



## PRELIMINARY AGENDA

### SUNDAY, NOVEMBER 7, 2010

1:00PM - 2:00PM

#### Workshop Registration & Early Conference Registration

2:00PM - 5:00PM

#### WORKSHOP #1

##### From Intention to Execution: A Step-by-Step Case Study Taking an International Company to its First Clinical Operation in China

- Overview of Chinese healthcare and clinical trial system
- Development Strategy Design- expert panel evaluates the available development options for the case product based on in-depth analysis of its relevant regulatory, clinical and market considerations, and recommend a course of action
- Starting Your China Operations: An overview of China CRO industry and CRO selection options, plus an expert panel discussing the pros/cons of using the CRO resources vs. building a China operation from scratch

##### workshop leader:

Chloe Liu, Ph.D., *Managing Partner*

MODULAR R&D

#### WORKSHOP #2

##### Clinical Data Management in China & North Asia

##### workshop leader:

Samir Shah, M.D., *Vice President, Global Strategic Development*

RPS

5:00PM - 7:00PM

#### WORKSHOP #3

##### What Can Be Learned For China GCP-Based Training From FDA Warning Letters?

- A close look and analysis of what GCP rules that were violated?
- Focus on investigator/physician responsibilities

##### workshop leader:

Fidela Moreno, M.D., *Vice President, Global Development Operations*

ALLERGAN

#### WORKSHOP #4

##### Development Considerations for Non-Inferiority Studies

##### workshop leaders:

Ning Li, M.D., Ph.D., *Senior Group Director, Regulatory & Medical Policy*  
SANOFI-AVENTIS CHINA (INVITED)

Simon Li, M.D., Ph.D., *Global Clinical Leader, PC*  
BAYER HEALTHCARE

William Wang, Ph.D., *Head, Asia Pacific Op., Biostats & Research Decision Sciences*  
MERCK & CO.



## PRELIMINARY AGENDA

7:00PM - 8:30PM

### Welcome to Beijing Reception

## MONDAY, NOVEMBER 8, 2010

7:00AM - 8:00AM

### Registration, Breakfast & Exhibits

8:00AM - 8:05AM

### Chairpersons' Opening Remarks

8:05AM - 9:35AM

### The Green Channel: How Can the Pharmaceutical Industry Partner with the SFDA to Speed Up Development Cycle Times?

In January 2009, the SFDA introduced the Green Channel, a process for expedited review of clinical trial applications and new drug applications. How does the Green Channel work and what makes a drug eligible? What has been the experience of SFDA to date? How does FDA see the future for this process? What has been the experience of the sponsor of this process? At this session, you will hear from senior management at SFDA of their experience and perspective of the Green Channel as well as sponsors, both MNC and local pharma.

#### session leaders:

**Ning Li, M.D., Ph.D.**, Senior Group Director, Regulatory & Medical Policy  
SANOFI-AVENTIS CHINA

**Bradley Marchant, M.D.**, Head, Clinical Medicine- Asia  
PFIZER CHINA R&D CENTER

**Laurence Huang, M.D.**, Regulatory Affairs Director  
ASTRAZENECA

#### ■ Keynote Presentation: Regulatory Perspective

STATE FOOD & DRUG ADMINISTRATION (INVITED)

#### ■ Health Authority Perspective

#### ■ Multinational Perspective

**Laurence Huang, M.D.**, Regulatory Affairs Director  
ASTRAZENECA

#### ■ Local Pharma Perspective

#### ■ Panel Discussion with Audience Interaction

9:35AM - 10:10AM

### The Future of Targeted Therapy in Oncology Drug Development

**Mace Rothenberg, M.D.**, Senior Vice President, Clinical Development & Medical Affairs  
PFIZER ONCOLOGY



## PRELIMINARY AGENDA

10:40AM - 11:10AM

### Networking Exhibition Break

10:40AM - 11:40AM

### How Has Big Pharma's China/Asia Clinical Development Strategies Evolved from their Original Vision in the Past Few Years? What Has Been Learned?

At the inaugural ChinaTrials meeting in 2008, much of the discussion centered around opinions from big pharma's China development leaders on how the clinical industry in China would evolve in the coming years. Looking back, has China's clinical development industry evolved as expected? How has big pharma's strategy changed in the past few years based on a rapidly evolving industry in China? What lessons have been learned and do these lessons allow us to better predict how the industry will evolve in the next few years?

#### moderator:

**Frank Jiang, M.D., Ph.D.**, *Vice President, Global R&D, Head, China R&D*  
SANOFI-AVENTIS CHINA (INVITED)

#### panelists:

**Ole Molskov Bech**, *Vice President, Clinical & Medical*  
NOVO NORDISK

**Min Irwin, M.D., Ph.D.**, *Medical Director of BSP*  
BAYER HEALTHCARE

**Ling Su, Ph.D.**, *Senior Vice President, Head of Development China*  
NOVARTIS (INVITED)

**Frank Shen, Ph.D.**, *Asia Pacific Head of GPD Biometrics*  
ROCHE GLOBAL PRODUCTS DEVELOPMENT IN ASIA PACIFIC (INVITED)

11:40AM - 12:30PM

### The Increasing Regulatory Scrutiny of Global Clinical Trials By Regulatory Agencies: What Lies Ahead?

#### moderator:

**Samir Shah**, *Vice President, Global Strategic Development*  
RPS

12:40PM - 1:45PM

### Expert Luncheon

## TRACK A: CONDUCTING CLINICAL TRIALS IN THE USA BY CHINESE COMPANIES

1:45PM - 1:50PM

### Chairpersons' Opening Remarks

**Dan Zhang, M.D.**, *Chief Executive Officer*  
FOUNTAIN MEDICAL DEVELOPMENT



## PRELIMINARY AGENDA

1:50PM - 2:50PM

### **The Opportunities & Challenges For Chinese Companies Looking to Conduct Clinical Trials For Western Approvals**

**Dan Zhang, M.D., Chief Executive Officer**  
**FOUNTAIN MEDICAL DEVELOPMENT**

2:50PM - 3:25PM

### **Case Study: A Phase I Herbal Trial in US for Oncology**

**KANGLITE PHARMACEUTICALS (INVITED)**

3:15PM - 3:45PM

### **Mid-Afternoon Networking Break & Exhibits**

3:45PM - 4:10PM

### **Case Study: A Phase II Herbal Trial in US for Cardiovascular Indication**

**TIANJIN TIAN-SHI-LI PHARMA (INVITED)**

4:10PM - 4:35PM

### **Case Study: A Phase II Oncology Study**

**HUTCHISON MEDIPHARMA (INVITED)**

4:35PM - 5:00PM

### **Case Study: Bioequivalence Study in USA to Support An ANDA Application in USA**

**SIMCERE PHARMACEUTICAL (INVITED)**

5:00PM - 5:30PM

### **Open Discussion Between Panelists & Audience**

5:30PM

### **End of Track A & Day One**

## TRACK B: "PEOPLE" IN CLINICAL RESEARCH IN CHINA

1:45PM - 1:50PM

### **Chairperson's Opening Remarks**

**James Cai, Ph.D., Vice President, Clinical Development**  
**ATYR PHARMA**

1:50PM - 2:15PM

### **A Highly Attractive Talent Market – General Clinical Functions vs. Biostatistics**

Shortage of talent, high turn over rate, high expectation of the salary increase. Has your firm experienced these problems? As clinical departments keeps growing, many challenges have emerged in hiring and maintaining valuable employees. Are you prepared to face this competitive talent market? My presentation will help you think with a different perspective.



## PRELIMINARY AGENDA

**Catherine Qin**, *Consultant- Pharmaceutical Division*  
**THE MRI CHINA GROUP**

2:15PM - 3:00PM

### **Hiring, Managing & Retaining Top Clinical Talent in China: From Management's Perspective**

With regards to the challenges of clinical operations in China, much discussion is focused around the fast-changing regulatory environment. However, one of the key challenges that is currently affecting the industry is the market is so hot it seems impossible to keep the turnover rate below 10% within any company. Management teams are always asking, "What can we do to keep our people? It is already so hard to find any qualified talent." To answer this question, we should deeper into the motivations of know they are leaving. This panel will include panelists from top managers in China's life sciences industry to help us more fully understand these issues.

#### **PANELISTS:**

**James Cai, Ph.D.**, *Vice President, Clinical Development*

**ATYR PHARMA**

**Jennifer Jin**, *Executive Director, Human Resources*

**BEIJING NOVARTIS PHARMA**

**Min Irwin, M.D., Ph.D.**, *Medical Director of BSP*

**BAYER HEALTHCARE**

3:00PM - 3:30PM

### **Mid-Afternoon Networking Break & Exhibits**

3:30PM - 4:20PM

### **Hiring Biostatisticians in China: How Do The Different Characteristics Of Statisticians In China Reflect The Unique Business Environment?**

- Challenges in hiring the right people
- Comparison of roles of biostatisticians and understanding of GSP (Good Statistical Practices)
- Developing the 3 inter-dependent biometrics professions (biostatisticians, scientific programmers and database managers)

#### **MODERATOR:**

**William Wang, Ph.D.**, *Head, Asia Pacific Operation, Biostatistics & Research Decision Sciences*

**MERCK & CO.**

#### **PANELISTS:**

**Catherine Qin**, *Consultant- Pharmaceutical Division*

**THE MRI CHINA GROUP**

**Frank Shen, Ph.D.**, *Asia Pacific Head of GPD Biometrics*

**ROCHE GLOBAL PRODUCTS DEVELOPMENT IN ASIA PACIFIC (Invited)**



## PRELIMINARY AGENDA

### DATA MANAGEMENT & ELECTRONIC DATA CAPTURE IN CHINA

4:20PM - 5:15PM

#### Creating Global Standards For Clinical Data Interchange: CDISC'S China Initiative

MODERATOR:

**Claire Tan**, *Senior Director, Biostatistics*

QUINTILES

PANELISTS:

**Danny Hu**, *General Manager*

**REAL DATA MEDICAL RESEARCH (invited)**

**Ding Li**, *Clinical Data Management Site Director*

**SANOFI-AVENTIS CHINA**

**Shawn Wang**, *President & CEO*

**MEDXVIEW (invited)**

**Simon Wang**, *Manager*

**PAREXEL**

5:45PM

**End of Track B & Day One**

### TRACK C: ONCOLOGY CLINICAL DEVELOPMENT IN CHINA I

1:45PM - 1:50PM

#### Session Chairpersons' Opening Remarks

**Kenneth J. Pienta, M.D.**, *Director, Michigan Institute for Clinical & Health Research*

UNIVERSITY OF MICHIGAN SCHOOL OF MEDICINE

**Li Yan, M.D., Ph.D.**, *Director, Clinical Oncology,*

MERCK & CO.

*Managing Director, US CHINESE ANTI-CANCER ASSOCIATION (USCACA)*



## PRELIMINARY AGENDA

### ● EVOLVING EARLY PHASE ONCOLOGY CLINICAL TRIALS IN THE ERA OF MOLECULAR TARGETED DRUGS ●

1:50PM - 2:20PM

#### **Population-Based Design of Phase I Trials for Anticancer Drugs**

**Derick Lau, M.D., Ph.D.**, *Professor, Division of Hematology/Oncology*  
UNIVERSITY OF CALIFORNIA AT DAVIS- SCHOOL OF MEDICINE

2:20PM - 2:50PM

#### **Aspects of Early Clinical Trials Including Design & Biomarker Issues**

**Helen Chen, M.D.**, *Associate Chief & Senior Investigator- Investigational Drug Branch*  
NATIONAL CANCER INSTITUTE (INVITED)

2:50PM - 3:20PM

#### **Molecular Epidemiology in Oncology Drug Development**

**Wei Zhou, Ph.D.**, *Director, Molecular Epidemiology*  
PFIZER ONCOLOGY

3:20PM - 3:50PM

#### **Mid-Afternoon Networking Break & Exhibits**

### ● BIOMARKERS & TRANSLATIONAL MEDICINE IN EARLY PHASE ONCOLOGY DRUG DEVELOPMENT ●

3:20PM - 3:50PM

#### **Translating Biomarkers from Theory to Practice**

**Pearl Huang, Ph.D.**, *Vice President, Oncology Franchise Integrator*  
MERCK & CO.

3:50PM - 4:10PM

#### **Biomarker and Personalized Medicine in Early Phase Trials in China**

**Jason Jin, M.D., Ph.D.**, *Chief Executive Officer*  
SHANGHAI BIOCHIP CORPORATION

4:10PM - 5:00PM

#### **Open Discussion Between Session Speakers & Audience**

5:30PM

#### **End of Track C & Day One**



## PRELIMINARY AGENDA

**TUESDAY, NOVEMBER 9, 2010**

**TRACK A: CHINA DEVELOPMENT STRATEGIES FOR REGIONAL & GLOBAL DEVELOPMENT**

7:00AM - 8:00AM

**Registration, Breakfast & Exhibits**

8:00AM - 8:15AM

**Chairperson's Opening Remarks for Morning Session**

**Ruiping Dong, M.D., Ph.D.**, *Vice President, Head of R&D, Japan & China*  
BRISTOL-MYERS SQUIBB

8:10AM - 8:40AM

**New Initiatives of Japan/China/Korea Harmonization in Drug Development**

8:40AM - 9:10AM

**Introduction on Regulatory Review & Approval Process in Korea**

**Speaker TBA**  
KFDA

9:10AM - 9:40AM

**Cooperation of Taiwan and Asian Clinical Trials: From the Aspect of Taiwan**

- The involving regulatory infrastructure in Taiwan
- Competitiveness of regulatory infrastructure for clinical trial in Taiwan
- Bridging evaluation in Taiwan

**Li-Jiuan Hsu, M.D.**, *Division Director of Clinical Medicine*  
CENTER FOR DRUG EVALUATION- TAIWAN

9:40AM - 10:10AM

**Mid-Morning Networking Break & Exhibits**

10:10AM - 10:40AM

**Productivity Innovation: How To Secure The Synergistic Effect In The Pan-Asian Framework Of New Clinical Development**

**Hiroshi Sugii.**, *Vice President, Development Division/Director, Clinical Development Department*  
NOVO NORDISK JAPAN



## PRELIMINARY AGENDA

10:40AM - 12:10PM

### North Asia Simultaneous Drug Development Strategies

- Chinese-Japanese partnerships
- Acceptability of clinical trials data between Japan, China, Korea & Taiwan
- Navigating the regulatory differences between Asia-Pacific trials

MODERATOR:

**Ruiping Dong, M.D., Ph.D.**, *Vice President, Global Development & Medical Affairs*  
BRISTOL-MYERS SQUIBB

12:10PM - 1:10PM

### Networking Lunch

1:10PM - 1:15PM

### Chairperson's Opening Remarks for Afternoon Session

**Simon Li, M.D., Ph.D.**, *Global Clinical Leader*  
BAYER GLOBAL R&D CENTER

1:15PM - 1:45PM

### Regulatory Perspective on International Multicenter Clinical Trials (IMCT) for Category III Drugs

**Speaker TBA**  
CENTER FOR DRUG EVALUATION, SFDA

1:45PM - 2:15PM

### Conducting IMCT Studies for Registration of Category III Drugs in China & AP Countries

This talk will cover the key factors when planning for IMCTs, such as whether significant results in Chinese patients are needed for approval, when the CTA could be submitted to save time, how to define the reference country, etc. The talk will also discuss the factors to be considered when selecting 2 more countries in AP areas in order to ensure the approval in those countries with the IMCT data.

**Simon Li, M.D., Ph.D.**, *Global Clinical Leader*  
BAYER GLOBAL R&D CENTER

2:15PM-2:45PM

### Multinational Clinical Trials in Asia: Perspective of a Head of Medical Division of a Japanese Firm in Korea

Nowadays, Asian countries are contributing a lot to global drug development by participating in global clinical trials. According to the data in the [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) database (Oct 2005 to Sep 2007), Asia is involved in more sponsored trials than any other emerging region with 18.1%\* of all protocols globally. So, it is meaningful to observe some clinical trial environment in Asia and in addition, to introduce infrastructure of clinical trial in Korea which is one of the most active locations in Asia.

**Hyunju Yang**, *Director of Medical Division*  
DAIICHI SANKYO KOREA

2:45PM - 3:05PM

### Mid-Afternoon Short Break



## PRELIMINARY AGENDA

3:05PM - 3:35PM

### What Are the Challenges the CRO Industry is Facing When Conducting Multinational Clinical Trials in Asia Pacific?

3:35PM - 4:05PM

### Working With CROs to Conduct Multinational Clinical Trials in Asia Pacific

4:30PM

### Track A & Conference Concludes

## TRACK B: INNOVATION IN DEVELOPING OTC PRODUCTS

7:00AM - 8:00AM

### Registration & Breakfast

8:00AM - 8:10AM

### Chairpersons' Opening Remarks

**Qing Li, M.D., Ph.D.**, *Director, Global Medical Affairs & Clinical Research*  
JOHNSON & JOHNSON

8:10AM - 8:40AM

### Regulations of OTC Products in China

8:40AM - 9:10AM

### Regulation of OTC Products in the US

**John Zhuang, Ph.D.**, *Director of Global Regulatory Affairs*  
JOHNSON & JOHNSON

9:10AM - 9:40AM

### Understanding the Customers: From Consumer Insights to Innovative Products

Traditional areas for the use of OTC medicines include the treatment of mild to moderate pain, symptoms of the common cold, hay fever, heartburn, diarrhea, constipation, hemorrhoids, gingivitis, eczema, acne, as well as caries and sunburn prevention. New indications for which OTC medicines have been approved in the U.S. in recent years include smoking cessation, emergency contraception, and weight management. Outside the U.S., in particular in the United Kingdom, several medicines were "switched" from prescription only (Rx) to OTC in further new self-medication areas such as cholesterol lowering, bacterial conjunctivitis, lower urinary tract infections, and benign prostatic hyperplasia. The purpose of this presentation is to examine the data supporting and the factors driving the important role of OTC medicines in the U.S. healthcare system and the consumer benefits these products provide from a medical, convenience, economic, and unmet consumer need perspective. Ultimately, an innovative OTC product should meet the needs of consumer self care, provide unique "at hand" benefits, help to decrease Rx treatment gaps, be more convenient to maintain a good health, and eventually, lead to a happier life.

**Ding Ming, M.D., Ph.D.**, *Senior Director, CHC Medicine*  
BOEHRINGER-INGELHEIM



## PRELIMINARY AGENDA

9:40AM- 10:10AM

### Mid-Morning Networking Break & Exhibits

10:10AM - 10:40AM

#### Rx-to-OTC Switch Strategies

"Rx-to-OTC Switch" encompasses a multitude of clinical, regulatory, and behavioral issues. Every switch is different in each market; however there are common themes that drive switch strategies globally. This presentation will highlight several of these themes and the ways in which sponsors have tried to implement these strategies.

**Sandy Furey, M.D., Ph.D.,** *Vice President*

**PFIZER CONSUMER HEALTHCARE**

10:40AM - 11:10AM

#### Creating a World-Class Innovative Culture to Drive Growth

The session will examine the steps taken by GlaxoSmithKline management to turn-around an organization that delivered less than average industry growth. Specifically, in 2006, GlaxoSmithKline Consumer Healthcare moved to a new R&D and Business operating model to drive growth and business sustainability. This new model involved refreshing the Leadership, significant changes in the physical space which allow high levels of collaboration across the organization, a move to a global marketing model called "Future Teams" and the creation of an Open Innovation model to source breakthrough innovation. As a result, GlaxoSmithKline Consumer Healthcare has been recognized as a world leader in product innovation with its #1 innovation rating by UBS in 2009 and numerous awards for product innovation. Since implementing the new model, GlaxoSmithKline has been a consistent leader in sales growth within the consumer healthcare segment.

**Yan-Yan Starkey, M.D.,** *Medical Director- Global Medical Affairs*

**GLAXOSMITHKLINE CONSUMER HEALTHCARE**

11:10AM - 11:40AM

#### OTC Traditional Chinese Medicine: Evaluating Safety & Efficacy

Traditional Chinese Medicine (TCM) products represent about half of the OTC market in China. TCM has a long history of use and is widely accepted and believed by consumers in China and surrounding Asian countries. Comprehensive literature reviews, however, reveal limited evidence of efficacy and safety, i.e., results from double-blind, placebo-controlled studies. Generation of high quality clinical data of TCM is key for its modernization and acceptance in US and European markets.

**Qing Li, M.D., Ph.D.,** *Director, Global Medical Affairs & Clinical Research*

**JOHNSON & JOHNSON**

11:40AM - 12:10PM

#### What Are the Opportunities for Growth Within the China OTC Market?

- Perceived Mega-Trend areas within China
- Relative attractiveness and acceptance of OTC Switches, Western Branded Products, Medical Devices and TCM's
- Current Consumer habits, attitudes and challenges with self-medication
- Consumer and Professional perception of Branded vs. Generics products
- Key Challenges/Barriers to success

**MODERATOR:**

**Stanley Lech, B.S. Chem, MBA,** *Vice President of Venture Group & Strategic Relationships*

**GLAXOSMITHKLINE CONSUMER HEALTHCARE**

**PANELISTS:**

**Sandy Furey, M.D., Ph.D.,** *Vice President*

**PFIZER CONSUMER HEALTHCARE**

**Qing Li, M.D., Ph.D.,** *Director, Global Medical Affairs & Clinical Research*

**JOHNSON & JOHNSON**



## PRELIMINARY AGENDA

**Ding Ming, Ph.D.**, *Senior Director, CHC Medicine*  
BOEHRINGER INGELHEIM

**Yan-Yan Starkey, M.D.**, *Medical Director- Global Medical Affairs*  
GLAXOSMITHKLINE CONSUMER HEALTHCARE

**John Zhuang, Ph.D.**, *Director of Global Regulatory Affairs*  
JOHNSON & JOHNSON

12:10PM - 1:10PM

### Networking Lunch

## CLINICAL SAFETY ASSESSMENT IN CHINA

1:10PM - 1:55PM

### Clinical Safety Assessment & Risk Management During New Drug Development in China

Clinical safety is essential for a successful new drug which is determined based on its favorable benefit-risk profile. Good clinical safety depends on appropriate clinical trial design and monitoring to learn the safety risks of a new drug, timely decision to address safety issues, and best strategy to manage the identified risks. In this session, some key aspects of clinical safety during new drug development, particularly pertinent to clinical research practices in China, will be discussed, such as:

- Appropriate trial design to maximize the learning of safety risks
- Targeted and sensible collection of clinical safety data
- Effective monitoring and analysis of safety data
- Prompt decisions to protect subjects and to protect the development program
- Use of Data Safety Monitoring Board (DSMB) to enhance safety assessment and decision making
- Optimal risk management plan as a critical part of new drug applications

#### MODERATOR:

**Songlin Xue, M.D., Ph.D.**, *Senior Vice President & Global Head of Pharmacovigilance*  
TAKEDA PHARMACEUTICALS

#### PANELISTS:

**Connie Mo**

PFIZER CHINA R&D CENTER (INVITED)

**Yuan Meng**

BRISTOL-MYERS SQUIBB (INVITED)

1:55PM - 2:20PM

### Using Appropriate Processes and Technologies to Guarantee Patient Safety and High Quality Clinical Trials

Good clinical safety depends on appropriate clinical trial design and monitoring to learn the safety risks of a new drug, timely decision to address safety issues, and best strategy to manage the identified risks. In addition to addressing local safety concerns, global drug development requires adherence to some international standards. This session will discuss the need to appropriately balance these concerns as well as demonstrating some practical methods.

**Jonathan Seltzer, M.D., MBA, FACC**, *President*  
APPLIED CLINICAL INTELLIGENCE



## PRELIMINARY AGENDA

2:20PM - 2:45PM

### **Globalization and Global Outsourcing - Consideration of the Human Factor**

**Kon K. Fung, Ph.D.**, *Senior Director, Biometrics & Clinical Data Systems*  
JOHNSON & JOHNSON CONSUMER HEALTHCARE

2:45PM - 3:05PM

### **Mid-Afternoon Short Break**

## MEDICAL DEVICE & IVD TRIALS IN CHINA

3:05PM - 3:45PM

### **A Broad Outline Of Clinical Trials For Medical Devices And IVD In China**

- When are clinical trials required in China?
- Key regulations and considerations
- Pitfalls and success factors

**Janice Ma**, *Managing Director*  
CHINAGATE

3:45PM - 4:10PM

### **In-Vitro Diagnostics (IVDs) Clinical Studies & Registration in China: Roche's Experiences**

- Opportunities and challenges in China
- Critical considerations and relevant regulations/guidance
- Practical issues: minimizing risks, lowering costs, improving speed for product registration

**Vicky Tao, M.D.**, *Director, Medical Regulatory Affairs*  
ROCHE DIAGNOSTICS SHANGHAI

4:10PM-4:30PM

### **Medical Devices Clinical Studies & Registration in China: J&J's Experiences**

**Vivian Li, M.D.**, *Medical Director*  
JOHNSON & JOHNSON

4:30PM

### **Track B & Conference Concludes**

## TRACK C: ONCOLOGY CLINICAL DEVELOPMENT IN CHINA II

7:00AM - 8:00AM

### **Registration & Breakfast**



## PRELIMINARY AGENDA

8:00AM - 8:10AM

### Chairpersons' Opening Remarks

**Kenneth J. Pienta, M.D.**, *Director, Michigan Institute for Clinical & Health Research*  
UNIVERSITY OF MICHIGAN SCHOOL OF MEDICINE

**Li Yan, M.D., Ph.D.**

*Director, Clinical Oncology, MERCK & CO.*

*Managing Director, US CHINESE ANTI-CANCER ASSOCIATION (USCACA)*

## CURRENT STATE OF ONCOLOGY TRIALS IN CHINA:

### PERSPECTIVES FROM INVESTIGATORS, REGULATORY AGENCY, SPONSORS & CROs

8:10AM - 8:40AM

#### SFDA Regulatory View On Oncology Development In China

8:40AM - 9:10AM

#### Expedited SFDA Review: Approval of Phase I First-in-Human Oncology Clinical Trial Permit

**Tom Tang, M.D., Ph.D.**, *Vice President, Clinical & Regulatory Affairs*  
HUTCHISON MEDIPHARMA

9:10AM - 9:40AM

#### Early Clinical Development for Oncology Drugs- Experiences and Lessons

**Bin Peng, M.D., Ph.D.**, *Senior Director, Head of Oncology Translational Medicine China*  
NOVARTIS

9:40AM - 10:10AM

#### Mid-Morning Networking Break & Exhibits

11:10AM - 12:10PM

#### Challenges & Opportunities for Early Stage Oncology Drug Development in China

- How can China transform from a service provider in global oncology development into an innovative anti-cancer drug R&D hub?
- How can China transform cancer hospitals and cancer centers from global trial participants to leaders & initiators?
- How can China transform from merely a global trial patient recruitment center to a strategically critical country for oncology compound development?
- Global development and regulatory strategies to develop anti-cancer drugs in China for prevalent cancer types to expedite global compound development

MODERATOR:

**Li Yan, M.D., Ph.D.**

*Director, Clinical Oncology, MERCK & CO.*

*Managing Director, US CHINESE ANTI-CANCER ASSOCIATION (USCACA)*



## PRELIMINARY AGENDA

### PANELISTS:

**Tom Tang, M.D., Ph.D.**, *Vice President, Clinical & Regulatory Affairs*  
HUTCHISON MEDIPHARMA

**Peng Wang, Ph.D.**, *Chief Scientific Officer*  
SIMCERE PHARMACEUTICAL GROUP

12:10PM - 1:10PM

### Networking Lunch

## OTHER THERAPEUTIC AREAS FOR CLINICAL TRIALS IN CHINA & ASIA

1:10PM - 1:40PM

### Primary Endpoints and Sensitivity of the CNS Trials in China

Clinical pivotal trial in CNS has highest failure rate in drug development. The major factors resulting in such high failure rate include quality patient selection for the study, lacking of reliable biomarkers, and subjective primary endpoints. The presentation is intended to describe the current progress and personal experience on how to overcome the variations and increase the sensitivity of the trial, therefore, to maximize the probability of success.

**Yan-Ping Zheng, M.D.**, *Senior Director, Global Clinical Development*  
OTSUKA PHARMACEUTICAL

1:40PM - 2:10PM

### Opportunities & Challenges in Conducting Ophthalmology Clinical Studies in China & Asia: A Sponsor's Perspective

**Esther Chu**, *Director, Global Clinical Operations-Asia Pacific*  
BAUSCH & LOMB

2:20PM - 2:40PM

### Opportunities & Challenges for Biologic Clinical Trials in China

This presentation will present a case study of a biologic clinical trial in China. It will cover regulatory strategy, Phase III clinical protocol design, patient selection criteria, site selection, investigator training, and other logistic issues etc. Considerations in respect to biologic compound development in China will be discussed.

**Michael Song, M.D.**, *Medical Director, Immunology*  
CENTOCOR R&D

2:40PM - 3:00PM

### Mid-Afternoon Short Break



## PRELIMINARY AGENDA

### ● IMPROVING CLINICAL OPERATIONS IN CHINA ●

3:00PM - 3:30PM

#### **Patient Recruitment & Retention in China & East Asia Clinical Trials**

A sponsor's ability to identify, recruit and retain patients over the course of the clinical trial is a critical factor in successful drug development. Balancing the complexities of planning and conducting trials across multiple countries with varying regulatory, ethical, scientific and cultural requirements, especially in the Asia Pacific region, presents significant challenges. In this presentation, the speaker will share thoughts on:

- Impact of clinical trial globalization on patient recruitment
- Competition for study participants, availability of experienced investigators, GCP-focused training and other challenges
- Changing regulatory requirements that increase trial complexity and accessibility
- Recruitment enhancement tactics
- Creating and implementing a Patient Recruitment, Retention and Contingency Plan

4:30PM

#### **Track C & Conference Concludes**