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

March 10, 2023

Advisory Committee Meeting scheduled for May 19, 2023

PDUFA Target Action Date is June 22, 2023

MORRISTOWN, N.J., March 10, 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 that the Gastrointestinal Drugs Advisory Committee (GIDAC) of the U.S. Food and Drug Administration (FDA) will discuss Intercept's new drug application (NDA) for obeticholic acid (OCA) as a treatment for pre-cirrhotic liver fibrosis due to nonalcoholic steatohepatitis (NASH) on May 19, 2023. The Advisory Committee Meeting will be hosted as a virtual meeting.

"There are currently no approved treatment options for people living with NASH, a devastating disease and the most rapidly growing cause of liver transplantation in the U.S.," said Jerry Durso, President and Chief Executive Officer of Intercept. "We look forward to the opportunity to discuss with the Advisory Committee our clinical trial data demonstrating the strong and confirmed antifibrotic effect of OCA, as well as its manageable safety profile in NASH."

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

About the REGENERATE Study
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.

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 press release contains forward-looking statements ("FLS"), including regarding the timing of FDA review of our NDA; the timing of our PDUFA Target Action date; the possibility and timing of an FDA advisory committee meeting; the prospects for FDA approval of our NDA; the results of our clinical studies; drug efficacy, safety, and tolerability; the commercial opportunity for our product candidate; and the prospects of our product candidate compared to potential competitors. 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 complete response letter of June 2020 responding to our earlier submission; there could be efficacy, safety, or tolerability concerns about our product candidate; our clinical studies could have problems; and our product candidate could have less commercial potential than anticipated or could be superseded by a competing product.

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