INTERNATIONAL CONFERENCE ON DRUG DEVELOPMENT

THE UNIVERSITY OF TEXAS AT AUSTIN COLLEGE OF PHARMACY • AUSTIN • TEXAS

TRANSFORMATION OF DRUG DEVELOPMENT – CHALLENGES AND OPPORTUNITIES

ADVANCING INNOVATIVE SOLUTIONS TO MEET PATIENT'S MEDICAL NEEDS OF SERIOUS CONDITIONS AND RARE DISEASES

MONDAY, 24TH OF FEBRUARY 2014

12:00 – 1:30	**LUNCH**	*Hill Country Dinning Room*
2:15 - 3:00	**Welcome and Opening Remarks** **Salomon Stavchansky, Ph.D.** ICD2 Conference Scientific Chair Alcon Centennial Professor of Pharmaceutics The University of Texas at Austin College of Pharmacy	*All presentations located in the Forum*
3:00 – 3:45	**FDA/CDER Update: Improving Drug Access to Patients Expediting Drug Development – Risks and Rewards** **Janet Woodcock, M.D.** Director • Center for Drug Evaluation & Research FDA	**Moderator:** **Joseph Lamendola, Ph.D.** Vice President Global Regulatory Sciences, US and Regulatory Policy Bristol-Myers Squibb Company

ROUND TABLE SESSIONS: Transforming and Expediting Drug Development

3:45 – 4:00	**FDA Challenges Expediting Drug Development – Scientific, Clinical and Regulatory Considerations of Breakthrough Therapies and Accelerated Approvals** **Janet Woodcock, M.D.** Director • Center for Drug Evaluation & Research FDA	
4:00 – 4:15	**Market Access and Innovative Industry Therapies** **Ray Sacchetti** Senior Vice President, US Virology & Transplant Bristol-Myers Squibb	
4:15 – 4:30	**Break**	
4:30 – 4:45	**Payers Perspective of Expediting Drug Development –Integrated Health Care Benefits to Accelerate Breakthrough Therapies to Patients. Innovative Partnerships for Better Clinical Outcomes and Care at a Lower Cost** **Tracy J. Mayne, Ph.D.** Vice President, Global Health Economics and Outcomes Research Covance	**Moderator:** **Linda S. Carter** Senior Advisor Greenleaf Health LLC
4:45 – 5:00	**Patient Perspective of Expediting Drug Development – Patient Role in Knowledge Generation** **J. Russell Teagarden, RPh., M.A.** Senior Vice President, Medical & Scientific Affairs National Organization for Rare Disorders (NORD)	
5:00 – 5:15	**Oncologist Perspective – Towards Patient Drug Development Better Communication of Risk, Benefit and Medical Evidence** **Ethan Basch, M.D.** Director, Cancer Outcomes Research Associate Professor Medicine and Public Health Lineberger Comprehensive Cancer Center University of North Carolina-Chapel Hill	
5:15 – 6:00	**ROUND TABLE DISCUSSION WITH AFTERNOON SPEAKERS** *joined by Isaam Zineh, PharmD of CDER, FDA*	**Moderator:** **Maria Rivas, M.D.** Vice President Global Medical Affairs, R & D Abbvie Pharmaceutical

6:00 – 6:15 **Dean's Welcome**

M. Lynn Crismon, Pharm.D., FCCP, BCCP
Dean
James T. Doluisio Regents Chair in Pharmacy Fellowship, Behrens Inc., Centennial Professor of Health Outcomes & Pharmacy Practice
The University of Texas at Austin College of Pharmacy

6:15 – 7:00 **WELCOME RECEPTION** *Patio Outside Canyon Dinning Room*

7:00 – 8:00 **DINNER** *Canyon Dinning Room*

The New University of Texas at Austin Medical School

Robert Messing, M.D.
Vice Provost, Biomedical Sciences
The University of Texas at Austin

Moderator:
Salomon Stavchansky, Ph.D.
ICD2 Conference Scientific Chair
Professor of Pharmaceutics
UT Austin College of Pharmacy

TUESDAY 25TH OF FEBRUARY 2014

7:30 – 8:30 **CONTINENTAL BREAKFAST** *Outside Forum*

8:30 – 9:15 **Expedited FDA Programs Initiatives — Drugs and Biologics Building the Science (Clinical and Non Clinical) to Expedite Drug Development**

Janet Woodcock, M.D.
Director • Center for Drug Evaluation & Research
FDA

Moderator:
Joanne Palmisano, M.D., FACP
Vice President
Drug Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals

ROUND TABLE SESSIONS: A Vision for Expedited Drug Development in the XXI Century

9:15 – 9:30 **Clinical Perspective – Innovation in the Design of Clinical Studies**

Donald A. Berry, Ph.D.
Professor, Department of Biostatistics
The University of Texas MD Anderson Cancer Center

9:30 – 9:45 **Pharmaceutical Industry Perspective - Innovation in Clinical Drug Development**

Paula Rinaldi
North America Head, Drug Regulatory Affairs
Novartis Pharmaceuticals

9:45 – 10:00 **Risks and Opportunities for Acceleration of Drug Development in Rare Diseases**

Carlo Russo, M.D.
Senior Vice President, Alternative Development Program Head
Alternative Discovery & Development Interim Head, Rare Disease Development
GlaxoSmithKline

Moderator:
Lisa A. Shipley, Ph.D.
Vice President & Global Head
Pharmacokinetics Pharmacodynamics & Drug Metabolism
Merck & Co., Inc.

10:00 – 10:30 **Break**

10:30 – 10:45 **BIO Perspective - Innovation in Clinical Safety and Effectiveness**

Amy Waterhouse
Senior Advisor
Development Sciences
BioMarin

10:45 – 11:00 **Expediting Drug Development: Integrating Knowledge, Enabling Decisions and Submissions**

Sandy Allerheiligen, Ph.D.
Vice President Quantitative Pharmacology and Pharmacometrics
Merck Research Laboratories

11:00 – 12:00 **ROUND TABLE DISCUSSION WITH MORNING SPEAKERS**
joined by Janet Woodcock, MD, FDA/CDER

Moderator:
Jonathan Seltzer, M.D., MBA, MA, FACC
President
ACI Clinical
Director of Clinical Research
Lankenau Heart Institute

12:00 – 1:30 **LUNCH** *Hill Country Dinning Room*

ROUND TABLE SESSIONS: Finding Solutions to Quality and Safety Challenges of Breakthrough Therapies, Building Data to Minimize Risk and Systems to Maximize Lifecycle Quality

1:30 – 1:45 **FDA Challenges and Perspectives**

Steven Lynn, M.S.
Director, Office of Manufacturing and Product Quality (OMPQ)
OC, CDER, FDA

Moderator:
Terrance Ocheltree, Ph.D., R.Ph.
Sr Director Regulatory Affairs, CMC
Abbvie Pharmaceutical

1:45 – 2:00 **Industry Challenges and Perspectives**

Roger Nosal
Vice President, Global CMC
Pfizer, Inc.

2:00 – 2:15 **Clinical Safety Considerations for Expedited Approvals – FDA Perspective**

Mwango Kashoki, M.D. **(VIA Videoconference)**
Medical Officer, Office of New Drugs
CDER, FDA

Moderator:
Andrea Masciale
Global Regulatory Policy & Intelligence
Janssen, Pharmaceutical Companies of Johnson and Johnson

2:15 - 2:45 **Break**

2:45 – 3:00 **Companion Diagnostics and Breakthrough Therapies – Personalized Therapeutics**

Debra J Rasmussen, MBA, RAC
Senior Director Global Regulatory Affairs
Janssen Pharmaceuticals

3:00 – 4:00 **ROUND TABLE DISCUSSION WITH AFTERNOON SPEAKERS**
joined by Moheb M. Nasr, Ph.D. of GlaxoSmithKline

Moderator:
Charles Hoiberg, Ph.D.
Executive Director
Pfizer, Inc

5:30 – 6:00 **RECEPTION** *Patio Outside Canyon Dinning Room*

6:00 – 7:30 **DINNER** *Canyons Dinning Room*

7:30 – 8:30 **FDA PANEL** *Canyons Dinning Room*

Steven Lynn, M.S.
Director, Office of Manufacturing and Product Quality (OMPQ)
OC, CDER, FDA

Mehul Mehta, Ph.D.
Director, Division of Clinical Pharmacology I
Office of Clinical Pharmacology
OTS, CDER, FDA

Sarah Pope Miksinski
Division Director (Acting)
FDA, CDER, OPS, ONDQA, DNDQA 2

Isaam Zineh, PharmD, MPH, FCP, FCCP
Director, Office of Clinical Pharmacology Office of Translational Sciences
CDER, FDA

Janet Woodcock, M.D.
Director • Center for Drug Evaluation & Research
FDA

Moderator:
Gerald J. Yakatan, Ph.D.
Founder & Chairman
IriSys, Inc.

7:30 – 8:30 **BREAKFAST** *Canyons Dinning Room*