific discussions from distinguished speakers, we will also have a session on regulatory affairs, biotechnology investment, and entrepreneurship from a group of prestigious panelists with expertise in various healthcare sectors. This conference will be an ideal platform for all of us to learn and enjoy in a cherishable on-site environment.

We welcome you again to our annual conference and hope this will be an exciting and memorable scientific event for you. I would also like to take this opportunity to thank CBA's board members, advisors, and volunteers for your support and dedication over the past year in preparing for the conference. I also want to thank the speakers and panelists for allocating their precious time and the sponsoring organizations for providing generous financial support. Lastly, I want to thank you all for attending the conference. Enjoy the meeting!

Thank you!

Best,

Xinguo Jiang, M.D., Ph.D.
2022 Chair of CBA Annual Conference



CONFERENCE AGENDA

Morning Session		
Opening		
8:00-8:30am	Registration, Networking, and Exhibition	All
8:30-8:35am	State of the Association	Li-Fen Lee , CBA President
8:35-8:40am	Welcome Remarks and Keynote Speaker Introduction	Xinguo Jiang , Conference Chair
8:40-9:30am	Morning Keynote: Hypoxia-Inducible Factors in Physiology and Medicine	Gregg L. Semenza , M.D., Ph.D., Nobel Laureate, Professor of Johns Hopkins University
Morning Session 1: Innovative Drug Discoveries and Breakthroughs		
9:30-9:35am	Opening Statements / Introduction to Speakers	Li-Fen Lee , Session Chair
9:35-10:00am	AB521 is a Novel and Potent Clinical-stage HIF-2 α Inhibitor for the Treatment of Renal Cell Carcinoma	Kelsey Gauthier , Ph.D., Director, Arcus Bioscience
10:00-10:25am	Discovery of AIM-103, a Novel Immune Attenuating Target of the Tumor Microenvironment for Cancer Immunotherapy	Kan Lu , Ph.D., Director, Apex Immune Therapeutics
10:25-10:35am	Q & A	All
10:35-10:55am	Break, Network, and Exhibition	
Morning Session 2: Novel Cell Therapeutics		
10:55-11:00am	Opening Statements / Introduction to Speakers	Lin Sun-Hoffman , Session Chair
11:00-11:25am	Targeting Intracellular Tumor Antigens with TCR Mimics for Cancer Immunotherapy	Cheng Liu , Ph.D., Founder, President and CEO of Eureka Therapeutics
11:25-11:50am	Optimizing Gene Therapy Development for Successful IND Clearance	Ruhong Jiang , Ph.D., CEO of ASC Therapeutics
11:50-12:00pm	Q & A	All
12:00-1:00pm	Lunch, Network, and Exhibition	

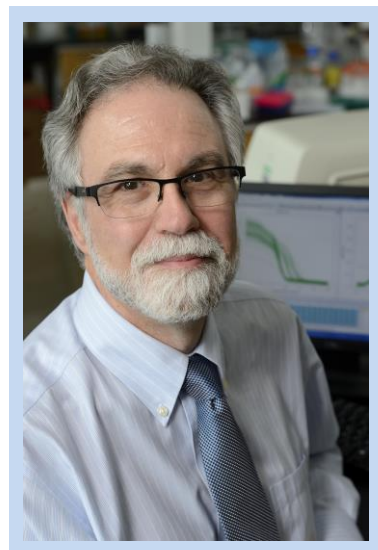


Afternoon Session 1: From Animal to Human		
1:00-1:05pm	Welcome Back / Summary of the Morning Session /Start of the Afternoon Session	Xinguo Jiang , Conference Chair
1:05-1:20pm	Comprehensive Model Organisms Services	Hua Wei , Ph.D., VP of Industrial Customers Department at Shanghai Model
1:20-1:35pm	Simultaneous Global Development of China-originated Innovative Drugs	Andy Liu , MBA, General Manager, Novotech China
Afternoon Keynote		
1:35-1:40pm	Introduction of Speaker for Afternoon Keynote	Xinguo Jiang , Conference Chair
1:40-2:20pm	Afternoon Keynote: Stem Cells & Genomics for Precision Medicine	Joseph Wu , M.D., Ph.D., Professor of Stanford University
Afternoon Session 2: State-of-the-Art Gene Therapy		
2:20-2:25pm	Opening Statements / Introduction to Speakers	Sydney Chen , Session Chair
2:25-2:50pm	Aiming to Cure Cancer and Genetic Diseases by Advancing the Next Generation Base Editing and Prime Editing Technologies	Han Ying , Ph.D., COO of Base Therapeutics Inc.
2:50-3:15pm	High-throughput Approaches for Optimizing Gene Editing Technologies	Nicholas Hughes , Ph.D., Founder of Acrobat Genomics, Inc.
3:15-3:25pm	Q & A	All
3:25-3:40pm	Accelerating Research Supporting Next Generation Medicine with Recombinant Proteins and Antibodies	Sumana Sundaramurthy , Ph.D., Technical Account Manager of Sino Biologicals
3:40-4:00pm	Break, Network, and Exhibition	
Afternoon Session 3: Regulatory and Investment in Entrepreneurship		
4:00-4:05pm	Opening Statements / Introduction to Speakers	Shuming Liu , Session Chair
4:05-4:30pm	Commercial IND Application in the US: Starting Initial Clinical Trials from Pre-clinical Stage	Frank Li , Ph.D., Founder of BLA Regulatory, LLC
4:30-5:20pm	Panel Discussion	Bing Liang , Session Chair Benjamin Chen, Srinivas Akkaraju, Chris Xu, Can Cui
5:20-5:25pm	Closing Remarks	Xinguo Jiang , Conference Chair
5:25-7:00pm	Networking	



MORNING KEYNOTE SPEAKER

Gregg L. Semenza, M.D., Ph.D., Nobel Laureate, Professor, Johns Hopkins University



Dr. Semenza is the C. Michael Armstrong professor of genetic medicine, with joint appointments in pediatrics, radiation oncology, biological chemistry, medicine, and oncology at the Johns Hopkins University School of Medicine. He serves as the founding director of the Vascular Program at the Johns Hopkins Institute for Cell Engineering and the 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. His current research interests include

investigating the molecular mechanisms of oxygen homeostasis and the role of HIF-1 in cancer progression. He has authored more than 450 research articles and book chapters, and his work has been cited by other scientists more than 175,000 times. Dr. Semenza is co-founder of HIF Therapeutics Inc., which is focused on the development of HIF inhibitors for the treatment of cancer and blinding eye diseases.

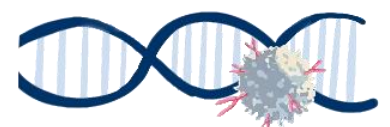
In addition to the Nobel Prize, Dr. Semenza has received the Albert Lasker Basic Medical Research Award (2016), Wiley Prize in Biomedical Sciences (2014), Lefoulon-Delalande Grand Prize from the Institut de France (2012), and the Canada Gairdner International Award (2010).

Title: Hypoxia-Inducible Factors in Physiology and Medicine

Abstract: Hypoxia-inducible factors (HIFs) are transcriptional activators that balance O₂ supply and demand by regulating the expression of genes that control the delivery and consumption of O₂, respectively. We purified HIF-1 and found that it was a heterodimer composed of an O₂-regulated HIF-1 α subunit and a constitutively expressed HIF-1 β subunit. In the presence of O₂, is subject to hydroxylation on two proline residues by prolyl hydroxylase domain proteins PHD1-3. Hydroxylated HIF-1 α is bound by the von Hippel-Lindau protein (VHL), which recruits a ubiquitin-protein ligase, leading the ubiquitination and proteasomal degradation of HIF-1 α . HIF-2 α and HIF-3 α are also O₂-regulated and dimerize with HIF-1 β , but unlike the ubiquitous expression of HIF-1 α , they are only expressed in a limited number of cell types. We now know of over 8,000 mRNAs which are directly activated by HIFs in response to hypoxia in one cell type or another. The critical role of HIFs in physiology has been demonstrated by the analysis of patients with hereditary erythrocytosis, which is defined by increased red cell production without changes in any other blood cell type. Loss-of-function mutations in the genes encoding PHD2



and VHL as well as gain-of-function mutations in the gene encoding HIF-2 α have been identified in affected individuals, who have dysregulated O₂ sensing that also affects cardiovascular and ventilatory responses to hypoxia. HIFs are also drug targets: HIF prolyl hydroxylase inhibitors stimulate erythropoiesis in patients with anemia due to chronic kidney disease, whereas a HIF-2 inhibitor was approved by the FDA for treatment of renal cell carcinoma.



MORNING SESSION I: INNOVATIVE DRUG DISCOVERIES AND BREAKTHROUGHS

Session Chair: Li-Fen Lee, Ph.D., 2022 President of CBA



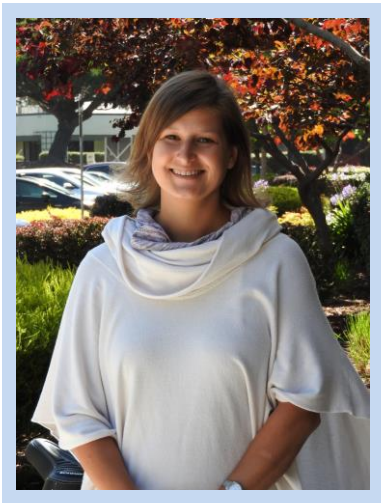
Li-Fen Lee, Ph.D. is Founder, Chief Executive Officer of Apeximmune Therapeutics. Dr. Lee is deeply versed in the fields of immunology and immuno-oncology (IO) and a leader with over 20 years of drug development experience and expertise in multiple therapeutic areas in the biotech and pharmaceutical industry. Dr. Lee held leadership positions at Abbvie and NGM where she led the IO group and established the core IO infrastructure and helped build the IO pipeline. Dr. Lee started her career at Pfizer where she led a drug discovery group and made significant contributions to the development of therapeutic antibodies against IL-7R and various costimulatory molecules such as 4-1BB aimed at treating autoimmune diseases and cancer. Her work, which included several IND filings, patents and numerous high impact publications, was recognized with the prestigious Pfizer Achievement Award. Prior to joining industry, Dr. Lee held a faculty position at the

Stanford University School of Medicine. She received her Ph.D. in Cancer Immunology at the University of North Carolina, Chapel Hill where she was a recipient of the Lineberger Graduate Fellow Award and completed postdoctoral training at Stanford University.



MORNING SESSION I SPEAKER

Kelsey Gauthier, Ph.D., Director of Biology, Arcus Bioscience



Kelsey was born and raised in Eastern Pennsylvania and has a B.S. in Microbiology with a minor in Biochemistry and Molecular Biology from the Pennsylvania State University. She went on to earn a Ph.D. in Microbiology and Immunology from the University of Michigan, where her thesis work focused on understanding the immune response to uropathogenic *Escherichia coli* infection as well as mechanisms of protection for subunit-based mucosal vaccines for urinary tract infection. Her postdoctoral research at UC Berkeley was centered on elucidating the impact of the host innate immune response upon pathogenesis of a common enteric pathogen, *Salmonella typhimurium*. From her postdoc, she transitioned to a scientific career in the biopharmaceutical industry, focused on the discovery, preclinical and clinical development of small and large molecule drugs to treat cancer, autoimmune, and inflammatory diseases. She is currently a Director of Biology at Arcus Biosciences in Hayward, CA.

Title: AB521 is a Novel and Potent Clinical-stage HIF-2 α Inhibitor for the Treatment of Renal Cell Carcinoma

Abstract: The transcription factor Hypoxia-inducible Factor (HIF)-2 α is an oncogenic driver in clear cell renal cell carcinoma (ccRCC). Post-translational regulation of the HIF-2 α protein is oxygen-dependent and, in hypoxic or pseudohypoxic conditions, results in the stabilization of HIF-2 α and transcription of protumorigenic genes. Inhibition of HIF-2 α has significant potential to mitigate tumor growth, particularly in hypoxic solid tumors and in cancers that have a high prevalence of molecular alterations associated with pseudohypoxia. Arcus Biosciences is developing AB521, a novel and potent small molecule HIF-2 α inhibitor. Biochemical assays and crystal structure elucidation demonstrated that AB521 avidly binds the PAS-B domain of HIF-2 α . In cell-based assays, AB521 potently inhibited HIF-2 α -dependent reporter-gene transcription and VEGF protein secretion in 786-O ccRCC cells. AB521 also selectively inhibited HIF-2 α , but not HIF-1 α , regulated gene expression in Hep3B hepatocellular carcinoma cells. *In vivo*, AB521 significantly induced regression of ccRCC xenograft tumors and decreased on-target pharmacodynamic (PD) markers in a dose-dependent manner. Additionally, AB521 enhanced anti-tumor activity of a VEGF-targeting tyrosine kinase inhibitor. Accompanying encouraging activity in tumor models, AB521 had a favorable pharmacokinetic (PK) profile *in vitro* and *in vivo*, rendering the molecule suitable for once-daily oral dosing in humans. The safety, tolerability, PK, and PD (erythropoietin hormone) of AB521 are currently being investigated in a randomized, placebo-controlled single and multiple ascending dose Phase 1 study in healthy volunteers (NCT05117554). In this first-in-human study, AB521 demonstrated PK/PD properties that are consistent with a potential best-in-class HIF-2 α profile. Additionally, published and novel gene signatures were applied to publicly available datasets to elucidate potential predictive biomarkers and additional therapeutic opportunities for AB521. Here, signatures related to hypoxia and HIF-2 α were associated with therapeutic response to HIF-2 α inhibition in preclinical models. In summary, AB521 is a novel and selective HIF-2 α inhibitor with profound anti-tumor activity in preclinical models, and clinical evaluation of this molecule is ongoing.



MORNING SESSION I SPEAKER

Kan Lu, Ph.D., Director of Biology, Apeximmune Therapeutics



Kan Lu is Director of Biology at Apeximmune Therapeutics, where he leads the identification and preclinical evaluation of novel biologics across all target programs aimed at activating host immune cells into targeting tumors. Kan joined Apeximmune as its first scientist from Pharmacyclics, an AbbVie Company, where he led efforts to characterize the immune modulating properties of the BTK inhibitor ibrutinib. He has extensive experience studying the interplay between tumor cells and immune components of the tumor microenvironment in cancer progression and during the course of therapeutic intervention, particularly in glioblastoma invasion and angiogenesis. Kan holds a Ph.D. in Cellular and Molecular Pathology from the University of California, Los Angeles, and completed postdoctoral training at the University of California, San Francisco.

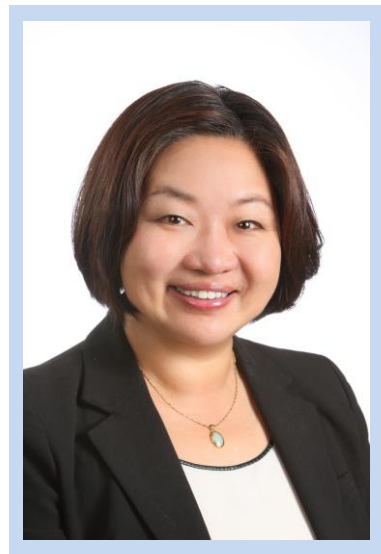
Title: Discovery of AIM-103, a Novel Immune Attenuating Target of the Tumor Microenvironment for Cancer Immunotherapy

Abstract: Currently approved immune checkpoint inhibitors (ICIs) represent a transformative advancement in cancer therapy, nevertheless the majority of patients fail to respond due to primary or acquired resistance. Identifying novel immune regulators and developing therapeutics targeting such molecules to complement or even supplant current ICIs is a current focus in immuno-oncology and the primary goal of Apeximmune Therapeutics. Using a bioinformatic target discovery approach correlating gene expression with effector T cell prevalence in tumors to uncover novel modulators of T cell activity or recruitment, we have identified AIM-103 as an important, undisclosed negative immune regulator that is highly expressed in various human tumors and positively correlated with well-characterized checkpoints including CTLA-4, PD-L1, and TIGIT. Primarily expressed in myeloid cells including dendritic cells (DC) and macrophages, AIM-103 has largely been characterized based on its enzymatic activity which gives rise to anti-inflammatory lipid mediators that suppress DC and T cell activity. Using an AIM-103 enzyme-dead mutant, we demonstrate that AIM-103 also potently and directly inhibits DC and T cell function, as well as macrophage phagocytosis, through mechanisms that are independent of its catalytic activity. Cell surface binding of AIM-103 to T cells is dramatically increased upon T cell activation, suggesting the presence of an inducible cell surface signaling receptor. Growth of various syngeneic tumor models in AIM-103-knockout mice is significantly decreased compared to wild type mice, with accordingly increased DC and CD8⁺ T cells and reduced Tregs and M2 macrophages, indicating that AIM-103 is a novel, targetable checkpoint for tumor immunotherapy. We have discovered a panel of antagonistic monoclonal anti-AIM-103 antibodies suitable for clinical translation that bind with low nanomolar affinity to human AIM-103, reverse its suppressive function in T cell activity assays, and block its binding to activated T cells. A subset of anti-AIM-103 antibodies cross-react with mouse AIM-103 and inhibit syngeneic tumor growth in mice as monotherapy, while enhancing the efficacy of anti-PD-1 therapy when combined. Collectively, these studies provide an attractive rationale for the development of anti-AIM-103 antibodies as a novel cancer immunotherapy for patients resistant to current ICIs.



MORNING SESSION II: NOVEL CELL THERAPEUTICS

Session Chair: Lin Sun-Hoffman, Ph.D., J.D., 2022 CBA Advisor



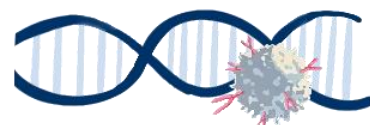
A founding partner in Liu, Chen & Hoffman LLP, Dr. Lin Sun-Hoffman is a patent attorney with more than 20-year experience focused on innovative life sciences. Lin has deep knowledge in all aspects of patent practices, ranging from patent preparation and prosecution, due diligence, opinion work, through 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 was 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 Bay Area Chapter head for the BayHelix Group, Secretary General of US-China Green Energy Council, advisor for California Life Science Association FAST program and Stanford University SPARK 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 Grocery Manufacturers Association (GMA) during 2011-2015, and Chief Advisor for Asia at Biotechnology Innovation Organization's (BIO) during 2009-2011.

Lin was active in community activities including serving on the PTA executive council board (2015-2017) of Palo Alto School District, and taught underprivileged students in rural area Yunnan China with Bay Area based PEACH program.

Lin holds her J.D., and Ph.D. in Biochemistry/Cell and Molecular Biology. She is admitted in Maryland and U.S. Patent and Trademark Office.



MORNING SESSION II SPEAKER

Cheng Liu, Ph.D., Founder, President and CEO, Eureka Therapeutics



Dr. Cheng Liu is the Founder, President and CEO of Eureka Therapeutics. Prior to founding Eureka, Dr. Liu was a Principal Scientist in antibody drug discovery at Chiron (now Novartis).

With over 20 years of experience in the field, he holds more than 500 patents and published patent applications of which over 100 patents have issued worldwide and has authored numerous peer-reviewed papers on cancer immunotherapy.

He is the inventor of multiple first-in-class, clinical-stage cancer drugs against various tumor targets, including drugs targeting CSF1 for the treatment of bone metastasis, BCMA for multiple myeloma, and AFP and GPC3 for liver cancer. In 2007, he was awarded Special U.S. Congressional Recognition for his contributions to improving human health.

He is the editor of the book “Biosimilars of Monoclonal Antibodies: A Practical Guide to Manufacturing, Preclinical, and Clinical Development”. Dr. Liu received his B.S. in Cell Biology and Genetics from Peking University and a Ph.D. in Molecular Cell Biology from the University of California, Berkeley.

Title: Targeting Intracellular Tumor Antigens with TCR Mimics for Cancer Immunotherapy

Abstract:

- Targeting tumor-specific intracellular cancer antigens with antibodies
- Designing a better T-cell engineering technology to address the major hurdles in treating solid tumor
- Infiltrating into solid tumor under immunosuppressive microenvironment
- T cell therapy targeting Alpha-fetoprotein (AFP) and Glypican 3 (GPC3) in advanced hepatocellular carcinoma (HCC)



MORNING SESSION II SPEAKER

Ruhong Jiang, Ph.D., CEO of ASC Therapeutics Inc.



Dr. Ruhong Jiang, is CEO of ASC Therapeutics Inc. - a global leading company in gene therapy and allogenic cell therapy. Under his leadership, the company has successfully moved two programs into clinical stage within two years. Ruhong has held a variety of technical and managerial roles in several biotechnology/biopharmaceutical companies. Prior to starting Applied StemCell, he was general manager of MicuRx(Shanghai)Pharmaceutical, Inc. a California-based biopharmaceutical company and he set up its entire China operation. From 2005-2007, Dr. Jiang was head of the Pharmacogenetics Program at Stanford Research Institute International (SRI) where he managed multiple pharmacogenetic and molecular genetics projects with multi-million annual budgets. Before relocating to California, Dr. Jiang was pharmacogenomics consultant at Boehringer Ingelheim Pharmaceuticals and served as senior scientist, then director of project management at Genaisance Pharmaceuticals from 2000-2004 where he played an

important role in biomarker discovery, pharmacogenetics and clinical bioinformatics, diagnostic product development, alliance management and business development. Dr. Jiang graduated from Fudan University with a B.S. degree in biology and received his M.S. degree in reproductive biology from China Agricultural University and a Ph.D. degree in Genetics from Oklahoma state University in 1997. He later went to Baylor College of Medicine where he furthered his education as a postdoctoral fellow in Dr. Douglas Burrin's lab. Dr. Jiang has published more than 40 articles in the fields of human genetics, pharmacogenetics and disease animal models. In addition, Ruhong has a deep interest in the science, ethics and societal issues of personalized medicine, regenerative medicine and global health. His demonstrated leadership has led to an established track record of success; especially in the areas of biomarker-based molecular assays or diagnosis, CRO service, and drug research and development.

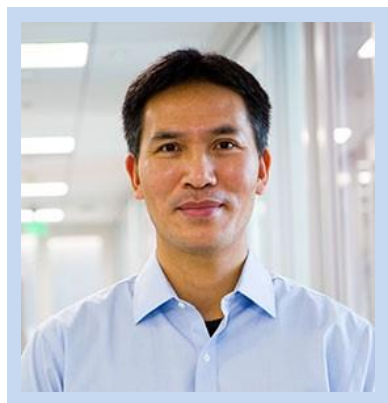
Title: Optimizing Gene Therapy Development for Successful IND Clearance

Abstract: Gene therapy-related research and development continue to grow at a fast rate, with a number of products advancing in clinical development. We are sharing the challenges in gene therapy product development via a case study ASC618 – the 2nd generation gene therapy for hemophilia A, possible solutions to these challenges and what to expect in the future.



AFTERNOON SESSION I: FROM ANIMAL TO HUMAN

Session Chair: Xinguo Jiang, M.D., Ph.D., 2022 Chair of CBA Annual Conference

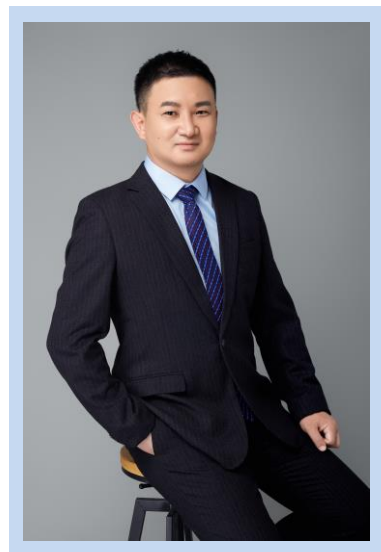


Xinguo is Associate Director/Sr. Principal Scientist at Apeximmune Therapeutics, where he leads efforts in elucidating target biology mechanisms and translational medicine. Dr. Jiang is also a PI at VA Palo Alto, studying hypoxic signaling and leukotriene biology in various human diseases. He received his Ph.D. in Biochemistry from the University of Illinois at Urbana-Champaign, and a degree in Medicine from Zhejiang University in China. Dr. Jiang completed his post-doc training at Stanford University. He has published more than 40 peer-reviewed articles in areas of tumor immunity, pulmonary hypertension, COPD, lymphedema, and transplant rejection.



AFTERNOON SESSION I SPEAKER

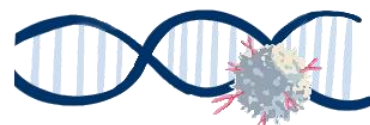
Hua Wei, Ph.D., VP, Industrial Business Department, Shanghai Model Organisms Center (USA), LLC



Hua Wei is a seasoned biotechnology professional currently serving as VP of Industrial Customers Department at SMOC-USA. Prior to this role, Mr. Wei was preclinical senior director of Artvira Biopharma and the preclinical director of Gloria Bioscience. In his 10+ years of industry experience, Mr. Wei has marketed 1 antibody product and submitted 2 INDs and taken numerous assets into preclinical development. Mr. Wei's career spans most of drug development paradigm from target identification and validation, mono and bi-specific antibody development, IND and NDA, up to translational medicine and across multiple therapeutic areas. Earlier in his career, he worked as a PI at Chinese National Human Genome Center. Mr. Wei received his Ph.D. in biochemistry at The Ohio University and completed his post-doctoral training at MD Anderson cancer center.

Title: Shanghai Model Organisms Center

Abstract: Founded in 2000, Shanghai Model Organisms Center Inc. (SMOC) is a leading company in Asia to offer high-quality animal models and related services to global customers with its highly efficient and reliable technology platforms. Committed to gene editing and disease fighting, SMOC has dedicated to developing a comprehensive product portfolio like GEM models and off-the-shelf products. Currently SMOC operates multiple AAALAC accredited breeding facilities and owns 100K cages that are available for 500K specific-pathogen free mice. Using three core technologies of gene editing, SMOC has built more than 13K genetically engineered animal models such as knockout, knockin, overexpression, and provided more than 7K catalog models widely used in metabolic and cardiovascular disease, neurodegeneration, immunology, and oncology studies. In addition, SMOC established a list of mouse models in which distinct immune cell types were labeled by luciferase and EGFP, providing simple, sensitive, robust means for immune cell infiltrate and *in vivo* drug efficacy studies as well as many DTREGFP mouse models in which distinct immune cell types were ablated. Moreover, SMOC has generated over 450 immune checkpoint humanized mouse models, including single, double, and triple genes humanized models and the list is still rapidly expanding to facilitate drug development. SMOC can also provide preclinical studies including blood cell and blood biochemical testing, CT image analysis, pathological section and immune-histochemistry analysis, FACS sorting, cytokines detection, gene expression and protein analysis, whole-body *in vivo* imaging, metabolic analysis, and behavioral analysis.



AFTERNOON SESSION I SPEAKER

Andy Liu, MBA, General Manager, Novotech, China



Andy is the General Manager of Novotech China overseeing the business and clinical operations in China. Andy has extensive operational experience in CRO industry and a deep understanding of the Asian market. Prior to joining Novotech, Andy was the General Manager of Covance Central Laboratory (Asia Pacific), where he managed a multi-functional team of approximately 500 employees across multiple regions. He holds an MBA from the University of Chicago Booth School of Business, an MS in Electrical Engineering from Rose-Hulman Institute of Technology, and a BS in Electrical Engineering from Tsinghua University.

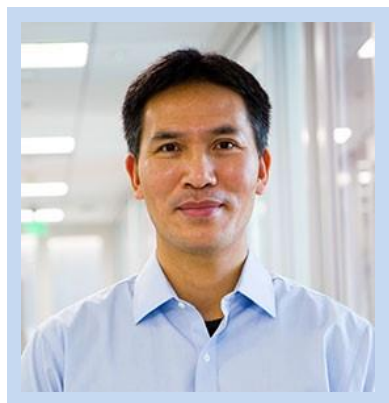
Title: Simultaneous Global Development of China-originated Innovative Drugs

Abstract: The significant increase in clinical development in China over the last 5 years is unprecedented. The China market has also seen a rapid rise in local biotech companies. The rapid rise of local biotech's in China brings some challenges and dilemmas. Hear more on this and the potential globalisation strategies that local Chinese biotech companies are cultivating to expand their clinical development programs to the West in this highly competitive market.



INTRODUCTION TO SPEAKER FOR AFTERNOON KEYNOTE

Session Chair: Xinguo Jiang, M.D., Ph.D., 2022 Chair of CBA Annual Conference



Xinguo is Associate Director/Sr. Principal Scientist at Apeximmune Therapeutics, where he leads efforts in elucidating target biology mechanisms and translational medicine. Dr. Jiang is also a PI at VA Palo Alto, studying hypoxic signaling and leukotriene biology in various human diseases. He received his Ph.D. in Biochemistry from the University of Illinois at Urbana-Champaign, and a degree in Medicine from Zhejiang University in China. Dr. Jiang completed his post-doc training at Stanford University. He has published more than 40 peer-reviewed articles in areas of tumor immunity, pulmonary hypertension, COPD, lymphedema, and transplant rejection.



AFTERNOON KEYNOTE SPEAKER

Joseph Wu, M.D., Ph.D., Professor, Stanford University



Dr. Wu (M.D., Ph.D.) is a physician-scientist whose research focuses on using clinical genomics, induced pluripotent stem cells, and AI/ML (artificial intelligence and machine learning) to accelerate drug discovery. His clinical interests include adult congenital heart disease and cardiovascular imaging. Dr. Wu has published >450 manuscripts with H-index of 114 on Google scholar and recognition as top 1% of highly cited researchers in Web of Science for past 4 years (2018, 2019, 2020, 2021). Among his trainees, >40 of them are principal investigators in the US or abroad.

Dr. Wu is Director of the Stanford Cardiovascular Institute and the Simon H. Stertzer, MD, Professor of Medicine and Radiology. He is the President-Elect of the American Heart Association.

Title: Stem Cells & Genomics for Precision Medicine

Abstract: Precision medicine seeks to link molecular data with the clinical disease phenotypes and to identify patient subpopulations that differ in their disease susceptibility, progression, and prognosis. Instead of one-drug-fits-all model, the ultimate goal is to customize prevention and treatment tailored for individual patient. Dr. Wu's lab has been integrating stem cells, genomics, and other big data approaches to answer this question.



AFTERNOON SESSION II: STATE-OF-THE-ART GENE THERAPY

Session Chair: Sydney Chen, Ph.D., 2022 CBA Advisor



Dr. Chen has twenty-five plus years in pharmaceutical and biotech industry with experiences in the processes and challenges in moving a drug from development, clinical phases, to commercialization. Dr. Chen has broad knowledge and hands on experience working with gene therapy product, therapeutic monoclonal antibodies, and small molecules and has held various leadership roles in many companies from innovative start-up to big pharma, including Bristol-Myers Squibb, diaDexus, Audentes, Telik, Solstice Neurosciences and Revance Therapeutics. She has been the technical director, responsible for analytical development and product quality control and quality assurance of various biologic drug products. She has also been the analytical lead for regulatory submission and correspondences with USFDA and

EMA. Under her leadership, she and her team have successfully filed numerous INDs with US FDA for novel therapeutic antibody drugs, and have received FDA, EU, Japan and KFDA approval of several commercial products.

Currently Dr. Chen is president of her own consulting firm and serves a senior consultant in QA/QC, supporting biopharma companies in managing CDMOs and in setting up phase appropriate GMP management system for sterile manufacturing, assay validation, quality assurance and quality control. Dr. Chen received her doctoral degree in Biochemistry and Cell Biology from Rutgers, State University of New Jersey.

Dr. Chen was a founding member of CBA and has since been a long-time volunteer. She has served in various capacities in the past, including one term as president in 2010 and two terms as vice president in 1999 and 2009.



AFTERNOON SESSION II SPEAKER

Han Ying, Ph.D., COO, Base Therapeutics Inc.



Dr. Ying has over 20-year experience in immunology, pharmaceutical industry, biotech start-ups, operation, project management and fund raising. He received his PhD at Stanford University in Cancer Biology and immunology, completed his postdoctoral training in immunotherapy with Drs. Nicholas Restifo and Steven Rosenberg at the US National Cancer Institute. He was one of the first scientists in the world to develop RNA and DNA vaccines, and he published 6 important scientific articles on RNA and DNA vaccines from 1998-2002, including two in Nature Medicine. He became a principal investigator at MDNI (affiliated with UCLA), where he oversaw a clinical laboratory conducting Dendritic Cell Vaccine trials for malignant brain tumor. He joined Berlex Biosciences (R&D arm of Schering A.G.) as a project manager in cancer research department, then joined Monogram Biosciences, a personalized medicine company that developed biomarker assays for selection of patients for novel targeted drugs. In 2010, Dr. Ying co-founded Immunnova, a biotech company

focused on dendritic cell vaccines and antigen-specific T cells. He has served as senior members for several early or late-stage biotech companies in the field of immunotherapy, including HRYZ (DC-based Cell Therapy), Sanpower Group/Dendreon in China and the US. He was the key technical expert in an international M&A team that completed the acquisition of Dendreon by Sanpower group (0.9 billion dollars), and acquisition of China Life Science in Hong Kong. He helped build Dendreon China team and a state-of-the-art GMP cell manufacturing facility in Shanghai. He was a founding team member of T-Cure Bioscience in Los Angeles and helped successfully raised A and A+ round (22 million dollars). In 2021, he co-founded a new biotech company Base Therapeutics which focuses on prime-editing/base editing of NK cells for cancer therapy. He is currently a venture partner of Panacea Venture.

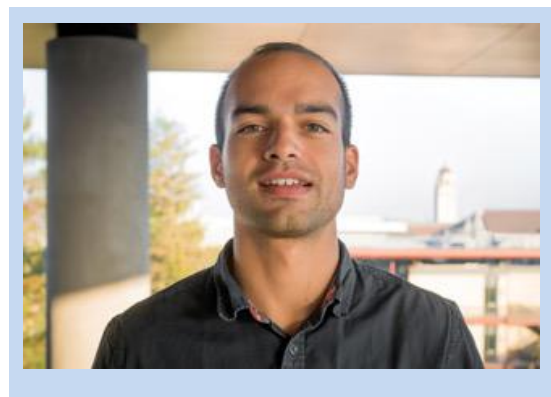
Title: Aiming to Cure Cancer and Genetic Diseases by Advancing the Next Generation Base Editing and Prime Editing Technologies

Abstract: The Base Therapeutics founding team is a combination of the top scientists and industry leaders. The co-founders include the most cited scientists in base editing and prime editing field in the world, leading NK scientists in the industry, top cell therapy industry experts, and a clinical genetics physician and seasoned biotech investor. Our high-fidelity Base Editor is highly efficient and has no off-target-editing effect. Our enhanced prime editor (“ePE”) is currently the most efficient PE in industry. Our first-in-class peripheral blood derived base-edited Super-NKTM demonstrates superior safety and efficacy comparing to current NK technologies in the industry. Our best-in-class iPSC-derived Super-iNKTM employs the next generation of site-specific gene integration technology to enhance its safety and clinical efficacy.



AFTERNOON SESSION II SPEAKER

Nick Hughes, Ph.D., Founder of Acrobat Genomics, Inc. (Illumina Startup Company)



Nicholas Hughes is the founder of Acrobat Genomics. He was a post-doctoral associate within laboratory of Prof. Le Cong in Department of Genetics at Stanford University. Prior to this, he completed a Ph.D. in the Department of Genetics at Stanford University where he developed a CRISPR-based barcoding tool that harnessed advancements in machine learning for lineage tracing of single cancer cells. Prior to his Ph.D., he worked at the Broad and Whitehead Institutes where he worked on the team that developed the original CRISPR/Cas9-based genetic screening technologies to identify genetic interactions in cancer.

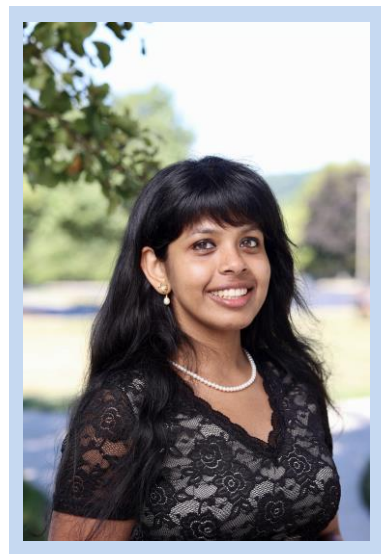
Title: High-throughput Approaches for Optimizing Gene Editing Technologies

Abstract: The recent development of CRISPR-based genetic barcoding presents an exciting opportunity to understand cellular phylogenies. To track large numbers of lineages, we present a compact, tunable and high-capacity Cas12a-based evolving barcoding system, named Dual Acting Inverted Site arraY (DAISY) barcoding. We combined high-throughput screening and machine-learning to predict and optimize the 60-bp DAISY barcode sequences. After optimization, the top-performing barcodes achieved ~10-fold improvement in tracking capacity relative to the best random-screened designs and performed reliably across diverse cell types. Thus, optimized DAISY barcodes – while being a fraction of the size of Cas9 barcodes – achieved high-capacity, scalable barcoding. In the future, we are applying similar high-throughput screening approaches to optimize CRISPR/Cas modulatory proteins from phage to increase gene editing precision and to expand our ability to knock-in large genetic payloads.



AFTERNOON SESSION II SPEAKER

Sumana Sundaramurthy, Ph.D., Technical Account Manager, Sino Biological



Sumana Sundaramurthy joined Sino Biological as a Technical Account Manager in early 2022, as a member of the CRO team supporting the various protein and antibody service platforms. She leads R&D projects for a number of industry and academic clients, who are based on the west coast.

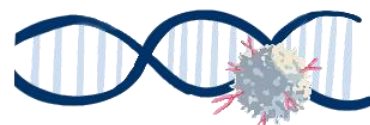
Prior to joining Sino Biological, Sumana completed her doctoral studies in Cell and Developmental Biology at SUNY Upstate Medical University under Dr. David Pruyne, where she studied how formins regulated cytoskeleton development in striated muscles. She has presented her work at multiple national and local conferences. In addition to her academic pursuits, Sumana held various leadership positions supporting student life at Upstate. She is also passionate about biotech innovations and she interned at the Office of Innovation and Partnerships at SUNY-RF. She has been a member of ASCB and NYAS for more than five years, supporting career development initiatives, and currently, is also one of the co-chairs of the career subcommittee within COMPASS-ASCB.

Sumana also holds a Masters in Cell Biology from Illinois Institute of Technology and a Bachelors in Biotechnology from Anna University. She has also worked for a preclinical CRO and a few notable research groups at Loyola University, the University of Chicago, and Sanofi Pasteur.

Title: Accelerating Research supporting Next Generation Medicine with recombinant proteins and antibodies

Abstract: The advancement in the field of biomedical sciences has led to many innovations like cell therapy, gene therapy, mRNA vaccines, and other technologies that comprise next-generation medicine. With such rapid advancements, research projects are becoming more collaborative with academic/medical centers teaming up with industry partners. Research required for these collaborative efforts will always require specialized expertise. As a global leader in recombinant protein and antibody technology, Sino Biological is open to collaborating with researchers in academic institutes and industry. Sino Biological is a 'one-stop' reagent and CRO service provider. Apart from having the world's largest viral antigen bank, we have a number of catalog products: 7k proteins, 14k antibodies, ELISA kits, and CRO service platforms that could support next-generation medicine research.

Our primary platforms include mammalian, CHO, and HEK cell expression systems, but we also have Baculovirus-based insect cell and *E. coli* expression systems that support the expression of recombinant protein production. Our expertise in recombinant antibodies ranges from full-length IgGs, IgMs, to reformats like Bispecifics, Fabs, VHHs, scFv, among others. We also specialize in monoclonal and polyclonal antibody development. We have our mature mouse hybridoma platform and rabbit phage platforms for monoclonal antibody development. Our Beacon and



FACS-based single B-cell platforms can support fast mAb development besides its superior screening capabilities.

We also offer antibody maturation and humanization services using artificial intelligence (AI) technology in collaboration with Ainnocence. The platform is designed based on protein sequence information where no structural information is required. The protein-protein, protein-antibody, and protein-small molecule interactions can be predicted by an advanced Deep Learning Engine powered by Graph Neural Network and Protein Language Modeling. The interactions can then be validated through protein/antibody production and SPR/BLI binding assays. The services are ultra-high throughput and very efficient to perform in silico search over 10^{10} mutations at 10,000x speed than the conventional physics-based protein-protein docking model. This platform demonstrates AI's capability in antibody design with in vitro efficacy as well as drastically reduced time and cost of antibody engineering such as affinity maturation and humanization. Sino Biological can help accelerate your research by supporting next-generation medicine with recombinant proteins and antibodies.



AFTERNOON SESSION III: REGULATORY AND INVESTMENT IN ENTREPRENEURSHIP

Session Chair: Shuming Liu, M.D., 2022 CBA Advisor



photography and traveling.

Dr. Liu received her doctoral degree in Medicine from Linköping Medical School in Sweden. She obtained her postdoctoral training at UCSF and worked as a scientist with expertise in molecular cell biology at BD Biosciences. Shuming is passionate about cancer research and education. She is currently the president of the Save Life and Talent Foundation, where she has devoted her time in raising cancer awareness in communities such as schools and hospitals. Her educational seminars on cancer prevention, diagnosis, and treatment have attracted people from all over the world. Many of the attendees now belong to a growing online support group which she created to not only offer her counsel but to offer a community for those fighting cancer. Dr. Liu joined CBA at the beginning of 2019 and has been actively involved in organizing symposiums, social events, and the annual meeting. She served as President of CBA in 2021. In her leisure time, she enjoys cooking,



AFTERNOON SESSION III SPEAKER

Frank Li, Ph.D., RAC, Founder of BLA Regulatory, LLC



Dr. Li is the Founder of BLA Regulatory and an expert in Clinical and Regulatory Affairs. Dr. Li has been working in the Biopharmaceutical industry as a regulatory professional for more than 15 years such as in AstraZeneca, MedImmune, AZ BioVenture, Ascentage Pharma, and SNBL. Dr. Li contributed significantly as the Regulatory 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 obtained his Ph.D. 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 researches 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.

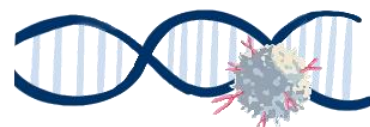
Dr. Li was the 22nd President of the Chinese Biopharmaceutical Association (CBA 2018-2019 <https://www.cba-usa.org>) and a member of the board of directors.

Title: Commercial IND Application in the US: starting initial clinical trials from pre-clinical stage

Abstract: An IND submission is usually the first time FDA hears from a sponsor about the development program for an investigational product. In 2019, CDER alone received 7471 INDs for review. Some of the investigational new drugs (INDs) were placed on clinical hold during the IND-30-day review. A systematic analysis of new commercial IND submitted to the FDA's Office of Hematology and Oncology Products (OHOP) in the CDER shows less than 10% of INDs went on hold or were withdrawn within the 30-day safety review period. The deficiencies were mainly clinical, followed by concerns related to pharmaceutical quality and nonclinical development.

A good first step to creating a successful IND is to understand the basics of IND requirements with a rationale for the various pieces of information included in the IND. The IND application contains all available preclinical and clinical testing information, and all manufacturing information for the investigational product, along with clinical protocol, informed consent template, investigator's brochure and other relevant information.

This presentation focuses on IND requirements, IND strategy/execution, FDA communication and IND defense. The presentation will also touch to INDs with gene and cellular therapy products.



AFTERNOON SESSION III PANEL DISCUSSION

Session Chair: Bing Liang, Ph.D., J.D., 2022 CBA Board Member



Dr. Bing Liang represents biotechnological and pharmaceutical companies on the procurement and protection of intellectual property. Her practice encompasses global patent portfolio development, management, and enforcement, particularly in the areas of biologics and diagnostics.

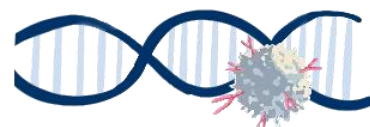
She prepares and prosecutes patent applications in a variety of technologies including antibody therapeutics, immunoncology therapeutics, cell therapies, genome editing, antisense therapeutics, enzyme replacement therapies, stem cells, and whole genome sequencing.

Bing advises clients regarding patentability, validity, infringement, and freedom-to-operate issues and performs due diligence evaluations of patent portfolios in connection with venture capital and private equity financings, collaborations, and/or partnering deals. She is experienced in licensing agreements and matters related to U.S. Food & Drug Administration (FDA) approval.

Her practice also includes various post-grant proceedings before the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office (USPTO), including *inter partes* reviews (IPRs).

Her representative clients include AbbVie, BioMarin Pharmaceutical, Celgene, and Genentech, as well as other start-up companies, established companies, academic institutions, and investment firms.

Prior to practicing law, Bing obtained her Ph.D. in biomedical sciences from Mount Sinai School of Medicine of New York University, where her research focused on chromatin remodeling and its functions in maintaining genome integrity. During this time she discovered important roles of chromatin remodeling complexes in DNA damage repair and telomere length maintenance. Bing has extensive technical experience in biochemistry, molecular biology, genetics, immunology, and cell biology.



AFTERNOON SESSION III PANELIST

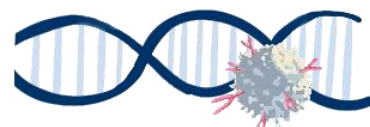
Benjamin Chen, Ph.D., Partner, Panacea Healthcare Venture



Benjamin is a scientist, entrepreneur, investor, and merchant banker. He was most recently the CEO of ImaginAb, Inc. a ventured-backed company developing a cutting-edge platform to address an urgent unmet need in immuno-oncology. Prior to that, he served as the Chairman and CEO of London-based Immune Targeting Systems, Ltd., leading the immune therapy company through significant strategic growth, innovative product development, and establishing presences in France and North America. Before his return to operational roles, he spent nine years as a Managing Director at Burrill & Company, a global life sciences venture firm where he evaluated investment opportunities and assisted a global clientele in completing licensing, partnering and M&A transactions. He also played a key role in establishing the Malaysian Life Sciences Fund I, and served as a director. Earlier in his career as an R&D executive, he had experience in building talented research teams in immunology, stem cell biology, genomics, gene therapy, and molecular diagnostics in both biotechnology start-ups and multinational pharmaceutical companies, including

Roche Diagnostics and Novartis.

Benjamin received his academic training in Microbiology and Immunology at the University of Wisconsin-Madison and Stanford University.



AFTERNOON SESSION III PANELIST

Srinivas Akkaraju M.D., Ph.D., Founder and Managing General Partner at Samsara BioCapital



Srinivas Akkaraju, M.D., Ph.D. is a Founder and Managing General Partner at Samsara BioCapital. Previously, from April 2013 to February 2016, he served as a General Partner of Sofinnova Ventures. From January 2009 until April 2013, he served as Managing Director of New Leaf Venture Partners. Previously, he served as a Managing Director at Panorama Capital, LLC, a private equity firm. Prior to co-founding Panorama Capital, he was with J.P. Morgan Partners, which he joined in 2001 and of which he became a Partner in 2005. From October 1998 to April 2001, he was in Business and Corporate Development at Genentech, Inc. (now a wholly owned member of The Roche Group), a biotechnology company, most recently as Senior Manager.

Prior to joining Genentech, Dr. Akkaraju was a graduate student at Stanford University, where he received his M.D. and a Ph.D. in Immunology. He received his undergraduate degrees in Biochemistry and Computer Science from Rice University. Dr. Akkaraju serves as a director of Chinook Therapeutics,

Intercept Pharmaceuticals, Syros Pharmaceuticals, Scholar Rock, and Jiya Acquisition Corp. Previously, Dr. Akkaraju served as a director on the boards of Seattle Genetics, Barrier Therapeutics, Eyetech Pharmaceuticals, ZS Pharma, Synageva Biopharma Corp., aTyr Pharma, and Amarin Corporation plc.



AFTERNOON SESSION III PANELIST

Chris Xu, Ph.D., Chairman, Healthbankds



Chris Xu received his Ph.D. degree in Immunology from Washington University School of Medicine (St. Louis) and an Executive MBA degree from Emory University (Atlanta).

A successful serial entrepreneur and investor in life science and biomedical field. Dr. Xu has served various leadership roles in a number of public companies, including Pfizer (NYSE:PFE), AtheroGenics (Nasdaq:AGIX), Repligen (Nasdaq:RGEN), PKU-Healthcare (000788.SZ), and ThermoGenesis (Nasdaq:THMO).

Dr. Xu's professional expertise spans several therapeutic areas, including arthritis & inflammation, autoimmunity, diabetes and cancer. He has authored over forty publications and has been recognized by various professional societies for his contributions to biomedical research.



AFTERNOON SESSION III PANELIST

Can Cui, Ph.D., J.D., Partner, Goodwin Procter LLP



Dr. Can Cui is a partner in the Life Sciences practice group of Goodwin Procter LLP, and a co-leader of the firm's Life Sciences practice in Asia. His practice focuses on technology transactions and investment in the life sciences industry, especially those transactions related to China, including cross-border technology licensing and acquisition, collaboration and strategic partnership, joint venture (JV), and other forms of investment.

Dr. Cui has extensive experience representing both licensors and licensees in U.S.-China life sciences licensing transactions. In private equity and venture capital transactions, he regularly represents institutional and individual investors, established life sciences companies and startups in intellectual property (IP) due diligence and the negotiation and drafting of related investment documentation. He also advises clients on IP

aspects of mergers and acquisitions.

Dr. Cui has deep knowledge of China's increasingly complex regulatory landscape, including not only the IP laws, but also regulations governing cross-border transactions, such as technology import and export regulations and regulations of human genetic resources. He also has rich experiences in corporate matters, patent prosecution and IP dispute resolution, which, together with his scientific background, make him a go-to person for advice in various legal matters life sciences companies may have.

Dr. Cui has been selected for inclusion in *The Legal 500 U.S. 2022*, and is recognized by Berkeley Center for Law & Technology as one of the "leading practitioners in biotech and life sciences."

Dr. Cui received his B.Sc. in Biotechnology from Peking University, his Ph.D. in Biological Chemistry and Molecular Pharmacology from Harvard University, and his J.D., *magna cum laude*, from New York University School of Law.



CBA ORGANIZING COMMITTEE

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Communication Director: Ruei-Shian (Raymond) Wang, M.S.

Volunteer Director: Jing Folsom, Ph.D.

Webmaster: Jia Jun Chia, M.S.

Advisors

Shuming Liu, Advisor (2021 CBA President)

Dannis Chang, Advisor (2020 CBA President)

Huifang Li, Advisor (2019 CBA President)

Mark Chen, Advisor (2018 CBA President)

Patrick Yang, Advisor (2017 CBA President)

Kai Zheng, Advisor (2016 CBA President)

Shih-Chen Chang, Advisor (2015 CBA President)

Michelle Chen, Advisor (2014 CBA President)

Lin Sun-Hoffman, Advisor (2013 CBA President)

Patty Kiang, Advisor (2011 CBA President)

Sydney Chen, Advisor (2010 CBA President)

Kelley Liu, Advisor (2007 CBA President)

Shian-Jiun (SJ) Shih, Advisor (CBA Founding President)

Volunteers (in alphabetical order of last name)

Kai-Wen Cheng, Caesar Ho, Sonny Huang, Ta-Kai Li, Xinxin Li, Qiang Liu, Anne Tseng,
Chen Wang, Liuyi Wang, Jessie Zhang, Mengning Zhou



CBA KEY EVENTS: 2021 ANNUAL CONFERENCE

Thriving in a New Healthcare Paradigm

Date: October 2-3, 2021, Virtual Conference

In the middle of the COVID-19 pandemic, CBA showed its resilience and hosted a virtual annual conference to discuss the unprecedented challenge and opportunities presented to the health care system and life science community. This conference has 'brought together' world-class researchers to give a series of seminars—from the topics of the origin of COVID-19 to therapeutic antibody development, the benefit of cancer immunotherapy to the management of its side effects, human microbiota to cancer research, and from biotech research and development to bio-manufacturing. During a time of mostly social isolation, this conference has greatly boosted interactions among the attendees and injected confidence in the community much needed to recover from the pandemic.



KEY EVENTS: CBA WORKSHOP

Current and Future Challenges and Opportunities in Biotech Investment

Date: March 26, 2022, Zoom Meeting

Organizers: CBA

On March 26, 2022, CBA hosted an online panel discussion with four experts who specialize in biotech, medical devices as well as cross-boarding investment. The panelists shared their views about the recent down-turning trend in investment in the biotech industries and discussed with the audience about how to seek opportunities in this challenging environment. The discussion is full of inspiring ideas.



CBA Workshop: VC Panel Discussion Current and Future Challenges & Opportunities in Biotech Investment



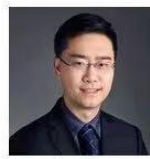
Alexis Ji, Ph.D.
Partner
Illumina Ventures



Vincent Xiang, Ph.D.
Founding Managing Partner
7G BioVentures



Seth Lieblich, Ph.D.
Principal
8VC



Frank Zhang, Ph.D.
Partner
CEC Capital Group

March 26th, 2022 (Saturday)
3:30 PM to 5:00 PM, Pacific Time

Moderators:



Li-Fen Lee
CBA President

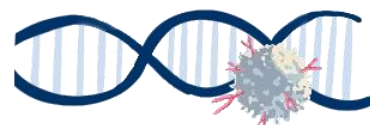


Raymond Wang
CBA Communications
Director



Register here!

Zoom Meeting ID: 869 6798 4771
Passcode: cbasf2022



KEY EVENTS: MENTOR TALK BY PATRICK YANG

Date: August 5, 2022

Venue: 5201 Great America Pky, Santa Clara, CA 95054

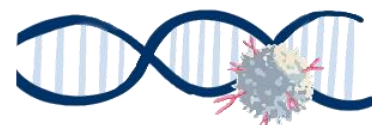
Organizers: TECO and CBA

Dr. Patrick Yang shared his view on Indian's ten keys to career success in Silicon Valley. It was held in Santa Clara on the evening of August 5, 2022. It was one of the mentor talk series targeting the audience of young people from Taiwan who was finishing their short-term visiting internship at Silicon Valley. It was organized by CBA and Taiwan's Science & Technology Division in San Francisco. Several CBA members also attended this event.

Patrick shared a lot of his astute insights from cultural and historical perspective on the reasons why Indian immigrants are so successful that the CEOs of many top high-tech companies are taken by them. During the talk, the speaker raised many vivid examples and elucidated his points persuasively. The talk was well received from the audience.

Patrick is a recognized author in the field of Silicon Valley development and many other topics. He is the director of Analytical Development and Quality Control at Chemocentryx. He was also the former president for CBA in 2017.

從印度人統治硅谷
看職場成功的關鍵



KEY EVENTS: SUMMER PICNIC

Date: August 6, 2022

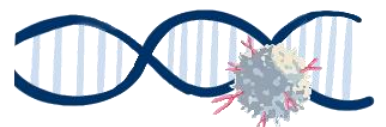
Venue: Mitchell Park, Palo Alto, CA 94306

Organizer: CBA

On a very pleasant summer day, CBA resumed its tradition of hosting an annual picnic at the lovely Mitchell Park in Palo Alto. This is a long-awaited event where old and new CBA members, friends and family gathered to reconnect with each other and enjoy the delicious food made by CBA members and volunteers.



KEY EVENTS: SUMMER PICNIC



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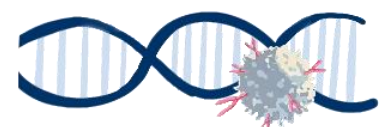
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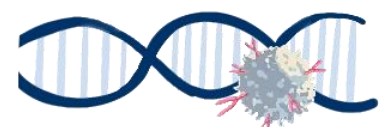


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About Us

Founded in 2000, SMOC is committed to providing professional, comprehensive and integrated animal model services to global researchers.

Our highly productive R&D platform combined with high-throughput production capacity enables the development of customized animal models in a fast and cost-effective manner.

The rapidly growing research-ready repository supports immuno-oncology and other cutting-edge biomedical research.

The supply of animal models to global clients is assured by our state-of-art animal facilities.

Qualification



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Targeted over-expression
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Breeding services

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Rare disease
Infectious disease
Metabolic disease
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Autoimmune disease
Nervous system disease
Digestive system disease

Tumor Cell Lines

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Wild-type





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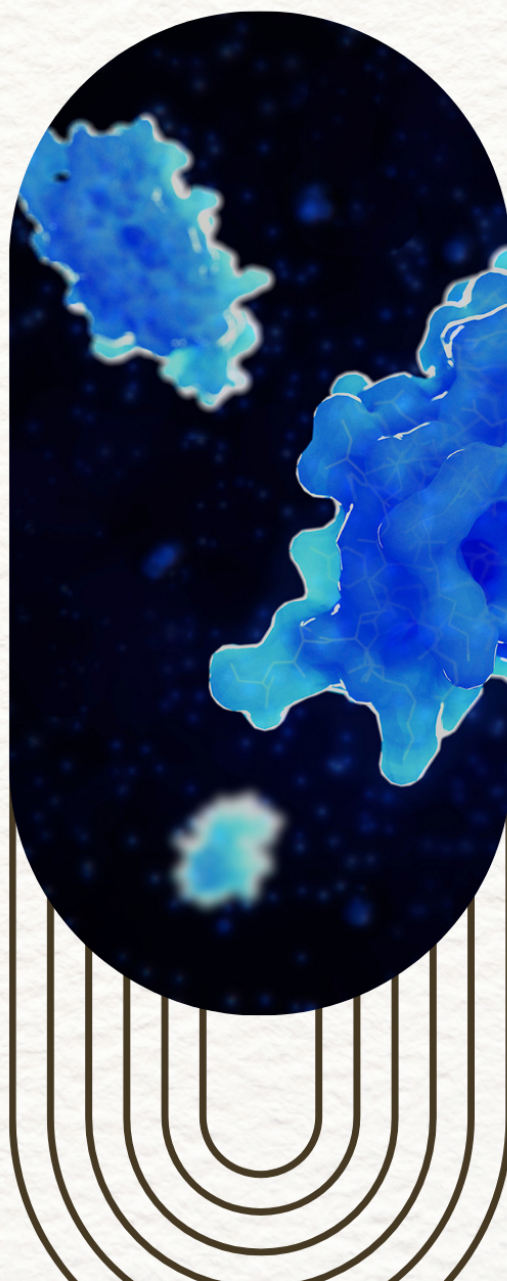
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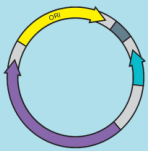
Antibody / Protein engineering: ADC; BSMAB

Assay development: Research, IVD, and clinical assay development; Chicken pAb, rabbit pAb, and mouse mAb

Animal studies: PK/PD; Mouse tumor / metabolism models

CHO-C High Yield Protein Drug Manufacture Platform

Vector Design



- Codon optimization
- Ideal HC/LC ratio
- IP protected signal peptides



< **2.5 Weeks**

Transient Expression
100 mg purified proteins

Protein Production & Cell Line Development



- cGMP banked & tested host
- DNA->RCB in 17 weeks
- ~100 generation stability



< **8 Weeks**

Stable CHO-C pools
1g purified proteins/mAbs

Process Development & Process Optimization



- DOE/ In-line Monitor
- Stable pools: 600~1000mg/L
- Stable clone: 3~5 g/L



4 Months

CHO-C Clone/ RCB
3-5 g/L



Flexible manufacturing of pre-clinical therapeutic antibody / protein, and CHO-C cell line development (CLD) services tailored to project-specific requirements.



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Innovation



into
Therapy

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James Huang
Founder & Managing Partner



Andrew Ng
Partner



Nikki Zhang
Partner







Jeffry Wu
Partner



Andrew Aherrera
Partner

Focus

-  Innovative science/technologies
-  Company formation
-  Early-stage opportunities
-  Late-stage opportunities

Bay Area-Based Team



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ST
續創第一



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PIC/S GMP

MANUFACTURING

- Antibody and Recombinant Protein
- Antibody-Drug Conjugate
- Plasmid DNA & Viral Vector


CERTIFICATION

- Taiwan FDA approved
- Japan PMDA approved
- US FDA Inspection in 2022 Q2
- EU EMA Inspection expected in 2022 Q4

CELL LINE & PROCESS DEVELOPMENT

ANALYTICAL & QUALITY CONTROL



	PRODUCT DEVELOPMENT	PRE-CLINICAL	PHASE I	PHASE III	MAA/BLA	CAPACITY EXPANSION	
HER2 FAMILY PRODUCTS	EG12014/EG1014 Trastuzumab Biosimilar Signed license agreement with Novartis Sandox		●	●	●	MAMMALIAN GMP PRODUCTION <ul style="list-style-type: none"> • Zhubei Facility: 28,000L (12 x 2,000L & 4 x 1,000L SUBs) by 2023 • Xizhi Facility: Multiple 1,000L & 200L SUBs MICROBIAL GMP PRODUCTION <ul style="list-style-type: none"> • Zhubei Facility: 1,350L (1 x 1,000L Fermentor & 1 x 350L Fermentors) by 2024 • Xizhi Facility: 1x 150L Fermentor  <p>www.eirgenix.com service@eirgenix.com</p>	
	TSY010/EG12043 ADC Biosimilar Co-develop with Formosa Pharmaceuticals, Inc.		●				
	EG1206A Pertuzumab Biosimilar		●	●			
	EG13074 TRZ Biosimilar (SC Formulation)		●				
	EG13084 TRZ+PRZ Biosimilar (SC Formulation)		●				
	EG42054 Biosimilar		●				
EG74032 CRM197 Carrier protein		●			●		



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- From pre-IND scale to commercial scale
- From chemical sourcing to CMC documentation
- From drug substance to drug product

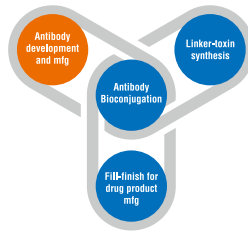
Dedicated production line for Peptide, Hormone, Cytotoxic and Fermentation products.



Antibody-Drug-Conjugate(ADC)

Comprehensive services

- Antibody development and manufacturing
- Linker-payload design, synthesis and manufacturing
- Bioconjugation, and purification (TFF and chromatography)
- Sterile Drug Product liquid filling and lyophilization



Injectable Manufacturing Services

One-Stop-Shop Solution

- From Chemicals to Pharmaceuticals
- From IND to NDA/ANDA/BLA filing
- From Lab to Commercial manufacturing
- From GSP compliant RD lab to GMP compliant manufacturing

Capability & Capacity

Filling Line	INJ Type	Filling Quantity	Compounding Volume	Batch Size(vials)	Lyophilizer
V1 (Non-cytotoxic)	Vial	2mL~100mL	10L~1000L	10,000~250,000	30m ²
	Lyophilized	2mL~100mL			
V2 (Non-cytotoxic)	Vial	2mL~20mL	1L~60L	100~24,000	2.3m ²
	Lyophilized	2mL~20mL			
	Pre-filled	0.5mL~3mL			
D1 (Cytotoxic/High Potent)	Vial	2mL~100mL	1L~50L	1,000~40,000	7.2m ²
	Lyophilized	2mL~50mL			
	Pre-filled*	0.5mL~3mL			

* Long term expansion plan

- All GMP-compliant inspected by USFDA, EDQM, PMDA, BGV, COFEPRIS and TFDA.
- PIC/S Good Distribution Practices(GDP) for labeling, packaging and logistics.

GenScript Catalog Products Overview

Molecular Bio	CRISPR	Peptide & Peptide pools	Recombinant Proteins	Antibodies	Protein Analysis	Protein Purification	Stable Cell Lines	Cell Separation	Chemical Libraries	COVID-19
PCR Reagents	Cas Nucleases	Beta-Amyloid Peptides	Cytokines	Anti-Camelid VHH	Precast Gels	AmMag SA Plus	Immune Checkpoints	NanoBeads	GenDECL Encoded Chemical Library	COVID-19 Proteins
GenBuilder Cloning kit	Ultra Nucleases	Cosmetic Peptides	Growth Factors	Epitope Tag Antibodies	Protein Standards	Magnetic Beads	GPCRs			COVID-19 Antibodies
Benz-Neburase	Kits and Antibodies	Amino Acid Derivatives	Chemokines	Anti-idiotype Antibodies	Related Reagents	Magnetic Racks	Fc Receptors			COVID-19 Peptide Pools
		Other Peptides	Tag Cleavage Enzymes	Immune Checkpoint Antibodies	eStain Protein Staining System	Protein Purification Resins				COVID-19 Stable Cell Lines
			Immune Checkpoints	Primary Antibodies	eBlot Protein Transfer System	eBlot Protein Transfer System				COVID-19 Serology Detection Kits
			Hormones	Secondary Antibodies	eZwest Automated Western System	Endotoxin Detection and Removal System				COVID-19 Pseudovirus
			Neurotrophins	Rabbit Monoclonal Antibodies						



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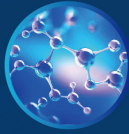


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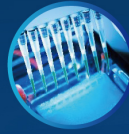
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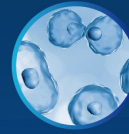
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