AGENDA *(Preliminary)*

Fetal Pharmacology & Therapeutics

Workshop sponsored by US FDA and University of Maryland CERSI

Thursday, October 21, 2021

10:00 – 10:05 AM: Welcome and Introduction

Gilbert J. Burckart, Pharm.D. – **Moderator**
Associate Director for Pediatrics, Office of Clinical Pharmacology
Center for Drug Evaluation and Research (CDER)
US Food and Drug Administration (FDA)

10:05 – 10:20 AM: General regulatory considerations

Dionna Green, M.D., FCP
Deputy Director, Office of Pediatric Therapeutics
Office of the Commissioner (OC), FDA

10:20 – 10:40 AM: Antenatal steroids to prevent respiratory distress syndrome in the preterm newborn – considerations for fetal safety and efficacy

Alan Jobe, M.D., Ph.D.
Cincinnati Children's Hospital
Emeritus Professor of Pediatrics

10:40 – 11:00 AM: Ethical and Regulatory considerations

Kevin Prohaska, DO, MPH
Associate Director/Senior Medical Policy Advisor,
Office of Good Clinical Practice
OC, FDA

Fetal Safety Studies – Moderator: Kyunghun Park, Pharm.D. (Reviewer, Division of Biotechnology Review & Research II, Office of Pharmaceutical Quality, CDER, FDA)

11:00 – 11:20 AM: Nonclinical assessment to inform maternal and fetal safety in clinical trials enrolling pregnant women

Kim Hatfield, Ph.D.
Lead Toxicologist
Division of Pharmacology Toxicology for Rare Diseases, Pediatric Urology and Reproductive Medicine
CDER, FDA

11:20 – 11:40 AM: Clinical assessment of fetal well-being and fetal safety indicators

Anna David, Ph.D.
Professor of Obstetrics and Maternal Fetal Medicine
Maternal & Fetal Medicine
UCL EGA Institute for Womens Health
Faculty of Population Health Sciences
University College, London, UK

11:40 – 12:00 PM: Model development and effects of opioids on neural tube defects

Amy Inselman, Ph.D.
Research Biologist, Division of Systems Biology
National Center for Toxicological Research (NCTR), FDA

Grace Lee, Ph.D.
Pharmacologist, Division of Pharmacology Toxicology for Neuroscience
CDER, FDA

12:00 – 12:30 PM: LUNCH BREAK

<u>Fetal Therapeutics</u> – Moderator: Gerri Baer, M.D. (Team Leader, Pharmacovigilance & Neonatology Team, Office of Pediatric Therapeutics, OC, FDA)

12:30 – 12:50 PM: Fetal diagnostics

Louise Wilings-Haug, M.D., Ph.D.
Associate Obstetrician & Gynecologist, Brigham and Women's Hospital
Professor of Obstetrics, Gynecology and Reproductive Biology, Harvard Medical School

12:50 – 1:10 PM: Fetal arrhythmias

Janette Strasburger, M.D.
Pediatric Cardiology, Pediatrics
Children's Wisconsin
Researcher, Herma Heart Institute
Professor, the Medical College of Wisconsin

1:10 – 1:30 PM: Fetal therapies to target inflammation

Dr**.** Sarah Stock MD, Ph.D. ,
Reader and Honorary Consultant Maternal and Fetal Medicine
Usher Institute, University of Edinburgh
NINE Edinburgh BioQuarter, 9 Little France Road,
Edinburgh EH16 4UX

1:30 – 1:50 PM: In utero stem cell transplantation for the treatment of prenatally diagnosed diseases

Tippi Mackenzie, M.D
Professor, Surgery, UCSF Division of Pediatric Surgery and fetal treatment center
Pediatric Surgeon, UCSF Benioff Children's Hospital, San Francisco

1:50 – 2:05 PM: BREAK

2:05 – 3:00 PM: Panel Discussion and Questions

3:00 – 3:15 PM: Wrap up and Adjourn Day 1

Gilbert J. Burckart, Pharm. D.

<u>Friday, October 22, 2021</u>

10:00 – 10:05 AM: Welcome and Introduction

André Dallmann, Ph.D.
Scientist Systems Pharmacology
Research & Development, Pharmaceuticals,
Bayer AG, Germany

<u>General aspects of maternal-fetal modeling & simulation</u> – Moderator: André Dallmann (Bayer AG)

10:05 – 10:25 AM: Pregnancy-induced anatomical and physiological changes relevant to physiologically-based pharmacokinetic (PBPK) modeling

Anne Zajicek, M.D., Pharm.D., FAAP
Deputy Director, Office of Clinical Research
National Institutes of Health

10:25 – 10:45 AM: Quantifying placental drug transfer with ex vivo cotyledon perfusion assays as PBPK input

Rick Greupink, Pharm.D., Ph.D.
Assistant professor of Pharmacology, member of staff at
Department of Pharmacology & Toxicology
Radboud University Medical Center, Nijmegen, The Netherlands.

10:45 – 11:05 AM: Selecting the Right Dose for Pregnant Women Using PBPK

Ping Zhao, Ph.D.
Senior Program Officer
Bill & Melinda Gates Foundation
Seattle, Washington, United States

<u>Modeling & simulation case studies</u> – Moderator: Varsha Mehta, Pharm.D. (MS Office of Clinical Pharmacology-Pediatrics, CDER, FDA)

11:05 – 11:25 PM: Successful prediction of fetal exposure to transported and non-transported drugs using *in vitro* studies and PBPK M&S

Jashvant D. Unadkat, Ph.D.
Milo Gibaldi Endowed Professor, Department of Pharmaceutics
School of Pharmacy, University of Washington

11:25 – 11:45 AM: Mechanistic modeling of placental drug transfer and fetal-neonatal drug exposure

André Dallmann, Ph.D.
Scientist Systems Pharmacology
Research & Development, Pharmaceuticals,
Bayer AG, Germany

11:45 – 12:05 AM: Maternal-fetal PBPK modeling of antipsychotic drugs as case study

Miao Li, Ph.D.
Visiting Scientist
Division of Biochemical Toxicology
NCTR, FDA

12:05 – 12:25 PM: Predicting drug exposure in fetus and genital tract during pregnancy

Adeniyi Olagunju, Ph.D.
Tenure Track Fellow
Centre of Excellence for Long-acting Therapeutics
Department of Pharmacology & Therapeutics
University of Liverpool, Liverpool, UK

<u>Regulatory perspective</u> – Moderator: Dionna Green, M.D. (Deputy Director, Office of Pediatric Therapeutics, OC, FDA)

12:25 – 12:45 PM: MHRA perspective on pregnancy PPBPK models

Paola Coppola, MSc
Pharmacokinetics Assessor
Medicines and Healthcare Products, Regulatory Agency
London, UK

12:45 – 1:05 PM: FDA perspective on pregnancy-fetal PBPK models

Lynne Yao, M.D.
Director, Division of Pediatric and Maternal Health
CDER, FDA

1:05 – 1:55 PM: Panel Discussion and Questions

1:55 – 2:00 PM: Wrap up and Adjourn Day 2
André Dallmann, Ph.D.

Note: all times are in ET