

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
January 16, 2020

AGENDA

The committee will discuss new drug application (NDA) 204803, bupivacaine extended-release solution for instillation, submitted by DURECT Corp., for the proposed indication of post-surgical analgesia. The committee will discuss whether the Applicant adequately demonstrated the safety and efficacy of bupivacaine extended-release solution for post-surgical analgesia and the appropriateness of the proposed patient populations. The committee will also be asked to discuss the approvability of this product.

8:00 a.m.	Call to Order and Introduction of Committee	Ronald S. Litman, DO, ML Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	Moon Hee V. Choi, PharmD Designated Federal Officer, AADPAC
8:10 a.m.	FDA Introductory Remarks	Rigoberto Roca, MD Acting Division Director Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP) Office of Neuroscience (ON) Office of New Drugs (OND) CDER, FDA
8:15 a.m.	APPLICANT PRESENTATIONS	DURECT Corporation
	Clinical Context	Tong J. Gan, MD, MHS, FRCA, MBA Professor and Chairman Department of Anesthesiology Stony Brook School of Medicine
	Introduction to Clinical Program	Neil Verity, PhD Executive Director, Pharmacology Project Leader and Principal Scientist DURECT Corporation
	Efficacy and Safety	Jon Meisner, MD Sr. Medical Director, Medical Affairs DURECT Corporation
	General Surgeon's Perspective	Asok Doraiswamy, MD, FACS General Surgeon Methodist Hospital of Southern California Huntington Memorial Hospital

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Anesthesiologist's perspective

Harold Minkowitz, MD
Anesthesiologist
Memorial Hermann Katy Hospital
Memorial Hermann Memorial City Medical
Center

9:45 a.m. Clarifying Questions

10:00 a.m. **BREAK**

10:15 a.m. **FDA PRESENTATIONS**

Current Postsurgical Analgesic Treatment
Options & Summary of Clinical
Development Program

Renee Petit-Scott, MD
Medical Officer
DAAP, ON, OND, CDER, FDA

Statistical Review of Efficacy Data

Katherine Meaker, MS
Statistics Reviewer
Division of Biometrics I, Office of Biostatistics
Office of Translational Sciences, CDER, FDA

Clinical Implications of Efficacy Data

Renee Petit-Scott, MD

Assessment of Safety Data from Studies
Submitted in Support of NDA

Renee Petit-Scott, MD

11:45 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Charge to the Committee

Rigoberto Roca, MD

2:05 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**