Intercept Announces Outcome of FDA Advisory Committee Meeting for Obeticholic Acid as a Treatment for Pre-Cirrhotic Fibrosis due to NASH

May 19, 2023

12 of 16 voting-eligible advisors vote "no" (with two abstentions) on question, "given the available efficacy and safety data, do the benefits of OCA 25 mg outweigh the risks in NASH patients with stage 2 or 3 fibrosis?"

15 of 16 voting-eligible advisors vote to "defer approval until clinical outcome data from trial 747-303 are submitted and reviewed, at which time the traditional approval pathway could be considered"

PDUFA Target Action Date set for June 22, 2023

Company to host conference call on Monday, May 22, 2023, at 8:30 a.m. ET

MORRISTOWN, N.J., May 19, 2023 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced the outcome of the U.S. Food and Drug Administration (FDA) Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting to review the Company's New Drug Application (NDA) for obeticholic acid (OCA) for the treatment of pre-cirrhotic fibrosis due to nonalcoholic steatohepatitis (NASH).

Twelve of 16 voting-eligible GIDAC members voted "no" (with two abstentions) on the voting question, "given the available efficacy and safety data, do the benefits of OCA 25 mg outweigh the risks in NASH patients with stage 2 or 3 fibrosis?" Fifteen of 16 voting-eligible GIDAC members (with no abstentions) voted to "defer approval until clinical outcome data from trial 747-303 are submitted and reviewed, at which time the traditional approval pathway could be considered."

"We are disappointed in the outcome of today's meeting," said Jerry Durso, President and Chief Executive Officer of Intercept. "We continue to disagree with the FDA on certain characterizations of OCA's efficacy and safety in pre-cirrhotic fibrosis due to NASH and the role of non-invasive tests (NITs), as discussed in today's meeting. The robust body of evidence provided by Intercept was underscored by public testimony from the liver community, who supported OCA as an option to address the urgent treatment need in NASH and the use of NITs to manage this devastating disease in clinical practice."

Advisory Committee votes, while not binding, are considered by the FDA when making its decision regarding the potential approval of a regulatory application. 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.

Conference Call on Monday, May 22, 2023, at 8:30 a.m. ET
The Company will host a conference call on Monday, May 22, 2023, from 8:30 – 9:00 a.m. ET to discuss the Advisory Committee Meeting. The conference call will be available via a listen-only webcast on the investor page of the company's website at http://ir.interceptpharma.com. Participants who wish to ask a question may register here to receive dial-in numbers and a unique pin to join the call. A replay of the call will be available on the Intercept website shortly following the completion of the call and will be available for one year.

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.

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 REGENERATE
REGENERATE (Randomized Global Phase 3 Study to Evaluate the Impact on NASH with Fibrosis of Obeticholic Acid Treatment) is an ongoing Phase 3, randomized, double-blind, placebo-controlled, multicenter, international study assessing the safety and efficacy of obeticholic acid (OCA) on clinical outcomes in patients with liver fibrosis due to NASH. A pre-specified interim analysis was conducted in 931 subjects who had a liver biopsy at Month 18 to assess the effect of OCA on liver histology as compared to baseline biopsies. REGENERATE is fully enrolled with 2,480 randomized participants and is expected to continue while collecting data on the incidence of clinical outcomes for verification and description of clinical benefit. The end-of-study primary endpoint will compare the impact of treatment group (placebo, OCA 10 mg or OCA 25 mg daily) on all-cause mortality and liver-related clinical outcomes, as well as on long-term safety.

Forward-Looking Statements
This press release contains forward-looking statements ("FLS"), including regarding the timing of our PDUFA target action date; 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; our product candidate could not receive FDA approval in a timely manner or at all; the FDA could impose label restrictions that are not clinically or economically feasible; 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.

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Source: Intercept Pharmaceuticals, Inc.