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

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting

May 19, 2023

DRAFT AGENDA

The committee will discuss new drug application (NDA) 212833, obeticholic acid (OCA) 25mg oral tablets, submitted by Intercept Pharmaceuticals, Inc., for the treatment of pre-cirrhotic liver fibrosis due to nonalcoholic steatohepatitis (NASH).

9:00 a.m.	Call to Order	**Benjamin Lebwohl, MD, MS** Chairperson, GIDAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Jessica Seo, PharmD, MPH** Acting Designated Federal Officer, GIDAC
9:10 a.m.	FDA Introductory Remarks	**Ruby Mehta, MD** Medical Team Leader Division of Hepatology and Nutrition (DHN) Office of Immunology and Inflammation (OII) Office of New Drugs (OND) CDER, FDA
9:20 a.m.	**APPLICANT PRESENTATIONS**	**Intercept Pharmaceuticals, Inc.**
	Introduction	**M. Michelle Berrey, MD, MPH** President, Research & Development; Chief Medical Office Intercept Pharmaceuticals
	Medical Need	**Kris Kowdley, MD, AGAF, FAASLD, FACG, FASG** Director, Liver Institute Northwest Professor of Medicine, Elson S. Floyd College of Medicine Washington State University
	Non-Invasive Tests	**Rohit Loomba, MD, MHSc** Director, NAFLD Research Center Professor of Medicine Vice Chief, Gastroenterology; Director, Hepatology University of California at San Diego
	Efficacy Results	**Thomas Capozza, MD, FACP** Executive Director, Clinical Research Intercept Pharmaceuticals
	OCA Safety	**Sangeeta Sawhney, MD** Vice President, Clinical Development Intercept Pharmaceuticals

	Clinical Perspective	**Arun Sanyal, MD** Chair of NIDDK NASH Clinical Research Steering Committee Professor of Medicine Virginia Commonwealth University School of Medicine
	Conclusions	**M. Michelle Berrey, MD, MPH**
10:35 a.m.	Clarifying Questions	
10:55 a.m.	**BREAK**	
11:05 a.m.	**FDA PRESENTATIONS**	
	Regulatory Framework, Study Design, and Efficacy	**Rebecca Hager, PhD** Statistical Team Leader Division of Biometrics III (DBIII) Office of Biostatistics (OB) Office of Translational Sciences (OTS) CDER, FDA
	Drug-Induced Liver Injury (DILI) Assessment	**Paul H. Hayashi, MD, MPH, FAASLD** DILI Team Leader DHN, OII, OND, CDER, FDA
	Safety Assessment (non-DILI)	**Charmaine Stewart, MD, FAASLD, AGAF, FACP** Medical Officer DHN, OII, OND, CDER, FDA
	Conclusion	**Ruby Mehta, MD**
12:20 p.m.	Clarifying Questions	
12:40 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Charge to the Committee	**Frank A. Anania, MD, FACP, AGAF, FAASLD** Director (Acting) DHN, OII, OND, CDER, FDA
2:40 p.m.	Questions to the Committee/Committee Discussion	
3:45 p.m.	**BREAK**	

DRAFT AGENDA (cont.)

3:55 p.m.	Questions to the Committee/Committee Discussion (cont.)
5:00 p.m.	**ADJOURNMENT**