Intercept Statement on Briefing Documents for Upcoming FDA Advisory Committee Meeting for Obeticholic Acid as a Treatment for Pre-Cirrhotic Fibrosis due to NASH

MORRISTOWN, N.J., May 17, 2023 – The U.S. Food and Drug Administration (FDA) today publicly posted briefing documents (click here) in advance of the May 19, 2023, Gastrointestinal Drugs Advisory Committee (GIDAC) meeting to review information that supports Intercept's New Drug Application (NDA) for obeticholic acid (OCA) for the treatment of pre-cirrhotic fibrosis due to nonalcoholic steatohepatitis (NASH).

This week's Advisory Committee meeting is an important step in the regulatory process, allowing the opportunity to discuss in depth the strong and consistent antifibrotic effect of OCA in NASH and its monitorable and manageable safety profile. Intercept has outlined a robust body of evidence in its briefing book which demonstrates the Company's belief that OCA has the potential to become an impactful therapy for patients with pre-cirrhotic fibrosis due to NASH.

Intercept looks forward to a constructive discussion with the Advisory Committee, including addressing areas where the Company's viewpoints do not align with certain characterizations of OCA's efficacy and safety in NASH and the role of non-invasive tests (NITs) in clinical practice, as articulated by the FDA in its briefing book.

During the public meeting, Intercept will present data from two independent positive 18-month interim analyses from the pivotal Phase 3 REGENERATE study of OCA in NASH and a pooled safety database of 2,860 patients, with nearly 1,000 patients on study drug for four years. In these analyses, OCA 25 mg consistently demonstrated double the response rate of placebo in reduction in liver fibrosis stage without worsening of any of the three histologic components of NASH. This endpoint is defined within the FDA's draft guidance which reflects scientific consensus that fibrosis is considered the strongest predictor of adverse clinical outcomes, including liver-related death. Further, the safety database of OCA in NASH is the largest in the NASH field with the longest duration of patient exposure. This database provides a well-characterized safety and tolerability profile that supports the potential chronic administration of OCA. Finally, independent evidence will be presented to support the role of NITs for clinicians to identify and monitor the vast majority of at-risk NASH patients without the need for liver biopsy.

As previously reported, the FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 22, 2023. The timeline for review of the NDA by the FDA remains subject to change.

About Liver Fibrosis due to NASH
Nonalcoholic steatohepatitis (NASH) is a serious progressive liver disease caused by excessive fat accumulation in the liver that induces chronic inflammation, resulting in progressive fibrosis (scarring) that can lead to cirrhosis, eventual liver failure, cancer and death. Advanced fibrosis is associated with a substantially higher risk of liver-related morbidity and mortality in patients with NASH. There are currently no medications approved for the treatment of NASH.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, including primary biliary cholangitis (PBC), nonalcoholic steatohepatitis (NASH) and severe alcohol-associated hepatitis (sAH). For more information, please visit www.interceptpharma.com or connect with the Company on Twitter and LinkedIn.

Forward-Looking Statements

This statement contains forward-looking statements ("FLS"), including regarding the timing of FDA review of our NDA; the timing of our PDUFA target action date; the timing and subject matter of an FDA advisory committee meeting; the prospects for FDA approval of our NDA; the results of our clinical studies; and drug efficacy, safety, and tolerability. Important factors could cause actual results to differ materially from the FLS. For example, the FDA could take longer than expected to review our NDA; the FDA advisory committee meeting could be delayed or canceled; our product candidate could not receive FDA approval in a timely manner or at all; the FDA could require us to provide additional information that is not timely or economical to provide; we could be unable to address to the satisfaction of the FDA the issues raised in its May 2023 briefing book or in its complete response letter of June 2020 that responded to our earlier submission; there could be efficacy, safety, or tolerability concerns about our product candidate; and our clinical studies could have problems.

Contacts

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