

**Food and Drug Administration
Center for Drug Evaluation and Research**

**Summary Minutes of the Gastrointestinal Drugs Advisory Committee
October 18, 2018**

Location: Bethesda Marriott, the Grand Ballroom, 5151 Pooks Hill Road, Bethesda, Maryland

Topic: The committee discussed new drug application (NDA) 210166 for prucalopride tablets for oral administration, submitted by Shire Development, LLC, proposed for the treatment of chronic idiopathic constipation in adults.

These summary minutes for the October 18, 2018 meeting of the Gastrointestinal Drugs Advisory Committee of the Food and Drug Administration were approved on November 13, 2018.

I certify that I attended the October 18, 2018, meeting of the Gastrointestinal Drugs Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/
Jay R. Fajiculay, PharmD
Designated Federal Officer, GIDAC

/s/
Jean-Pierre Raufman, MD
Chairperson, GIDAC

Summary Minutes of the
Gastrointestinal Drugs Advisory Committee Meeting
October 18, 2018

The Gastrointestinal Drugs Advisory Committee (GIDAC) of the Food and Drug Administration, Center for Drug Evaluation and Research, met on October 18, 2018 at the Bethesda Marriott, the Grand Ballroom, 5151 Pooks Hill Road, Bethesda, Maryland. Prior to the meeting, the members and temporary voting members were provided briefing materials from the FDA and Shire Development, LLC. The meeting was called to order by Jean-Pierre Raufman, MD (Chairperson). The conflict of interest statement was read into the record by Jay R. Fajiculay, PharmD (Designated Federal Officer). There were approximately 50 people in attendance. There were eight Open Public Hearing (OPH) speaker presentations.

A verbatim transcript will be available, in most instances, at approximately ten to twelve weeks following the meeting date.

Agenda: The committee discussed new drug application (NDA) 210166 for prucalopride tablets for oral administration, submitted by Shire Development, LLC, proposed for the treatment of chronic idiopathic constipation in adults.

Attendance:

Gastrointestinal Drugs Advisory Committee Members Present (Voting): Joy McVey Hugick, BA (Consumer Representative); Sandeep Khurana, MBBS; Jennifer C. Lai, MD, MBA; Benjamin Leibold, MD, MS; Jean-Pierre Raufman, MD

Gastrointestinal Drugs Advisory Committee Members Not Present (Voting): David N. Assis, MD; Lin Chang, MD; Christopher S. Coffey, PhD, MS; Darrell S. Pardi, MD, MSc; Rachel L. Rosen, MD, MPH; Lisa L. Strate, MD, MPH

Gastrointestinal Drugs Advisory Committee Member Present (Non-Voting): Douglas Levine, MD (Industry Representative)

Temporary Members (Voting): Sally Hunsberger, PhD; Sabrina Numann (Patient Representative); Steven F. Solga, MD; John Teerlink, MD; Udho Thadani, MD

FDA Participants (Non-Voting): Victor Crentsil, MD, MHS; Joyce Korvick, MD, MPH; Juli Tomaino, MD; Charles Line, MD; Ling Lan, PhD; Joel Weissfeld, MD, MPH

Designated Federal Officer (Non-Voting): Jay R. Fajiculay, PharmD

Open Public Hearing Speakers: Varuna Srinivasan, MD (National Center for Health Research); Ellen Stein, MD (Johns Hopkins Bayview Gastroenterology and Hepatology); Baha Moshiree, MD, MSc (statement read by Ellen Stein, MD); William Hasler, MD (American Neurogastroenterology and Motility Society); Brad Conway (American College of Gastroenterology); Trent Nichols Jr, MD (Quietmind Foundation); Jeffrey Roberts, MEd, BSc (IBS Patient Group); Jessica Roth (American Gastroenterological Association)

October 18, 2018
Gastrointestinal Drugs Advisory Committee

The Agenda was as follows:

Call to Order and Introduction of
Committee

Jean-Pierre Raufman, MD
Chairperson, GIDAC

Conflict of Interest Statement

Jay Fajiculay, PharmD
Designated Federal Officer, GIDAC

FDA Introductory Remarks

Juli Tomaino, MD
Clinical Team Leader
Division of Gastroenterology and Inborn Errors
Products (DGIEP)
Office of Drug Evaluation (ODE) III
Office of New Drugs (OND), CDER, FDA

APPLICANT PRESENTATIONS

Shire Development, LLC

Introduction

Sunil Kadam, PhD
Senior Director, Global Regulatory Affairs
Shire

Unmet Need in Chronic Idiopathic
Constipation

Michael Camilleri, MD
Gastroenterologist and Professor of Medicine,
Pharmacology, and Physiology
Mayo Clinic

Prucalopride Efficacy Results

Heinrich Achenbach, MD
Global Clinical Development Team Lead
Shire

Prucalopride Safety

John Caminis, MD
Therapeutic Area Head, Global Drug Safety
Shire

Clinical Perspective on Prucalopride

Jan Tack, MD, PhD
Professor of Medicine
Head of Clinic, Department of Gastroenterology
University Hospital KU Leuven

Concluding Remarks

Debra Silberg, MD, PhD
Therapeutic Area Head, VP of Clinical Development
Shire

Clarifying Questions to the Presenters

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