The 2011 BIO International Convention in China – Program

Opening Ceremony

James C. Greenwood, President & CEO, Biotechnology Industry Organization
- Mr. Zuxin XU, Deputy Director, Science and Technology Commission of Shanghai Municipality
- Mr. Song PENG, Deputy Governor, Shanghai Pudong New Area People's Government
- Mr. Lei DING, President & Managing Director, Shanghai Zhangjiang Group. Co., Ltd.

Keynote Sessions

Qiyu Chen, Chairman, Fosun Pharma
Dr. Jörg Reinhardt, CEO, Bayer HealthCare

Opening Keynote Plenary Session

The Honorable Elaine Chao, Secretary, U.S. Department of Labor 2001-2009

Zhangjiang Sessions

1) Biopharma Development in China and International Cooperation

China is one of the world’s fastest growing emerging pharmaceutical markets. With its international position and influence on the rise, it has attracted a growing number of multinational pharmaceutical companies and research institutions to the country. An international cooperation has emerged between China and the worldwide bio-pharmaceutical industry, creating great opportunities, and challenges to be explored.

As such, the bio-pharmaceutical industry has been positioned as one of the national strategic and emerging industries, and the Chinese government is paying great attention to its developments. The government has established funds for research and development, aiming to give special support to the enterprises focused on innovation and participation in international cooperation; and to promote the bio-pharmaceutical industry with rapid and healthy development.

Zhangjiang Hi-Tech Park is one of the earliest National Hi-Tech Parks with the leading bio-pharmaceutical industry as its major industry. With Zhangjiang hosting dual development opportunities for the international and local bio-pharmaceutical industries, the concept of "innovation and integration" will positively undertake and promote the bio-pharmaceutical industry.

During this session, we will share the national strategic planning for the Chinese bio-pharmaceutical industry, the development of Zhangjiang Bio-Pharmaceutical industry cluster, and successful international case studies from Zhangjiang. We’ll also be exploring how to promote the global bio-pharmaceutical industry through enhanced international cooperation so that it may continue to flourish.

Moderator:
- William R. Keller, Vice General Manager, Shanghai Zhangjiang Biotech & Pharmaceutical Base Development Co. Ltd.

Panelists:
- Mr. Yuliang Huang, CEO, Generon (Shanghai) Corporation
- Dr. Douglas Khoo, Corporate VP Operations China & Indonesia, BPE, Boehringer Ingelheim
- Mr. Jun Ren, CEO, Newsummit Biopharma Group
- Richard Wang, Senior Director & Head of Operations, GSK R&D China
- Mr. David Wilkinson, Global Product Director, AstraZeneca R&D Charnwood
- Dr. Yichun Zhu, Dean of College Pharmacy, Institute of Drug R&D, Fudan University
Speech 1: Topic: “The registration and regulatory of China biological products and the overview of China pharmaceutical industry”  15 mins
Mrs He Bai, Division of Biological Products, Department of Drug Registration, SFDA

Speech 2: Topic: Innovation and Integrations-Development Strategy of Zhangjian Pharmaceutical Industry  15 mins
Mr. Lanzhong Wang, General Manager, Shanghai Zhangjiang Biotech & Pharmaceutical Base Development Co. Ltd

Speech 3: Topic: Chance and Challenge for MNEs’ in the area of new drug R&D in China  15 mins
Richard Wang, Senior Director and Head of Operations, GSK R&D China.

2) Innovation in Zhangjiang

As a passport to China innovation, ZJ High-Tech Park played a pivotal role in leading biotech and pharmaceutical development in China. In this session you will meet leaders from the different sectors in Zhangjiang who have contributed to the establishment of the innovation ecosystem in Shanghai. While it is important for you to hear their successful experiences and lessons learned in our session, you can expect more; they will collectively address the frequently asked Big Question "When can China become a leader in drug discovery innovation and what does it take to make China discovery far more productive than what we have done in the last two decades in the western world?"

Moderator:
- Dr. Li Chen, President and CEO, Hua Medicine Co., Ltd.

Panelists:
- Mr. George Baeder, Monitor Group Company
- Mr. Kevin Chen, President & COO, ShangPharma Group
- Mr. Leon Chen, Partner, Fidelity Asia Growth Partners
- Dr. Samantha Du, CEO, Hutchison MediPharma Limited (HMPL)
- Lingshi Tan, General Manager (China) R&D Center and VIP, Worldwide Development Operations, Pfizer, Inc.
- Mr. Tony Zhang, Vice President of Global R&D, Asia, Eli Lilly and Company

Business Development Panels

1) China-It's a Big Deal

M&A and drug development deals between Western and Chinese companies are on the rise. This session will profile one of the most high-profile China-West collaborations of the past year. The principal dealmakers from both companies will be on hand to discuss the deal’s development and will offer candid advice for companies pursuing China-West collaborations.

Moderator:
- Bernard Ng, Managing Director, Transaction Advisory Services (China), Ernst & Young

Panelists:
- Frank K. Au, Chief Executive Officer, Cowen and Company Asia
- Charles Hsu, PhD, MBA, Venture Partner, Mustang Ventures
- Mark Lotter, CEO China Operations, SciClone Pharmaceuticals, Inc. and Former CEO, NovaMed
- Gary Titus, Chief Financial Officer, SciClone Pharmaceuticals, Inc
2) **Chinese Start-Ups**

A new wave of start-ups is moving forward pursuing innovative molecules. These companies frequently feature officers with US/EU experience in drug development, and offices and operations in both the US and China. The research being pursued has IP, as well as financing that is sourced in both the West and China. These companies face numerous challenges and choices: where to locate discovery research or development operations? Which market should be primary for development? Where should financing be pursued? What are investors looking for from these companies? How to look at financing, given the health of the IPO market in China? This panel will feature a number of CEOs of these new companies, as well as venture capitalists who are seeking to finance new companies in China.

**Moderator:**
- Howard Liang, PhD, Managing Director, Biotechnology, Leerink Swann

**Panelists:**
- Leon Chen, Partner, Fidelity Asia Growth Partners
- James Li, Partner, KPCB China
- Dajun Yang, MD, PhD, President & CEO, Ascentage Pharma Group Corporation

3) **A 360° on China's Healthcare Capital Markets**

In a time where the global financial markets are in crisis, China’s equities markets have increased more than tenfold in the last 6 years alone. As a young and evolving market, China has the unique opportunity to shape and define its presence in the global capital markets. The establishment of the ChiNext on the Shenzen Stock Exchange (SZSE) opened the door for several biopharma start-ups in China. 2010 was characterized by an IPO boom in the Chinese markets, but is this sustainable? What trends can we expect to see emerge from China’s nascent financial markets? Seasoned investment bankers will provide a 360 degree overview of the capital markets in China—past, present and future.

**Panelists:**
- Ross Hammerman, Director, Citi Corp Healthcare Group
- Ling Zhang, Director, Citigroup Global Markets Asia Ltd.

**Intellectual Property Panels**

1) **Protection of Biotechnology Inventions in China, US and Europe: A Comparative Perspective**

The panel will compare what can be patented and the scope of protection in China, EU and the US including protections that are afforded to plants (utility, PVP, etc.). The panel will also explore the impact of changes in patent laws or regulations in each of these jurisdictions on biotechnology patenting. The panel will consider aspects of the Third Patent Law Amendments in China, patent reform in the US, and the European Directive and other related policies and their impact on biotechnology patenting.

**Moderator:**
- Thomas T. Moga, Of Counsel, Shook, Hardy and Bacon

**Panelists:**
- Francisco Fernandez y Branas, Director Biotechnology, European Patent Office
- Jasemine Chambers, Deputy Administrator for Policy and External Affairs, United States Patent and Trademark Office (USPTO)
- Zhang Qingkui, Director General, Pharmaceutical and Biotech Examination Department, State of Intellectual Property Office, People's Republic of China
2) Effective IP Mechanisms for Bringing Pharmaceuticals to Market

China’s investment in its 12th Five-Year Plan has resulted in a significant boost in biotechnology R&D. Innovative technologies and discoveries are resulting from investment in biotechnology. China’s nascent innovative biopharmaceutical sector will be faced with challenges and opportunities for bringing their products to market. A panel of experts will explore various IP mechanisms for protecting research data including trade secret and regulatory data protections as means for bringing discoveries to market. The panel will also look to systems in the U.S. (Hatch Waxman) and in Europe (Biosimilars) as possible mechanisms for approval of biopharmaceuticals.

Moderator:
- Jonathan Z. Yuan, Managing Partner, US & European IP Practice, Shangcheng & Partners

Panelists:
- Haiyan Chen, PhD, JD, Senior Patent Counsel, GlaxoSmithKline R&D China
- Jeffrey D. Hsi, Partner, Edwards Angell Palmer & Dodge, LLP
- Joseph P. Taormino, Ph.D., Partner, Co-leader of Biotech Group, Hoffman Eitle
- Yang Xu, PhD, JD, Chief Patent Counsel, Simcere Pharmaceuticals

3) Encouraging Innovation through Robust Patent Enforcement

A panel of experts will explore how enforcement of IP can support the goals of the 12th Five-Year plan in a competitive global economy. The panel will explore the challenges to enforcement in face of limited resources and will compare and contrast enforcement in the US and China.

Moderator:
- Frank S. DiGiglio, Managing Partner, Scully Scott Murphy & Presser PC

Panelists:
- Brian P. Barrett, R.Ph., JD, Senior Director, Assistant General Patent Counsel, Eli Lilly
- David Shen, Regional Legal Counsel, AstraZeneca

Health & Regulatory Issues Panels
1) Navigating Changes in China's Registration & Regulatory Process

To successfully introduce a new product in China requires in-depth knowledge of Chinese regulatory requirements. At the same time, sponsors are increasingly looking to conduct trials simultaneously in multiple countries, putting a premium on a regulatory system that has strong standards that are similar among countries. How are changes in China's regulatory structure supporting increased innovation? How is the SFDA operating in a manner to foster both more rapid drug development to improve public health and internationally simultaneous trials? Are there constraints that make changes to the registration and regulatory process more difficult to achieve? In this session, experienced representatives from multi-national and local Chinese companies will discuss the registration process for products manufactured in China, import licensing issues for products exported to China, and the connotations of these processes for innovative global drug development.

Moderator:
- Romi Singh, Executive Director, Regulatory Affairs, Amgen, Inc.

Panelists:
- He Bai, Official, Drug Registration Department, SFDA
2) **A Bold Initiative to Support Biotechnology - China's 12th 5 Year Plan**

China’s recently announced 12th 5-Year Plan provides considerable support for biotechnology innovation. This plan, which aims to support both the development and manufacture of new biotechnology products, holds substantial promise to elevate China’s position and leadership in the industry. What does the government support for biotechnology portend for the sector? What are the various forms of support that will be created? Which are the areas of greatest need? This panel will discuss key aspects of China’s new initiative to support biotechnology.

**Moderator:**
- Richard Davies, Vice President & General Manager, Japan & Asia Pacific, Amgen, Inc.

**Panelists:**
- George Baeder, Vice President, Monitor Group Asia
- Samantha Du, PhD, Chief Executive Officer, Hutchinson Medipharma
- Kewen Jin, PhD - General Manager, Charles River Greater China
- Song Ruilin, Executive President, SINO-PhIRDA

3) **Challenges and Opportunities for Clinical Development in China**

China is broadening its clinical trials infrastructure and improving safety, presenting new, innovative opportunities for clinical R&D. In this session, seasoned representatives from major CROs and drug development companies will discuss their experiences in China in key areas such as site selection, IRB approval processes, and content requirements to initiate trials in China. Experts in designing clinical studies conducted in China will address their experiences with the use of clinical data in China, and talk about what conducting studies in China means in terms of global development.

**Moderator:**
- Joanne Jiang, PhD, MBA, Co-Founder, VP, Business Development and Project Management, Fountain Medical Development

**Panelists:**
- Nathaniel Brown, MD, Chief Medical Officer and SVP, Clinical Development, Presidio Pharmaceuticals
- John Z. Gong, PhD, MD, SVP and Chief Technology Officer, JOINN Laboratories
- Bing Yan, MD, MBA, Head of Clinical Development Asia & China Vaccines Lead, Emerging Markets, Pfizer, Inc.

4) **Balancing Biosimilar Expansion and Innovation - China's Regulatory Landscape for Large Molecules**

China’s expansion and improvement of health coverage for its population through health reform has considerable implications for the biosimilars market. Numerous Chinese companies are in this market segment, as are an increasing number of western companies. Likewise, China is taking dramatic steps to support the development of innovative molecules. How does China’s regulatory system balance the development of both an expanding biosimilars segment along with innovative biotech development? What are key differences between the US, EU, and Chinese approaches? What are key global regulatory and market trends that impact biosimilars development? The regulation of both innovator and follow-on biotechnology products in the US, Europe, and China will be discussed by leading experts.

**Moderator:**
- Shaoyu Chen, Managing Director, China Food & Drug Practice, Covington & Burling LLP

**Panelists:**
- John Z. Gong, PhD, MD, SVP and Chief Technology Officer, JOINN Laboratories
Vaccines & Global Health Panels

1) Innovations in Prevention & Treatment: Global Trends in Vaccine Platform Development

This session will highlight global advances in technologies for new vaccines. Advances in recombinant, cellular and protein sciences as well as the availability of adjuvants may allow for significant improvements in vaccine technology. These advances should lead to both new and improved preventive vaccines through their ability to elicit broad antigenic responses and streamline manufacturing techniques. In addition, they may lead to the development of therapeutic vaccines to treat complex immune diseases such as cancer, Alzheimer’s and other chronic conditions. Companies will present scientific and clinical data and discuss their approaches to and uses for these new platforms.

Moderator:
- Phyllis Arthur, Senior Director, Vaccines, Immunotherapies and Diagnostics Policy, Biotechnology Industry Organization

Panelists:
- Stephen W. Cook, PhD, Vice President, Head of Worldwide Vaccine Registration Management & Regulatory Operations, GlaxoSmithKline Biologicals
- Stanley C. Erck, President & CEO, Novavax, Inc.
- Peter Khoury, Vice President, Global Marketing, Baxter International
- Jueren Lou, Director of Technology, Shanghai Biological Product Research Institute
- Dr. Jean-Denis Shu, Medical Director, Sanofi Pasteur China

2) Health Reform Implementation in China: Attaining New Levels of Prevention through Public-Private Partnerships

New government investments in urban health care reforms present an important opportunity to increase immunization rates across all ages. Local and multi-national vaccine developers, working with government entities and non-governmental organizations, are collaborating on new vaccines to conquer emerging infectious diseases. Panelists will share new developments in vaccines targeted to children, adolescents and adults for both rural and urban areas. Panelists will discuss their strategies, successes and challenges in their attempts to build productive relationships with their various partners. Opportunities for contract research and manufacturing, technology transfer and other partnering options will be evaluated and discussed as well as the role of government.

Moderator:
- James McGregor, Senior Counselor, APCO Worldwide, China

Panelists:
- Sam Liao, Asia Head of Business Development & Licensing, Novartis Vaccines & Diagnostics, Inc.
- Michel Younatsos, Senior VP & Head of MSD, China, Merck Sharp & Dohme
- Bing Yan, Senior Regional Medical Director, Pfizer, Inc.