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

***Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting***

May 19, 2023

**AGENDA**

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*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).*

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| 9:00 a.m. | Call to Order | **Benjamin Lebwohl, MD, MS**<br>Chairperson, GIDAC |
| 9:05 a.m. | Introduction of Committee and Conflict of Interest Statement | **Jessica Seo, PharmD, MPH**<br>Acting Designated Federal Officer, GIDAC |
| 9:10 a.m. | FDA Introductory Remarks | **Ruby Mehta, MD**<br>Medical Team Leader<br>Division of Hepatology and Nutrition (DHN)<br>Office of Immunology and Inflammation (OII)<br>Office of New Drugs (OND)<br>CDER, FDA |
| 9:25 a.m. | **APPLICANT PRESENTATIONS** | **Intercept Pharmaceuticals, Inc.** |
| | Introduction | **M. Michelle Berrey, MD, MPH**<br>President, Research & Development;<br>Chief Medical Office<br>Intercept Pharmaceuticals |
| | Medical Need | **Kris Kowdley, MD, AGAF, FAASLD, FACG, FACP, FASG**<br>Director, Liver Institute Northwest<br>Professor of Medicine,<br>Elson S. Floyd College of Medicine<br>Washington State University |
| | Non-Invasive Tests | **Rohit Loomba, MD, MHSc**<br>Director, NAFLD Research Center<br>Professor of Medicine<br>Vice Chief, Gastroenterology; Director, Hepatology<br>University of California at San Diego |
| | Efficacy Results | **Thomas Capozza, MD, FACP**<br>Executive Director, Clinical Research<br>Intercept Pharmaceuticals |
| | OCA Safety | **Sangeeta Sawhney, MD**<br>Vice President, Clinical Development<br>Intercept Pharmaceuticals |

**AGENDA (cont.)**

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| | Clinical Perspective | **Arun Sanyal, MD**<br>Professor of Medicine, VCU School of Medicine<br>Chair of NIDDK NASH Clinical Research Network Steering Committee |
| 10:40 a.m. | Clarifying Questions | |
| 11:00 a.m. | **BREAK** | |
| 11:10 a.m. | **FDA PRESENTATIONS** | |
| | Regulatory Framework, Study Design, and Efficacy | **Rebecca Hager, PhD**<br>Statistical Team Leader<br>Division of Biometrics III (DBIII)<br>Office of Biostatistics (OB)<br>Office of Translational Sciences (OTS)<br>CDER, FDA |
| | Drug-Induced Liver Injury (DILI) Assessment | **Paul H. Hayashi, MD, MPH, FAASLD**<br>DILI Team Leader<br>DHN, OII, OND, CDER, FDA |
| | Safety Assessment (non-DILI) | **Charmaine Stewart, MD, FAASLD, AGAF, FACP**<br>Medical Officer<br>DHN, OII, OND, CDER, FDA |
| | Benefit:Risk | **Ruby Mehta, MD** |
| 12:25 p.m. | Clarifying Questions | |
| 12:45 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**<br>Director (Acting)<br>DHN, OII, OND, CDER, FDA |
| 2:40 p.m. | Questions to the Committee/Committee Discussion | |
| 3:45 p.m. | **BREAK** | |
| 3:55 p.m. | Questions to the Committee/Committee Discussion (cont.) | |
| 5:00 p.m. | **ADJOURNMENT** | |