SAPA 2018 Scientific Symposium

Current Trends in Drug Development:
From Discovery to Clinical Application

Saturday, April 7, 2018
McDonnell Hall
Princeton University
Princeton, NJ 08540

Sino-American Pharmaceutical Professionals Association
Dear SAPA members and friends,

You are cordially invited to attend the SAPA 2018 Scientific Symposium “Current Trends in Drug Development: From Discovery to Clinical Application” on April 7, 2018, at Princeton University, Princeton, New Jersey.

Symposium Co-Chairs

Frank Gan, PharmD, Junfang Li, PhD, and Lin Yan, PhD

Organization Committee

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8:00 – 8:50 am  Registration

8:50 – 9:10 am  SAPA Scientific Symposium Introduction

Frank Gan, PharmD, Director of Clinical Research, Janssen

Frank Gan is currently a Director of Clinical Research working in the Oncology Department of Janssen Pharmaceuticals. In this role, he develops clinical research strategies, contributes to the development and execution of clinical research programs for company products and ensures the compliance of regulatory authority’s regulations and company SOPs. He has more than 14 years clinical research experiences in both small molecules and biologic drug candidates. He has extensive hands-on experience in study design, protocol development and implementation of different phases of clinical trials and has successfully managed several global clinical trials in metabolic disease and oncology areas while working at Merck, BMS, and Eli Lilly. Prior to his clinical research career, he has more than 10 years working experiences as a bench scientist both in academic and biopharmaceutical industry settings.

Frank received his Bachelor and Master degrees in pharmaceutical sciences from Shanghai Medical University and earned his Pharm.D. degree from Shenandoah University.

Welcome Remarks and SAPA Introduction

Jian Liu, PhD, Principal Scientist, External Discovery Chemistry, Merck; SAPA 2017-2018 President

Jian Liu, Ph.D. is currently a Principal Scientist in the External Discovery Chemistry Department at Merck. Dr. Liu has managed many projects on target validation, lead identification, and lead optimization in the discovery chemistry department, and has generated multiple clinical candidates which went into first-in-man, phase I, and phase II clinical trials. Dr. Liu is an expert in drug discovery for many therapeutic areas such as osteoporosis, obesity, diabetes, cardiovascular disease, rheumatoid arthritis, oncology, infectious disease, pain and neuro-degenerative diseases. Dr. Liu has also been in charge of outsourcing and collaboration with several external CRO companies. Based on his research work, Dr. Liu has published 31 peer reviewed papers, and obtained 47 US and international patents. Dr. Liu obtained a Ph.D. degree in organic chemistry from UCLA in 1998. He is the 2017-2018 President of Sino-American Pharmaceutical Professionals Association (SAPA).
Plenary Session (Part 1)
Session Moderators: Frank Gan, PharmD, Junfang Li, PhD, and Lin Yan, PhD

From Orphan Drugs to Major Contenders, Can Gene Therapy Do the Job?
Xiao Xiao, PhD, Professor, University of North Carolina at Chapel Hill, Eshelman School of Pharmacy

Gene therapy has made great strides in clinical trials as a commercially viable treatment for genetic diseases and rare cancers, etc, targeting 5,000 or so orphan diseases. The already approved gene therapy drugs are primarily for the orphan indications as well. The most broadly used and robust gene delivery tools are the viral vectors. While lentivirus-derived vectors are most suitable for cell-based therapy such as CAR-T and other blood orders, the adeno-associated virus (AAV) vector is a vector of choice for direct injections into patients.

In addition to the traditional gene replacement therapy, gene editing has rapidly emerged as an important player with phase I clinical trials in human patients for cancer and genetic diseases. Numerous clinical trials, including hemophilia and the spinal muscle atrophy (SMA) trial in infants by a simple intravenous (IV) injection to cross the blood brain barrier, have shown very encouraging safety and therapeutic outcomes. Bodywide muscle and heart gene delivery by IV injection to replace the defective gene is also a promising approach to treat muscle, heart and liver diseases, etc. However, off-target on genes and delivery into unintended tissues and cell types remain a significant shortcoming. A variety of molecular biology methods are used to generate tissue-targeting vectors by gene shuffling, random mutations and rational design. New generation vectors are being created, able to be regulatable and target specific tissues and evade immune responses. Along with the success in the rare disease territory, gene therapy will eventually become a major contender for common diseases such as cardiovascular, neurodegenerative, autoimmune, infectious diseases, diabetes and even aging, etc.

Dr. Xiao Xiao, Ph.D., is the Eshelman Distinguished Professor of Gene Therapy at the University of North Carolina at Chapel Hill. He also worked in and co-founded a number of gene therapy companies before. Xiao has studied adeno-associated virus (AAV) and gene therapy for over 30 years. His research interests are in basic AAV virology, gene vector technology and translational research for disease treatment. He discovered that AAV could infect non-dividing cells such as neurons, skeletal muscle and heart, and also co-developed triple plasmid transfection method for AAV vector production, which has become a mainstream technology worldwide. In the past 20 years, his lab’s main focus is on gene therapy for neuromuscular, cardiac and genetic diseases. In particular, the minidystrophin technology he pioneered for Duchenne muscular dystrophy (DMD) is being explored for gene therapy clinical applications by a Pfizer subsidiary company, Bamboo Therapeutics. Furthermore, Xiao served as a Board member of American Society of Gene and Cell Therapy. He is also a member of editorial board and reviewer for numerous scientific journals and has served as an NIH grant reviewer for more than 20 years.
9:40 – 10:10 am  **CAR-T Cells for the Treatment of Leukemia and Lymphoma**  
**Eric Bleickardt**, MD, Global Program Clinical Head, CAR-T Program, Novartis

Individualized CAR-T therapy uses a patient’s own immune system to fight certain types of cancers. A patient’s T cells are extracted and reprogrammed outside of the body to recognize and fight cancer cells and other cells expressing a particular antigen. This presentation will share with the audience the CAR-T therapy development program and progress at Novartis.

**Eric Bleickardt is a Global Program Clinical Head for the CAR-T Program at Novartis.** A board certified physician with 16 years combined experience in the pharmaceutical industry and clinical medicine, Eric previously served as the medical lead at Bristol-Myers Squibb for the clinical development of Sprycel in CML and Ph+ ALL, Empliciti in multiple myeloma, and Opdivo in Hodgkin lymphoma. Eric received his M.D. degree from the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School, Piscataway, New Jersey. He completed his residency at Beth Israel Deaconess Medical Center/Harvard Medical School in Boston, Massachusetts, and his medical oncology/hematology fellowship at Yale-New Haven Hospital/Yale University School of Medicine, New Haven, Connecticut.

10:10 – 10:30 am  **Coffee Break**

10:30 am – 12:00 pm  **Plenary Session (Part 2)**  
**Session Moderators: Frank Gan, PharmD, Junfang Li, PhD, and Lin Yan, PhD**

10:30 – 11:00 am  **Pattern Recognition Receptor Signaling in Cancer**  
**Andy J. Minn**, MD, PhD, Associate Professor, University of Pennsylvania

Pattern recognition receptors (PRR) and interferon (IFN) signaling pathways are broadly active across multiple cancer types. These pathways are typically associated with pathogen infection, but their roles in cancer are not well understood. Nonetheless, emerging evidence indicates that these anti-viral signaling pathways orchestrates tumor progression and metastasis, response to both conventional therapies and immunotherapies, and immunosuppression through intricate feedback inhibition mechanisms. We are investigating how PRR/IFN signaling is activated in cancer, both cell intrinsically and through the tumor microenvironment, and its functional significance. We are also exploring how these PRR/IFN pathways can be therapeutically exploited to modulate the immune system, particularly when combined with immune checkpoint blockade, and how the feedback inhibition properties of IFN signaling may limit therapeutic efficacy. An overarching goal is to translate mechanistic findings to better inform the design of clinical trials. Some of these recent mechanistic and translational findings will be discussed.
Dr. Minn is an Associate Professor in the Department of Radiation Oncology and Abramson Family Cancer Research Institute at the University of Pennsylvania. He received his MD and PhD from the University of Chicago, and finished his residency in radiation oncology and post-doctoral training at Memorial Sloan-Kettering Cancer Center. His laboratory is focused on understanding how cancers acquire treatment resistance to both conventional therapies and to immunotherapies, and how resistance can be overcome.

11:00 – 11:30 am  Combination Development Strategies for Immunotherapy Treatment of Cancer

Keaven M. Anderson, PhD, Distinguished Scientist (Executive Director), Merck Research Laboratories

Many immunotherapies were studied initially as monotherapy options to toxic chemotherapy. This “replacement strategy” is usually very risky and the level of success achieved is surprising in that context. One frequent observation is that immunotherapy provides more extended benefit than chemotherapy, but there may be some patients who do not respond. Various strategies have been taken to further improve results with immunotherapies. Additional immunotherapy seems to be a preferred approach in some ways, but combination with chemotherapy has been highly successful recently in lung cancer. Merck has undertaken many partnerships to develop combinations of pembrolizumab, a checkpoint inhibitor, with other therapies of various types. Other companies and cooperative study groups have taken similar approaches. Some of these approaches will be noted as well as recently released results on treating lung cancer with chemotherapy in combination with pembrolizumab compared to treatment. This can be compared indirectly to comparison with pembrolizumab alone.

Keaven Anderson is a statistician who has been at Merck Research Laboratories since 2003 and previously worked with Centocor/J&J and with the National Heart, Lung and Blood Institute at the Framingham Heart Study. His doctorate in Mathematical Statistics from Stanford University was followed by post-doctoral work at the Harvard School of Public Health. Keaven is a Fellow of the American Statistical Association. His major interests are in clinical trials, survival analysis and group sequential design.
**Targeting Tumor-Stromal Interactions for the Treatment of Bone Metastasis**

Yibin Kang, PhD, Warner-Lambert/Parke-Davis Professor of Molecular Biology, Princeton University

During cancer metastasis, disseminated tumor cells often hijack existing physiological cellular interactions to facilitate their seeding, survival and outgrowth in distant organs. Bone metastasis is a frequent occurrence in breast cancer, affecting more than 70% of late stage cancer patients with severe complications such as fracture, bone pain, and hypercalcemia. The pathogenesis of osteolytic bone metastasis depends on cross-communications between tumor cells and various stromal cells residing in the bone microenvironment. We used advanced imaging techniques and molecular biology approaches to prove the signaling interactions between metastatic tumor cells and various stromal cells in bone, in order to identify potential new therapeutic targets for bone metastasis. We identified Jagged1 as a TGFβ target gene in tumor cells that engaged bone stromal cells through the activation of Notch signaling to provide a positive feedback to promote tumor growth and to activate osteoclast differentiation. Using genetically modified mouse models, we revealed a surprising role of Jagged1 in promoting chemoresistance of bone metastasis. Chemotherapy of bone metastasis induced elevated expression of Jagged1 in osteoblasts, which provide a pro-survival niche for tumor cells in the bone. These findings support the notion that development of organ-specific metastasis depends on the interactions between tumor cells and various stromal niche components in a given organ. Importantly, therapeutic targeting of Jagged1 significantly reduce bone metastasis and sensitize them to chemotherapy, suggesting possible avenues to dramatically improve the treatment of metastatic bone disease.

Dr. Yibin Kang is the Warner-Lambert/Parke-Davis Professor of Molecular Biology at Princeton University. Dr. Kang obtained his Bachelor’s degree from Fudan University in Shanghai, China and completed his graduate study at Duke University and postdoctoral training at the Memorial Sloan-Kettering Cancer Center. He joined the faculty of Princeton University in 2004 and was promoted to Associate Professor in 2010 and to Endowed Chair Professor in 2012. Dr. Kang is President of the Metastasis Research Society (2016-2018), Chair-Elect of the AACR Tumor Microenvironment Working Group (2018-2019) and President-Elect of Chinese Biological Investigator Society (2018-2020).

Dr. Kang’s research discovered new genes that promote recurrence, metastasis and chemoresistance of breast cancer, delineated tumor-stromal interactions that are essential for metastatic growth, and identified novel regulators with dual functions in mammary gland cell fate determination and tumor progression. Dr. Kang’s outstanding achievements have been recognized by many prestigious awards, including the 2011 Vicek Prize for Creative Promise in Biomedical Sciences (2011), and the American Association for Cancer Research (AACR) Award for Outstanding Achievements in Cancer Research (2012), and the AACR Outstanding Investigator Award in Breast Cancer Research (2014).
Bioanalysis in Antibody Drug Development
Renuka Pillutla, PhD, Executive Director, Bristol-Myers Squibb

The presentation will provide an overview of the evolution of platforms and method development in Ligand Binding Assay (LBA). A special focus will be on (1) reagent generation and screening which is a unique capability of Bioanalytical Sciences at BMS, (2) automation, the key for throughput and data quality in bioanalysis. Applications of hybrid LBA and LC-MS, state-of-the-art technology, in both biomarker analysis and immunogenicity assessment will be discussed as well as the bioanalytical strategy in advancing new modalities (ADCs and Probody).

Dr. Renuka Pillutla is Executive Director, Bioanalytical Sciences, in the Department of Translational Medicine at Bristol Myers Squibb in Princeton, NJ. Renuka received her Ph.D. degree in Molecular Biology & Biochemistry from the University of Medicine & Dentistry of New Jersey (UMDNJ), now part of Rutgers University, NJ. She has over 20 years of experience ranging from research in academia & Biotech to regulated drug development in GMP and GLP environments. In her current role as Executive Director, Bioanalytical Sciences at Bristol-Myers Squibb (BMS), Renuka oversees pharmacokinetic (PK), immunogenicity & biomarker testing in support of all modalities (biologics, small molecules, antibody drug conjugates [ADCs], oligonucleotides [OGNs], and gene therapies) at BMS from pre-clinical and clinical development, through filing and post-marketing support. She is a recognized expert in bioanalysis of biotherapeutics, and an active participant in scientific forums, e-learning activities and has co-authored several industry opinion papers.

ADC Strategy: from Discovery to Development and Regulatory Submission
Ola Saad, PhD, Senior Scientist, Genentech/Roche

Antibody-drug conjugates (ADCs) are drug constructs consisting of a monoclonal antibody (mAb), attached through a chemical linker to a small molecule, often cytotoxic, drug or payload. ADCs combine the target binding specificity of mAbs and the potency of cytotoxic drugs. Many ADC drug candidates are currently at different preclinical and clinical development stages in this rapidly evolving field. This decade has seen the FDA approvals of multiple ADCs, Adcetris® (brentuximab vedotin), Kadcyla® (ado-trastuzumab emtansine), Besponsa® (inotuzumab ozogamicin), Mylotarg® (gemtuzumab ozogamicin) for the treatment of cancer with many more ADCs in clinical development.

The success of ADC development requires technology advances across multiple fields: i.e., humanized monoclonal antibody production, genomic profiling to identify unique tumor antigens, stable chemical linker chemistry, cytotoxins with appropriate potency and mechanism of action, and novel hybrid large molecule/small molecule analytical/bioanalytical technologies. Because of the heterogeneous nature of ADC
molecules, multiple analyte species may contribute to the efficacy and toxicity of ADCs. ADC pharmacokinetic (PK) evaluation, human dose projection, PK/pharmacodynamic (PD) modeling, and the associated bioanalytical assay strategy are complicated. This presentation will provide an overview of the strategies of ADCs from Discovery to Development, and share the experiences in regulatory submission of Kadcyla.

Dr. Ola M. Saad is a Senior Scientist in BioAnalytical Sciences – Assay Development and Technology Department (BAS-ADT) at Genentech, a member of the Roche group, in South San Francisco, CA. She received her B.S. degree in Chemistry from Saint Mary’s College of California, and her Ph.D. degree in Chemistry from the University of California, Berkeley. Since joining Genentech in 2005, Ola has supported bioanalysis of all of the ADCs in the Genentech portfolio including Kadcyla (T-DM1), approved in 2013 and personally contributed to 20+ IND/CTA and BLA global regulatory filings. She has extensive experience analyzing biological materials by electrospray and nanospray mass spectrometry and expertise in LC-MS and MSn analyses using quadrupole and linear ion traps, and QTof mass spectrometers. Her responsibilities at Genentech include design of LC-MS based bioanalytical strategies for the characterization of antibody-drug conjugates (ADCs) and other biotherapeutics. Her group is focused on the development, evaluation, and implementation of bioanalytical LC-MS methods to characterize ADC biopharmaceuticals, quantify therapeutic antibody and drug levels, as well as characterize catabolites in a variety of biological matrices. Dr. Saad has published a number of original manuscripts, book chapter and patents covering bioanalysis of small molecules, carbohydrates, mAbs and ADCs.

Bispecific Antibodies and the Future of Drug Development in Biotechnology

John Lin, MD, PhD, VP, Immune oncology, Head of Bispecifics, Regeneron

- Bispecific antibodies can greatly expand the target(able) space of traditional biologics, by bridging two distinct epitopes, two molecules or two cells together.
- Such technologies have found great utility in hematology (e.g. hemophilia), immune oncology (e.g. ALL) and in many other areas of biology.
- Regeneron has developed a fully natural antibody-like platform of bispecific antibodies that are easy to scale up.
- I will use several vignettes to illustrate how new disease mechanisms can be interrogated, and how new drugs will be discovered with the help of these advances.

John heads up the bispecific antibody Research and Development programs at Regeneron. He is passionate about developing novel biologics to address critical challenges of human health and at Regeneron his work spans across multiple therapeutic focus areas. Prior to joining Regeneron in 2016, he spent 15 years working at Rinat Neuroscience Corporation with increasing responsibilities from its inception, through its acquisition by Pfizer and beyond. He spearheaded Pfizer’s renewed effort in cancer immunology, including checkpoint inhibitors, costimulatory agonists, genetically engineered T cell therapy and microbiome. Before focusing on the immune system, John was involved in developing both blocking and activating antibodies to target neurotrophins and other pathways in treating pain, appetite control, age-related macular degeneration and Alzheimer's disease. He received his Doctor of Medicine degree from the College of Medicine, National Taiwan University, and his PhD in Biological & Biomedical Sciences from Harvard University, followed by a postdoctoral fellowship at Genentech.
Additional Panelists:

**Haishan Xiong**, PhD, MBA, SVP, Business Development, Fountain Medical Development LLC.

Haishan is responsible for commercial operations at FMD, a full service clinical CRO with operations in Asia, Europe, and North America. Before joining FMD, Haishan was EVP and Chief Business Officer of KBP BioSciences, a clinical stage biotech company. Haishan was responsible for the overall operations of the company. Before joining KBP, Haishan was head of Commercial Strategy at WuXi AppTec. He was responsible for strategic planning and new business.

Haishan started his pharma career in commercial operations. He worked at Roche Labs for 10 years in marketing and sales. He later joined Spectrum Pharma, an oncology-focused biotech, managing all Government business. Haishan is an entrepreneur as well. He co-founded Vitalico LLC, a California-based consumer health company. Over the 3 years, Haishan and his team successfully launched 2 products and developed strategic alliances with major consumer health companies. Haishan received his PhD in physiology from Penn State University and MBA from the Wharton School.

**Amy Han**, PhD, Director of R&D Chemistry, Regeneron

Amy Han is a Director of R&D Chemistry in Regeneron, leading small molecular drug discovery and antibody drug conjugation programs.

3:00 – 3:30 pm  **Coffee Break**
Preclinical Models to Assess Microbiome Modulating Therapies in Immuno-Oncology and Beyond

Benjamin Cuiffo, PhD, Principal Scientist, Oncology, Biomodels

The microbiome is a key regulator of local/systemic immune activities. Additionally, dysbiosis or epithelial barrier breakdown can potentiate disease pathology and response to treatment, including anticancer immunotherapies. For these reasons, the microbiome is an emerging target for intervention in oncology and beyond. Microbiome mediation of immune activities should be considered/controlled as a potential variable in all preclinical oncology studies where the therapeutic mechanism of action has an immune component. I will discuss how preclinical models can be rationally designed to assess potential microbiome modulatory therapies in immunoncology.

Dr. Cuiffo joined Biomodels in 2015 after completing his postdoctoral studies at Beth Israel Deaconess Medical Center and Harvard Medical School, where he was an American Cancer Society Fellow. His postdoctoral work centered upon elucidating the molecular mechanisms of tumor metastasis in preclinical in vitro and in vivo models. Ben brings additional expertise in the biology of tumor-initiating (cancer stem cells) and invasive phenotypes, oncogenic signaling pathways, and noncoding RNAs in cancer. He received his Ph.D. in Molecular and Cell Biology from Brandeis University, where he developed novel strategies to target the RAS oncogene in animal models of leukemia. As the Lead Oncology Scientist at Biomodels, Ben’s active collaboration with clients has optimized the utility, efficiency and translational meaningfulness of a broad range of developing small molecules and immunologically-based therapies.

Effects of Microbiome on Clinical Responses to Cancer Therapeutics and Vaccines

Olga Danilchanka, Microbiome Lead, Merck Exploratory Science Center, Merck

Numerous preclinical and clinical studies have shown that the microbiome is the newly-discovered “organ” that is involved in numerous aspects of fundamental physiology and pathology. Recent discoveries are starting to shed light on the precise mechanisms by which the microbiome regulates both innate and adaptive immune responses, and are beginning to appreciate why and how this regulation affects disease initiation, progression, and treatment response. However, most current studies are performed using rodent animal models in discoveries which often fail to translate into human therapies. At the Merck Exploratory Science Center (MESC) in Cambridge we are using a systems biology approach to integrate human and microbiome pathways using well-curated clinical data to identify molecular mechanisms by which the microbiome regulates responses to vaccines and cancer immunotherapy.
Olga Danilchanka is currently a Microbiome Lead at Merck Exploratory Science Center (ESC) in Cambridge, MA. She is a microbiologist with a broad expertise in microbial physiology, genomics, molecular genetics, infectious diseases and NGS. Olga obtained her PhD degree from University of Alabama at Birmingham where she studied pathogenesis and drug resistance of Mycobacterium tuberculosis. For her postdoctoral training Olga focused on the interplay between bacteria and host immune system in the lab of Dr. John Mekalanos’ at Harvard Medical School. To apply her academic training in microbiology to development of treatment modalities, Olga joined a Flagship Ventures start-up Epiva (merged with Evelo Biosciences in 2016) where she was identifying gut bacteria that can be used for treatment of autoimmune diseases. Olga is now leading ESC microbiome team where she is focused on identifying novel pathways and therapeutics important for infectious diseases and immune responses in the context of microbiome-related diseases. Olga is a recipient of multiple merit awards and research grants, presented her work at national and international conferences, and published multiple highly cited papers.

A Role for Bacterial Urease in Crohn’s disease and Gut Dysbiosis

Josephine Ni, MD, Instructor of Medicine, University of Pennsylvania, Division of Gastroenterology

Gut dysbiosis during inflammatory bowel disease involves alterations in the gut microbiota associated with inflammation of the host gut. We used a combination of shotgun metagenomic sequencing and metabolomics to analyze fecal samples from pediatric patients with Crohn’s disease and found an association between disease severity, gut dysbiosis, and bacterial production of free amino acids. Nitrogen flux studies using 15N in mice showed that activity of bacterial urease, an enzyme that releases ammonia by hydrolysis of host urea, led to the transfer of murine host-derived nitrogen to the gut microbiota where it was used for amino acid synthesis. Inoculation of a conventional murine host (pretreated with antibiotics and polyethylene glycol) with commensal Escherichia coli engineered to express urease led to dysbiosis of the gut microbiota, resulting in a predominance of Proteobacteria species. This was associated with a worsening of immune-mediated colitis in these animals. A potential role for altered urease expression and nitrogen flux in the development of gut dysbiosis suggests that bacterial urease may be a potential therapeutic target for inflammatory bowel diseases.

Dr. Josephine Ni is a physician-scientist at the University of Pennsylvania where she is current an Instructor of Medicine in the Division of Gastroenterology. She is particularly interested in the mutualistic interactions between the gut microbiota and the host in inflammatory bowel disease with a particular focus on the role of nitrogen flux in dysbiosis associated with Crohn’s disease.
Development of Zinplava, a Novel Microbiota-Sparing Therapy for Prevention of Recurrent C. Difficile Infections
Todd A. Black, PhD, Exec. Director, Infectious Diseases, Merck

_Clostridium difficile_ is an anaerobic, Gram-positive, spore-forming bacterium that colonizes and infects patients whose normal gut microflora has been disrupted by treatment with broad-spectrum antibiotics. The symptoms of _C. difficile_ infection (CDI) include mild to severe diarrhea, pseudomembranous colitis and colonic rupture, and are caused by exotoxins released by the bacterium. The monoclonal antibody, bezlotoxumab (Zinplava), which neutralizes _C. difficile_ toxin B (TcdB) has been approved as a therapy for reducing the recurrence of CDI when used in combination with standard of care antibiotics. Non-clinical models have supported the mechanistic hypothesis that neutralizing TcdB with bezlotoxumab protects the host from the symptoms of _C. difficile_ infection, reducing the need for further antibiotic therapy thereby allowing the normal gut microbiota, the host’s natural defense against _C. difficile_, to recover and prevent further colonization/infection and recurrence.

Todd Black is the Executive Director for Merck’s antibacterial, antifungal, and HCV Basic Research Group and has over 20 years of experience in the discovery and development of novel antimicrobial agents. Todd received his doctorate degree from the Department of Biochemistry/Department of Energy Plant Research Laboratories at Michigan State University studying prokaryotic cellular differentiation and development in the cyanobacterium Anabaena. He joined the Ciba–Geigy Agricultural Biotechnology Research Unit initially as a postdoctoral associate and then full-time employee where he pioneered genomics-based target discovery in model fungal pathogens and studied toxin production in phytopathic fungi, quorum-sensing control of antifungal metabolite synthesis by Pseudomonas fluorescens and the expression and modification of secondary-metabolite pathways in Myxobacteria and Actinomycetes. He joined the Antimicrobial Therapeutics team at the Schering–Plough and now Merck in 1997, initially leading the genomics-based antibacterial and antifungal drug discovery team. Todd has been responsible for supporting the discovery and development of a variety of therapies for treatment of infectious diseases, including: evernimicin (Ziracin) a novel antibiotic; posaconazole (Noxafil) antifungal; garenoxacin (FQ-antibiotic); AN2690, a boron-based topical antifungal agent for onychomycosis; vicriviroc, an HIV CCR5 antagonist, Zepatier for HCV, Zinplava a _C. difficile_ anti-toxin therapy in addition to multiple ongoing programs for novel target discovery and ongoing support for clinical development of Merck’s extensive portfolio of antibiotics and vaccines.

Additional Panelist:
James Jin, PhD, Vice President, Biocytogen

Dr. James Jin received his PhD of virology at Wuhan University in 1997. He had his postdoctoral training in Colorado State University. He worked as a research assistant professor in University of Illinois at Chicago from 2005 to 2010. In 2010, he was recruited to Advanced Cell Technology, Inc. as a senior scientist. Dr. Jin joined Biocytogen as the Director of Technology in 2011, and then was promoted to Vice President to oversee Biocytogen in USA. His research covers virology, immunology, proteomics, protein structure, human stem cell, and gene-targeting animal model.

3:00 – 3:30 pm  **Coffee Break**
Forward and Reverse Translation: Charting Critical Paths in Immuno-Oncology Drug Development

Alex Huang, PhD, Group Director, Head of Early Development Immuno-Oncology Biomarkers, Bristol-Myers Squibb

As technologies advance to improve accuracy and probability of success in scientific interrogations of human specimens during clinical trials, translational science has taken a profound and decision enabling role during the lengthy drug development process. In the era of personalized medicine, it is increasingly important to describe and measure the molecular responses to drug treatments in human, while provide insight to potential predictive factors for a given therapeutic. In areas where preclinical models provide relatively reliable translatability to human observations, the development path could be straightforward. However, in the space of immuno-oncology, the disparity between pre-clinical and clinical observations may sometime be significant and pose distinct sets of challenges. This presentation will encapsulate the advancement and lessons learned in the field and present a feasible path to integrate forward and reverse translation studies to facilitate speedy clinical development.

Dr. Alex (Shih-Min) Huang is a leader in drug discovery and development with hands-on experience spanning target discovery/validation, hit finding, lead optimization, lead nomination, development candidate selection, and forward/reverse translational investigation in early and late development.

As the Group Director and Head of Early Development Immuno-Oncology Biomarkers at BMS, Dr. Huang leads the early stage biomarker team and provides oversight for the entire early asset biomarker portfolio to deliver strategic vision and translational science objectives in early development programs.

Before joining BMS, Dr. Huang was Associate Director of Oncology Biomarker Development at Genentech, where he led a group of scientific personnel and provided overall guidance on clinical biomarker and CDx strategies for up to 12 pre-IND and early clinical development programs. Along with his expertise in HCC, Dr. Huang also headed the Overall GI Cancer Biomarker Strategy Team and was accountable for charting disease-specific biomarker landscapes in association with clinical responses, lines of therapies, disease etiologies or stages to guide rapid development of pipeline molecules as single agent or in combination for all GI indications, including CRC, GC, EC, HCC, and PDAC.

Prior to Genentech, Dr. Huang was with Novartis and Sanofi Oncology, where he led drug discovery teams to advance multiple programs through various stages of drug discovery to IND, while continuing his contribution to scientific community through lead or corresponding authorship in high profile journals such as Nature and Blood.
The discovery and development of Entresto® is an amazing journey and an excellent example of academia-industrial collaborations. Entresto® demonstrated a greater benefit in reducing the risk of cardiovascular death and hospitalization compared with current RAS-based standard of care in patients with heart failure with reduced ejection fraction, and is a breakthrough therapy for heart failure. This presentation will review the key moments of Entresto® development, share with the audience of the inspiring story, including the scientific background and clinical development strategies.

Dr. Jennifer Sheng is Director in Clinical Pharmacology & Pharmacometrics in Immuno-oncology & Oncology at BMS. Jenny received her Pharmacy degree from Peking University in China, and her Ph.D. in Biopharmaceutics under Prof. Gordon Amidon in 2007 from the University of Michigan. Currently at BMS, she serves as the Clin Pharm lead for Nivolumab lung program and CPP functional head for BMS China. She has worked in both small molecules and biologics, across FIH to Lifecycle-management, with both NDA/BLA submissions worldwide. Dr. Sheng is active involved in pharmacometric analysis. Prior to joining BMS, Dr. Sheng worked at Novartis Oncology, serving as the CP&P group lead for Gleevec and Tasigna. Externally, Dr. Sheng has served as organizing & chairing committee member for ASCPT, AAPS, FDA workshop, ACCP and ACoP. Dr. Sheng has authored/co-authored over 60 manuscripts, book chapters, abstracts and presentations.
Opportunities and Challenges Facing Cell-Based Therapeutics

X. Chris Xu, PhD, MBA, Chairman & CEO, Cesca Therapeutics Inc. - A Boyalife Company

In the past few years, the pharmaceutical industry dominated by small and large molecule drugs, has seen a revolution by the use of human cells as powerful therapeutics for cancer patients and other indications. The used of cell-based therapeutics, which includes naive stem cells and more sophisticated genetically engineered immune cells and other cell types, offers opportunities to target cancer and many genetic defects. Yet, sophisticated and labor intensive cellular manufacture process remains as a major hurdle that limits the capacity and causes high cost for drug developers. Cell-based therapeutics are often mixtures of different cell subsets, a challenge not encountered by the traditional small or large molecule drugs. Easier and more robust cellular processing and manufacturing tools are needed to enable more applications to be developed. CARTXpress, a low-cost, functionally closed and semi-automated system for high efficient cellular purification and manufacturing platform was recently introduced. Applications will be discussed using this new enabling technology.

Dr. Xu has served on Cesca’s board of directors since March 2016, and has served Chairman and CEO since November 2016. Dr. Xu over 15 years of leadership experience in the biopharmaceutical industry and has contributed to numerous successful product launches. In 2009, Dr. Xu founded Boyalife Group, a China-based diversified life sciences holding company. Under his leadership, Boyalife has grown into over 30 subsidiaries with operations in US, China, Japan, India and many other countries. Prior to founding Boyalife, Dr. Xu served as a project leader at Pfizer, as a director of research at two publicly-traded companies and as a vice president at Founder Group, a Chinese technology conglomerate focused on information technology, pharmaceuticals, real estate, finance, and commodities trading. Dr. Xu’s expertise spans several diverse therapeutic areas, including arthritis & inflammation, autoimmunity, and immuno-oncology. He has authored over forty publications and has been recognized by numerous professional societies for his contributions to biomedical research. Dr. Xu received his Ph.D. in immunology from Washington University School of Medicine (St. Louis, USA) and an executive MBA from Emory University (Atlanta, USA).
Applying Deep Learning to Biomarker Development and Drug Discovery for Aging and Age-Related Diseases
Qingsong Zhu, PhD, CSO, Insilico Medicine

The advances of throughput technologies help a massive accumulation of -Omics data. Deep learning algorithms are designed to analyze and use large volumes of data to generate relevant insights. We are applying recent advances in deep learning to enable programs to recognize biological patterns. The modular ensemble of deep neural networks (DNNs) of varying depth, structure and optimization were designed to predict a person's chronological age using a blood test. Insilico Medicine developed quantified pathway analysis strength (PAS) algorithms and uses the algorithms to reduce the dimensionality of the high-dimensional transcriptomic data. The DNNs trained on the transcriptional response data sets were used to score the drugs/compounds' therapeutic usage. The generative adversarial networks (GANs) have demonstrated surprising results in generating new images upon request using natural language as input. Our team is using the generative adversarial autoencoders (AAEs) to generate new molecular fingerprints on demand.

Qingsong Zhu, Ph.D. is the Chief Operating Officer of Insilico Medicine, Inc., a company that utilizes advances in genomics, big data analysis, and deep learning for in silico drug discovery and biomarker development for aging and age-related diseases. Dr. Zhu received his Ph.D. degree in biochemistry from Kansas State University. He was interested in integrating biochemistry, genomics, and bioinformatics to develop new targets for insect control. Prior to joining Insilico Medicine, he received his postdoctoral training at Johns Hopkins University School of Medicine under the supervision of Dr. Nancy Davidson. When he worked at Johns Hopkins University, his research focused on cancer epigenetic biomarker and anti-epigenetic cancer drug development. He is currently interested in applying deep learning to early diagnosis biomarker development and drug discovery for cancer and other age-related diseases.
Digital Medicine

Jonathan Knights, PhD, Associate Director, Data Sciences, Otsuka Pharmaceutical Development and Commercialization (OPDC)

**Digital:** Pertaining to, noting, or making use of computers and computerized technologies, including the internet

**Medicine:** The art or science of restoring or preserving health or due physical condition, as by means of…

Digital technologies are transforming our ability to measure and quantify daily life. Sensors and devices are generating an unprecedented level of access into daily patterns and biology, revolutionizing the way medicine can be practiced, and the way treatments are being developed. The ways in which patients are phenotyped and assessed now have digital equivalents (e.g., digital biomarkers and digital assessments of cognition): assessment periods are no longer limited to the time a patient is with a clinical investigator or their physician – we can now provide bidirectional feedback in near/real-time. Recent FDA approvals of ingestible sensors and video games, are just two examples of the expanding digital footprint in medicine. This increase in information is not without its challenges: the regulatory pathway for these products is largely being carved on a case-by-case basis, and the analytical landscape in the digital space is much different than traditional clinical endpoint testing. Additionally, our understanding of the concepts of placebo response and the ‘white-coat’ effect in this space is still very much in its infancy. Benefits and challenges aside, it is evident that digital technologies and the fields of healthcare and medicine will continue to evolve together.

1 – dictionary.com (digital: sixth definition)
2 – dictionary.com (medicine: second definition)

Jonathan Knights holds a PhD in pharmaceutical science from the University at Buffalo, building applications of information theory on high-dimensional pharmaceutical datasets, and undergraduate degrees in mathematics and chemistry. Over the last five years, Jon has worked in both the pharmaceutical and software spaces. He currently leads a data science team at Otsuka Pharmaceuticals focused on ways of leveraging data generated from digital technologies in drug development and treatment. Jon has contributed work in textbooks, peer-reviewed publications, and conferences in the fields of computer science, information theory, pharmacometrics, and clinical development.
How ML/AI and Other Algorithms Based Computational Approaches are Helping Speed Drug Development: XtalPi Experience

Yide Alan Jiang, PhD, Chief Strategy Officer, XtalPi Inc.

Bringing a new pharmaceutical drug to market takes more than ten years and can spend the billions in R&D expenditures. It is a strategic obligation for industry leaders to seek more efficient methods of approaching this process and machine learning (ML)/artificial intelligence (AI) is emerging as a potential solution.

The ability to solve solid-state structures through organic crystal structure prediction (CSP) has remained elusive despite many years of industry and academic research. More recently, however, advances in computer technology and modeling have combined to rekindle enthusiasm for CSP. The pharmaceutical industry is particularly interested in CSP due to the importance of solid-state structures and properties in the drug development process.

XtalPi, the industry pioneer in innovative CSP technology, deploys a combination of ML/AI, quantum physics algorithms and cloud high performance computing to predict the crystal structure of drug molecules as part of its Intelligent Digital Drug Discovery and Development (ID4). The technology has emerged from proof-of-concept through rigorous and extensive internal and external challenges and is particularly well suited for the pharmaceutical industry. Indeed, XtalPi has already integrated its CSP technology into drug design and pharmaceutical product development in collaboration with industry partners.

Dr. Jiang as Chief Strategy Officer of XtalPi Inc. is responsible for company’s strategy development including identification of growth opportunities, strategic planning and execution. He joined XtalPi in 2015 bringing over fifteen years of scientific and research management experience, most of it gained in positions of increasing responsibility at Genzyme and then Sanofi-Genzyme. His early tenure at Genzyme was in disease biology research focusing on oncology and genetic diseases. Following Sanofi’s acquisition of Genzyme in 2011, Dr. Jiang was appointed as liaison and director of Asia R&D Strategy of the Sanofi-Genzyme R&D Center and in that capacity he was responsible for the development of Genzyme Asia/China R&D strategy and led cross-functional R&D external collaborations and projects in Asia. He was also a key member of the Translational Medicine team and focused on strategic implementation of pharmacogenomics and biomarker in early clinical development.

Alan received his medical degree from Shanghai Medical University (Fudan University) and doctorate in molecular biology from the University of Tennessee at Memphis, followed by post-doctoral research in hematology and oncology at Brigham & Women’s Hospital, Harvard Medical School.
Precision Medicine with Functional Diagnostics - Conditional Reprogrammed Cell Line, Organoid and Mini-PDX/PDX

Danyi Wen, MD, MBA, President & CEO, Shanghai LIDE Biotech, Co. Ltd

The rapid pace of discoveries in tumor biology, imaging technology, and human genetics hold promise for an era of personalized oncology care. The successful development of functional diagnostic tools has generated much hope and hype about the delivery of safer and more effective new treatments for cancer.

NCI recommended using three functional diagnostic model systems to replace traditional ATCC cell line or NCI-60 panel in oncology drug screening. Three edge tools are: Conditional Reprogramed Cell Lines (CR Micro Tumor); Organoid and Patient Derived Xenograft (PDX) and Mini-PDX. In these systems, interactions between cancer cells and stromal cells are preserved to some degree. Because the tumor microenvironment can influence drug efficacy and the development of drug resistance, CR, Organoid and PDXs should be better models for developing anticancer therapies and screening drugs for precision medicine applications than earlier models. Mini-PDX, a 7 days in vivo assay system that has very high correlation with clinical end point, has a great potential on personalized precision medicine.

We have established a functional diagnostics service platform. Translational application of this platform promotes the discovery of novel therapeutic approaches that can be assessed in clinical trials and provides personalized therapeutic options for individual patients where standard clinical options have been exhausted. Together these new functional diagnostic tools can greatly accelerate the evolution of precision medicine and its implementation into routine cancer care.

Dr. Danyi Wen is President & CEO of Shanghai LIDE Biotech Co. Ltd, a company focusing on translational medicine services. Shanghai LIDE has two subsidiary companies: Xian LIDE and Shanghai LIWEN. LIDE is pre-clinical CRO, LIWEN is a third party independent clinical testing lab with CAP certification. LIDE was public listed on New Third Board on Aug 2016.

Prior to LIDE, she was Vice President of Biology at Shanghai ChemPartner. She worked with her colleague to establish ChemPartner biology department from scratch. Prior to ChemPartner, Danyi Wen was a group leader at Preclinical and Clinical Development Science Dept (PCDS) of Biogen-Idec, focused on large molecule immunogenicity assay development, biomarker identification and GLP operation. Prior to Biogen, Danyi worked at Inflammation Department of Millennium Pharmaceuticals, Inc. for 10 years.

Prior to Millennium, Danyi Wen held two years faculty position (Instructor of Medicine) at Dept of Hematology/ Oncology at Harvard Medical School/Brigham & Women’s Hospital after 3 years postdoctoral training with Dr. Franklin Bunn. M.D from the Fourth Military Medical College; MS of Biochemistry & Pathology from Chinese Academy of Medical Sciences / Peking Union Medical College; MBA from Suffolk University.

She is an Adjunct Professor of Fudan University, School of Pharmacy; Visiting Professor at Translational Medicine Center at Peking Union Medical University (PUMC). 2013, Danyi was selected as “Thousand Talent” at Shanghai.
Discovery of RNAi Based Clinical Candidates for the Treatment of HBV and AATD
Zhen Li, PhD, SVP, Head of Discovery Chemistry and Manufacturing, Arrowhead Pharmaceuticals

This presentation will focus on the discovery and development of Arrowhead Pharmaceutical’s proprietary Targeted RNAi Molecule (TRiMTM) platform. The TRiMTM platform encompasses both hepatic delivery and extrahepatic delivery of siRNA. The talk will detail the discovery of the two clinical candidates ARO-AAT and ARO-HBV. Preclinical data of the two candidates will be presented.

Dr. Zhen Li, Senior Vice President of Chemistry and Manufacturing, joined Arrowhead Pharmaceuticals in April 2014. She leads discovery chemistry, CMC and manufacturing. She has led the development and is the key inventor of Arrowhead TRiM platform. She led the discovery of the two clinical candidates ARO-AAT and ARO-HBV. Prior to joining Arrowhead Pharmaceuticals, she held leadership positions at Merck, Schering-Plough and Novartis, and led teams in drug discovery and process development in small molecule pharmaceuticals as well as RNAi therapeutics covering a range of disease areas. Dr. Zhen Li was Director of Chemistry at Merck Research Laboratory and led a team in research and development in the field of siRNA. She led multiple development programs from early to late stage at Schering-Plough. Dr. Zhen Li served as the Head of Process and Analytical Research & Development at Novartis Changshu. She began her pharmaceutical career at Merck where she did research in medicinal chemistry and process development. Dr. Zhen Li received her bachelor of science degree from Peking University and her Ph.D. from Harvard University.
Moderator Biographies

Xiaodong Chen, PhD, Senior Research Investigator
Bristol-Myers Squibb

Xiaodong Chen is a senior research investigator in the Drug Product Science & Technology department at Bristol-Myers Squibb. As a drug product development team leader, he is responsible for developing and implementing strategies of biologics drug product formulation development, device and primary packaging, tech transfer to commercial manufacturing, and registration filing. Xiaodong is the key driver and leading the efforts to reduce and optimize freeze drying cycles of commercial lyo products (NULOJIX®, EMPLICITI™). Xiaodong has authored papers in this field and co-authored two book chapters. In addition, Xiaodong is actively involved in scientific and professional services. He is currently serving as an Editorial Advisory Board member of Journal of Pharmaceutical Sciences and a reviewer for NIH contract proposals. He is a steering committee member for two AAPS focus groups. He has advised two NSF funded projects and served as session chairs in AiChe and AAPS National Biotechnology annual conferences. He was elected as the SAPA Executive Council member since 2013 and appointed as the Director of Global Communication Team and Chair of China Affairs Committee. Xiaodong received his Ph.D. from the Ohio State University.

Hong-Ping Guan, PhD, Senior VP of Biology, Quixgen Inc.

Dr. Guan graduated from Peking University Health Sciences Center (Beijing Medical University). He received his Ph.D. degree from pharmacology department of University of Pennsylvania in 2004. He was awarded the Pfizer Fellow of the Life Sciences Research Foundation during his postdoctoral research at UT Southwestern Medical Center with the Nobel Laureates, Michael Brown and Joseph Goldstein. Dr. Guan worked in cardiometabolic disease department of Merck for 7 years. During his career at Merck, Dr. Guan led multiple research programs in preclinical and clinical stages for different indications including diabetes and NASH. His work had been published on Science, JBC, and JLR, etc. He is currently the co-founder and senior VP of biology of a startup biotech company, Quixgen Inc. Since 2015, Dr. Guan has served SAPA as volunteer, Executive Council member, and Director of Public Relations.
**Lisa Huang**, PhD, Director of Business Development, BGI

Dr. Lisa Huang is the director of business development in BGI Americas. Lisa has over 10 years of biopharmaceutical industry experience. Prior to BGI, Lisa was a drug discovery and development professional at Bristol-Myers Squibb and Medical Diagnostic Laboratory LLC, in immune-oncology and oncology fields with unique industry experience in clinical diagnostic and clinical biomarker. Lisa holds 9 US patents from her biopharmaceutical career. Lisa has also been in volunteer service for many years to promote biomedical development: She is an Adjunct Associate Professor in UMDNJ School of Medicine (now Rowan University); she has been an Executive Council for four terms in SAPA; and she also serves in the Editorial Board for the journal Annals of Translational Medicine. Lisa earned her Ph.D. degree from Purdue University and a B.S. degree from University of Science and Technology in China, Hefei. Lisa received her postdoctoral training at Medical School in Stanford University, CA.

**Cai Li**, PhD, External In Vivo Pharmacology Lead, Merck Research Laboratories

Cai Li received his Ph.D. in 1995 (mentor: Dr. Thomas Südhof, 2013 Nobel Laureate) from UT Southwestern. He trained at the Rockefeller University with Dr. Jeffrey Friedman as a postdoctoral fellow and returned to UT Southwestern in Sept. 1999 as a tenure-track Assistant Professor. In 2005, he joined Merck Research Laboratories (MRL), was appointed the Diabetes Pharmacology Lead in Jan., 2008, Biology Program Team Lead in 2009, an interim Head of the Department of Diabetes from Aug., 2010 to Jun., 2011. In Oct. of 2011, he was appointed the In Vivo Pharmacology China Lead of MRL and expatriated to China. Since 2015, he has been an External In Vivo Pharmacology Lead, responsible for all of MRL’s Oncology studies at CROs worldwide.

Cai Li was the recipient of a Career Development Award from the American Diabetes Association as well as grants from the NIH, ADA, JDRF, AHA, and the Welch Foundation, totaling $1,295,000 in direct support. He has published more than 50 peer-reviewed manuscripts. He co-Chaired MRL Global Forum from 2007 to 2008 and was the chair of SAPA - Johnson & Johnson Asia Outstanding Graduate Thesis Award in Bio-tech review committee in 2011 and 2012.
Jerry Li, PhD, Global Clinical Development, Merck & Co, Inc.

Dr. Li has been working on clinical trials from Phase 1 to 4 in multiple therapeutic areas at Biostatistics and Research Decision Sciences (BARDS) within Global Clinical Development (GCD), Merck. Dr. Li received his Ph.D. degree in Statistics from University of Maryland, College Park. He joined Merck in 2013 following two years at the U.S. FDA.

At Merck Dr. Li has provided critical support for clinical trial design, protocol development, statistical analysis, trial monitoring as well as authoring clinical study report (CSR) and common technical documents (CTD) for investigational new drug (IND) and new drug application (NDA) filing to regulatory agencies worldwide including U.S. FDA and European Medicines Agency (EMA). His clinical development expertise covers oncology, infectious diseases, immunology and neurosciences. Multiple NDAs have been approved under his lead and support.

Dr. Li has published numerous peer-reviewed articles in both discovery and clinical development. He also holds an advanced degree in molecular cell biology. He has been a member of Executive Council of Sino-American Pharmaceutical Professionals Association (SAPA) Headquarter since 2016.

Junfang Li, PhD, Vice President, Kyowa Kirin Pharmaceutical Development, Inc.

Junfang Li currently serves as Vice President, Biometrics at Kyowa Kirin Pharmaceutical. She has a unique industry career in the US and Japan, with a wealth of experience in management, data integrity, and clinical trial design and analysis focused on new drug development and approvals. She received her B.S. in Math from Lanzhou Univ., and her Ph.D. in Statistics from Colorado State University. She entered into industry as a biostatistician at Syntex and then P&G before moving to Kobe, Japan in 1998 to establish P&G’s biometrics functions in Asia. In 2001, she joined Sanofi-Aventis in Tokyo, where she and her biostatistics group achieved JNDA submissions & approvals of major portfolio compounds resulting in 7 approvals in Cardiovascular, Diabetes, Rheumatoid Arthritis, Oncology, CNS, Allergy, and Bone therapeutic areas. In Sanofi-Aventis US, she was on various positions with increased responsibility. From 2010 to 2013, she built and led Data Science Department at Mitsubishi Tanabe. Prior to joining Kyowa, she served as VP of Biostatistics Department at Otsuka accomplished 5 NDA/sNDA submissions and approvals, and successfully navigated through statistical challenges with FDA and EMA. She also coauthored research papers published on prominent journals, and co-organized industry/FDA workshops in statistics.
Jian Wang, PhD, Bristol-Myers Squibb

Dr. Wang is the Lead, LC-MS Technical Integration/Sr. Principal Scientist in the Bioanalytical Sciences/Translation Medicine Department at Bristol-Myers Squibb. Dr. Wang graduated from Beijing University (China) in 1987 and received his Ph.D. in analytical chemistry at Michigan State University in 1994. Following postdoctoral training at the National Institutes of Health (NIH) in Maryland USA, he joined GSK in 1996 and then Bristol-Myers Squibb in 1997. Dr. Wang has 20+ years of experience in discovery and regulated bioanalysis in pharmaceutical industry. Dr. Wang has contributed in high throughput bioanalysis and bioanalytical chromatography. In recent years, Dr. Wang has been leading a group of scientists in developing ligand binding and LC-MS/MS hybrid assays for ADC bioanalysis in an LBA and LC-MS integrated approach. Currently, Dr. Wang serves as the coordinator of Regulated Bioanalysis Interest Group at ASMS and a sub-team lead of AAPS ADC bioanalysis committee.

Jack Wu, PhD, Manager of Commercial Partnerships, ATCC

Jack Wu is currently the Manager of Commercial Partnerships at ATCC. He focuses on prospecting and developing new commercial and strategic partnership opportunities through engagement with external partners and customers, negotiating terms and preparing contracts for major commercial transactions and agreements with business-to-business partners and other commercial customers.

Prior to joining ATCC, Dr. Wu worked as the Sales & Marketing Manager of Discovery Biology Business Unit at GenScript USA. He led the business unit commercial team including marketing, sales, and customer care to support pharmaceutical and biotech clients, and was responsible for initiating and implementing marketing and sales plans to increase brand awareness and to achieve annual sales goals.

Dr. Wu obtained his BS degree from Xiamen University in 2002 and PhD degree from North Carolina State University in 2011.

Lin Yan, PhD, Principal Scientist, Merck

Lin obtained his BS in Chemistry from University of Science and Technology of China and did his PhD study in Chemistry with Professor Dan Kahne at Princeton. After his postdoctoral study with Professor George Whitesides at Harvard, he joined Bristol-Myers Squibb at Princeton in 1998, working in cardiovascular disease area. Since he joined Merck Research Lab in 2001, he has worked on research projects related to immunology, hematology, obesity, diabetes, hypertension, anti-infectious and oncology. Recently as a Principal Scientist, he is working in the area spanning from small molecule to large protein, such as bioconjugation, peptide chemistry, chemical and enzymatic ligation, and targeted delivery of nanoparticle.
Aming Zhang, PhD, Staff Scientist, Regeneron

Aming Zhang is currently Staff Scientist at Regeneron Pharmaceuticals. His role includes analytical method development and full characterization of antibody based biologics to support CMC development and regulatory submission under different stages of clinical developments. Prior to that, Dr. Zhang was principal scientist in the Biopharmaceutical Analytical Sciences department at GlaxoSmithKline, supporting IND and BLA enabling characterization and analytical strategy development. He received his PhD in Chemical Engineering from University of Virginia in 2011, and completed his Postdoc training at Amgen Inc. Dr. Zhang has been volunteering as Executive Council Member in SAPA since 2012, and is currently Deputy Director of Business Development at SAPA-HQ.
Admera Health is an advanced molecular diagnostics and genomics services company focused on personalized medicine, non-invasive cancer testing and digital health. Dedicated to developing cutting-edge diagnostics that span the continuum of care, Admera Health fulfills unmet medical needs with cost-effective tests and accurate analysis to guide patient care. Utilizing next generation technology platforms and advanced bioinformatics, Admera Health seeks to redefine disease screening, diagnosis, treatment, monitoring, and management through its innovative, personalized solutions.

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Biocytogen has established a global technical service network which relies on our unique technical platforms, standard operation procedures, strict quality control systems, talented scientists, and an efficient management team. The scientific team in our recently opened Boston branch at “50-C Audubon Road, Wakefield, MA” are focusing on preclinical animal in vivo efficacy and pharmacology service to speed up your drug development. We are recruiting talents in our Boston site.

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Kelun Pharmaceutical was founded in 1996, currently has over 100 subsidiaries (primarily in China and one in New Jersey, USA).
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Kelun-Biotech Biopharmaceutical Co. Ltd, a subsidiary of Kelun Pharmaceutical Group, was established in 2016, focusing on innovative small molecules and biologics.

For business and career opportunities, please contact: Hui Wang, PhD
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Shanghai LIDE Biotechnology Co., Ltd. ("Shanghai LIDE"), is committed to translational medicine and precision medical research of cancer, provide drug treatment guides to physicians, and proposing personalized treatment plans. The key technology platform is three functional diagnostics recommended by NCI. MINI PDX-PDX (Patient Derived Xenograft); CR (Conditional Reprogramming Cells) and Organoid. OncoVee® MINI PDX is company patented technology, a 7 days in vitro drug sensitivity test that can be used at pre-clinical for drug screening as well as translational use at clinic for personalized medicine.

The company owns AAALAC accredited SPF level animal centers and world-class equipment. Shanghai LIDE has two wholly-owned subsidiaries, "Xi'an LIDE Biotechnology Co., Ltd." and "Shanghai LIWEN Diagnostics" (hereinafter referred to as "Shanghai LIWEN") both with qualification of clinical testing laboratory. Shanghai LIDE was listed on the "New OTC Market" in August 2016 (stock code: 838848).

Shanghai LIWEN is a third-party medical institution for one-stop molecular diagnosis services to help doctors and patients on personalized and precision medicine, with most abundant and systematic pipeline of products for tumor diagnosis in China. The company owns safety level 2 laboratories and is certified for molecular tests from Shanghai Centre for Clinical Laboratory (SCCL) and for anatomical pathology and molecular pathology tests from College of American Pathology (CAP). As one of few GLP-like laboratories certified for anatomical pathology and molecular pathology tests by CAP in China, Shanghai LIWEN provides both pathological test and companion diagnosis services in drug development for global pharmaceutical companies, with FDA-approved data reports.

Additionally, Shanghai LIWEN - Promega joint laboratory co-founded by Shanghai LIWEN and Promega, is dedicated to the research, development and application of hotspot tumor markers (MSI, dMTR, etc.), and provides services for the tests of hotspot tumor markers and companion diagnosis in accordance with CAP standards.

As the public service platform for translational medicine of Xi'an Hi-tech industries development zone, Xi'an LIDE also owns a SPF-level laboratorial animal center with the certification of AAALAC.

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Logan Instruments is a leading lab instrument manufacturer with a focus on dissolution, physical, and now more than ever, topical/transdermal testing systems for pharmaceuticals and cosmetics. It prides itself on three core concepts that have been the pillars of the organization: INNOVATION, QUALITY, SERVICE. Logan Instruments consistently looks to the future in terms of product development while never ceasing to maintain and nourish its existing relationships with their current customers.

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1 At June 30, 2016, the latest date for which information was available for certain foreign insurance companies. 2 Based upon 2015 net premiums written (NPW) for commercial lines according to SNL Financial. 3 Based upon 2015 estimated European non-life NPW using the AM Best Global Database. 4 Based upon data from the China Insurance Regulatory Commission (CIRC) and Axxis Insurance Information Services Ltd (Axxis) as of March 6, 2017. 5 As of January 2017. 6 LMRA, based on full-year 2016 sales.

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