FDA/MCERSI Workshop AGENDA **Thursday, May 16, 2019**

Pediatric Ontogeny: Ready for Incorporation into Modeling in Pediatric Drug Development?

Kirschstein Auditorium, Natcher Conference Center, NIH Main Campus

Moderators:
Gilbert J. Burckart, Pharm.D., Associate Director for Pediatrics
Office of Clinical Pharmacology

Jian Wang, Ph.D., Associate Director for Regulatory Science
Office of Drug Evaluation IV, Office of New Drugs

Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Jill Morgan, Pharm.D., BCPS, BCPPS, Associate Professor and Chair
Department of Pharmacy Practice and Science
Un. of Maryland School of Pharmacy

INTRODUCTION

8:30-8:35 a.m. **Welcome / Pediatric Drug Development**

Gilbert J. Burckart, Pharm.D.

8:35-8:55 a.m. **Developmental Pharmacokinetics**

John van den Anker, MD, PhD, Pediatric Clinical Pharmacology

Children's National Medical Center, Washington DC

8:55 – 9:15 a.m. **Developmental Pharmacodynamics**

Greg Kearns, Pharm.D., Ph.D, President

Arkansas Children's Research Institute, Little Rock, AK

9:15-9:35 a.m. **Modeling and Simulation using Pediatric Ontogeny Information**

Stefan Willmann, Ph.D., Clinical Pharmacometrics

Research & Development, Bayer, Wuppertal, Germany

DRUG METABOLISM AND TRANSPORTER FUNCTION

9:35-10:00 a.m. **Ontogeny of Drug Transporter Function**

Shiew Mei Huang, Ph.D., Deputy Director, Office of Clinical Pharmacology

Center for Drug Evaluation and Research, US Food and Drug Administration

10:00-10:20 a.m. **Break**

10:20-10:45 a.m. **Ontogeny of Phase I Metabolism of Drugs**

Steve Leeder, Pharm.D., PhD.

Marion Merrell Dow Endowed Chair in Pediatric Precision Therapeutics

Mercy Children's Hospital, Kansas City, MO

10:45-11:10 a.m. **Ontogeny and Phase II Metabolism of Drugs**

Stephan Schmidt, Ph.D., Associate Professor

Un. of Florida Center for Pharmacometrics and Systems Pharmacology

Lake Nona, FL

11:10 a.m.-12:00 p.m. **Moderated Panel Discussion**

Moderators: Dr.'s Burckart and Morgan

Panelists: Dr.'s van den Anker, Kearns, Huang, Leeder, Willmann, Edress Darsey (Pfizer), Sander Vinks (Un. of Cincinnati)

12:00-1:00 p.m. **Lunch**

RENAL FUNCTION, PHARMACOGENOMICS ONTOGENY

1:00-1:25 p.m. **Ontogeny of Renal Function and Renal Drug Elimination**

Jian Wang, Ph.D.

Associate Director for Regulatory Science, Office of New Drugs

UD Food and Drug Administration

1:25-1:50 p.m. **Ontogeny and Application of Pharmacogenomics to Pediatrics**

Dionna Green, M.D., Deputy Director

Office of Pediatric Therapeutics, Commissioner's Office

US Food and Drug Administration

APPLICATIONS TO PEDIATRIC DRUG DEVELOPMENT

1:50 - 2:20 p.m. **Application of Ontogeny within MIDD for Pediatrics**

Hao Zhu, Ph.D., Deputy Director

Division of Pharmacometrics, Office of Clinical Pharmacology

Center for Drug Evaluation, US Food and Drug Administration

2:20 – 2:40 p.m. BREAK

2:40 – 3:10 p.m. **Industry Perspective on Utilizing MIDD for Pediatric Studies Requiring Integration of Ontogeny**

Solange Corriol Rohou, MD, PhD

Chair, ICHE11 M&S Subcommittee

Senior Director, Global Regulatory Affairs & Policy, Europe

AstraZeneca Global Medicines Development, France

3:10-4:00 p.m. **Moderated Panel Discussion**

Moderators: Dr.'s Burckart and Jian Wang

Panelists: George Giacoia (NIH); Issam Zineh (FDA), Yaning Wang, Solange Corriol Rohou (Astra Zeneca), Stephan Schmidt, Linh Van (Novartis), Dionna Green (FDA)

4:00-4:15 p.m. **Pediatric Ontogeny and Modeling and Simulation: Remaining Questions**

Dr. Gilbert Burckart

THANKS to Program Committee Members:

Gil Burckart (FDA), Jian Wang (FDA), Jill Morgan (Un. of Maryland), John van den Anker (Children's National, Washington DC), Andre Dallmann (Bayer), George Giacoia (NIH), Dionna Green (FDA), Sander Vinks (Un. of Cincinnati), George Giacoia (NIH)