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

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting

September 13, 2024

AGENDA

The Committee will discuss supplemental new drug application (sNDA) 207999 S-011, for OCALIVA (obeticholic acid) 5 mg titrated to 10 mg oral tablets, administered once a day, submitted by Intercept Pharmaceuticals, Inc., to fulfill the accelerated approval postmarketing requirements specified in the OCALIVA approval letter dated May 27, 2016. The sNDA included data proposed to describe and verify clinical benefit for the indication of reducing the risk of death, liver transplant, and hepatic decompensation in adult patients with primary biliary cholangitis without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

8:30 a.m.	Call to Order and Introduction of Committee	**Benjamin Lebwohl, MD** Chairperson, GIDAC
8:35 a.m.	Conflict of Interest Statement	**Jessica Seo, PharmD, MPH** Designated Federal Officer, GIDAC
8:45 a.m.	FDA Introductory Remarks	**Ruby Mehta, MD** Cross-Discipline Team Leader Division of Hepatology and Nutrition (DHN) Office of Inflammation and Immunology (OII) Office of New Drugs (OND) CDER, FDA
8:55 a.m.	**APPLICANT PRESENTATIONS**	**Intercept Pharmaceuticals, Inc.**
	Introduction	**Sangeeta Sawhney, MD** Senior Vice President, Head of US Research and Development Intercept Pharmaceuticals, Inc.
	Disease Background	**Robert S. Brown, Jr, MD, MPH** Vincent Astor Distinguished Professor of Medicine Chief, Division of Gastroenterology and Hepatology Editor-in-Chief, Liver Transplantation Weill Cornell Medical College
	Methods Used to Estimate Clinical Benefit	**Andrew Damokosh, PhD** Senior Vice President, Biostatistics Intercept Pharmaceuticals, Inc.
	Study 302 Efficacy and Safety	**Thomas Capozza, MD FACP** Vice President, Clinical Research Intercept Pharmaceuticals, Inc.

AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Drug-Induced Liver Injury	**Lily Dara, MD** Assistant Professor of Medicine Department of Medicine, Division of GI/Liver USC Research Center for Liver Disease Keck School of Medicine University of Southern California
	Study 405 and Other Real-World Evidence (RWE)	**Leona Bessonova, PhD** Executive Director, Medical Affairs Research Intercept Pharmaceuticals, Inc.
	Clinical Perspective	**David Jones, OBE** Director, Newcastle Health Innovation Partners Academy Director, Newcastle Center for Rare Disease Professor of Liver Immunology, Newcastle University Honorary Consultant Hepatologist, Newcastle upon Tyne Hospitals
	Conclusions	**Sangeeta Sawhney, MD**
10:10 a.m.	Clarifying Questions to the Applicant	
10:40 a.m.	**BREAK**	
10:55 a.m.	**FDA PRESENTATIONS**	
	Clinical Pharmacology	**Tao Liu, PhD** Clinical Pharmacology Reviewer Division of Inflammation and Immune Pharmacology (DIIP) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS) CDER, FDA
	Study 747-302	**Tram Tran, MD, FAASLD, FACG** Medical Officer DHN, OII, OND, CDER, FDA

AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

	Study 747-405	**Joel L. Weissfeld, MD, MPH** Senior Medical Officer Division of Epidemiology (DEPI) Office of Surveillance and Epidemiology (OSE) CDER, FDA **Eugenio Andraca-Carrera, PhD** Division of Biometrics-VII (DB-VII) Office of Biostatistics (OB) OTS, CDER, FDA
12:10 p.m.	Clarifying Questions to FDA	
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** Acting Director DHN, OII, OND, CDER, FDA
2:40 p.m.	Questions to the Committee/Committee Discussion	
3:40 p.m.	**BREAK**	
4:00 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	