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
October 11, 2018

AGENDA

The committee will be asked to discuss new drug application (NDA) 210730, for oliceridine 1 milligram/milliliter injection, submitted by Trevena, Inc., for the management of moderate-to-severe acute pain in adult patients for whom an intravenous opioid is warranted. The committee will also be asked to discuss the efficacy and safety data and benefit-risk considerations.

8:00 a.m.	Call to Order and Introduction of Committee	**Kevin Zacharoff, MD, FACIP, FACPE, FAAP** Acting Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Designated Federal Officer, AADPAC
8:10 a.m.	FDA Opening Remarks	**Sharon Hertz, MD** Director, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:25 a.m.	**APPLICANT PRESENTATIONS**	**Trevena, Inc.**
	Introduction	**Maxine Gowen, PhD** Founding President and CEO Trevena, Inc.
	Efficacy and Safety	**Mark Demitrack, MD** Chief Medical Officer Trevena, Inc.
	Special Safety Topics Clinical Interpretation of Hepatic Findings	**Paul Watkins, MD** Professor of Medicine, Toxicology, and Experimental Therapeutics University of North Carolina, Chapel Hill
	Special Safety Topics Cardiac Safety	**Robert B Kleiman, MD** Chief Medical Officer Vice President Global Cardiology ERT

AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Opioid-Related Adverse Events	**Jonathan Violin, PhD** Co-Founder and Senior Vice President of Scientific Affairs Trevena, Inc.
	Clinical Perspective	**Gregory Hammer, MD** Professor of Anesthesiology, Pediatric Perioperative and Pain, and Pediatrics Critical Care Stanford University Medical Center
9:40 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Introduction and Overview	**Elizabeth Kilgore, MD, MS** Medical Officer DAAAP, ODE-II, OND, CDER, FDA
	Abuse Potential of Oliceridine	**Katherine Bonson, PhD** Pharmacologist Controlled Substance Staff (CSS) Office of the Center Director (OCD), CDER, FDA
	Review of Efficacy	**James Travis, PhD** Statistical Reviewer Division of Biometrics II Office of Biostatistics Office of Translational Sciences (OTS) CDER, FDA
	Safety Assessment and Benefit/Risk Considerations	**Elizabeth Kilgore, MD, MS**
11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	

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AGENDA (cont.)

1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Charge to the Committee	**Sharon Hertz, 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**	