U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION & RESEARCH
OFFICE OF CLINICAL PHARMACOLOGY

Bridging Drug Efficacy and Safety to the Obese: Considerations and Scientific Approaches

Panel Discussion

3:10 PM - 4:00 PM

Panelists

Moderator **- Varsha Mehta, Pharm.D., MS**
Senior Staff Fellow – Pediatrics
Office of Clinical Pharmacology, CDER, FDA

Panelists:

Alexander Vinks Ph.D., Pharm.D.
Cincinnati Children's Research Foundation Endowed Chair
Professor of Pediatrics & Pharmacology
University of Cincinnati, College of Medicine

Jogga Gobburu, Ph.D
Professor of Pharmacy Practice and Science
Director, Center for Translational Medicine
University of Maryland

Gilbert Burckart, Pharm.D.
Associate Director-Pediatrics
Office of Clinical Pharmacology, CDER, FDA

Jaya Vaidyanathan, Ph.D
Associate Director-Therapeutic Review
Division of Cardiometabolic and Endocrine
Pharmacology, Office of Clinical Pharmacology,
CDER, FDA

Laura Higginbotham, MD, MPH
Lead Physician-Division of Diabetes, Lipid
Disorders, and Obesity, CDER, FDA

Kenneth T. Moore, MA, MS, FAHA
Scientific Director
Cardiovascular and Metabolism Medical Affairs
Janssen Pharmaceuticals Inc.
Titusville, USA

Panel Reflections

- Panelists' reflection considering today's workshop objectives

Workshop Objectives:

1. Review the implications of obesity on drug safety, efficacy, dosing and disposition in adult and pediatric patients.
2. Discuss:
    a. If adult and pediatric patients should be identified and studied as a specific population in new drug development programs
    b. When it may be appropriate to include obese patients in drug development studies to develop specific dosing guidelines for obese patients

Panel Question 1

- Currently there is a regulatory requirement to study patients with renal or hepatic failure as a specific population in clinical trials

- Should **Obesity** be considered a specific patient population like renal and hepatic failure, or should it be included as a diverse population akin to racial, ethnic, and gender diversity?

Panel Question 2

- Clinical trials use Body Mass Index (BMI), Weight (actual or lean) or both to categorize and recruit participants

- Is assessing the most extreme BMIs or weights (e.g. Morbidly Obese) 'good enough' as an extreme or worst-case scenario, or does each category above the "normal" BMI or weight need to be assessed, like the stages of renal impairment (with mild, moderate, severe, or end-stage renal disease (ESRD) stages) or hepatic impairment?

Panel Question 3

- What is an appropriate time during a drug development program to address drug disposition in the obese?

Panel Question 4

- Can Physiologically-Based Pharmacokinetic data act as a surrogate for actual clinical trial data in understanding drug disposition in the obese?

Panel Question 5

- In the renal failure population, studies in dialysis patients are performed as part of the drug development program.

- Similarly, beyond obesity, should the follow-up studies also be incorporated in clinical research programs to evaluate drug PK/PD in specific obese populations such as those with gastric bypass procedures? Should such studies be done during drug development?


FDA
U.S. FOOD & DRUG
ADMINISTRATION