# Intercept Pharmaceuticals Stock Trading Halted Today; FDA Advisory Committee to Review Obeticholic Acid as a Treatment for Pre-Cirrhotic Fibrosis due to NASH

May 19, 2023

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 that NASDAQ has halted trading of the company's common stock.

The U.S. Food and Drug Administration's (FDA) Gastrointestinal Drugs Advisory Committee (GIDAC) is meeting today to review obeticholic acid (OCA) as a treatment for pre-cirrhotic fibrosis due to nonalcoholic steatohepatitis (NASH). The Advisory Committee meeting is scheduled for 9:00 a.m. - 5:00 p.m. ET. The briefing materials can be found on the FDA website (click here).

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.

Trading of the company's common stock will resume at the discretion of NASDAQ.

**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 timing of an FDA advisory committee meeting; and the prospects for FDA approval of our NDA. 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 the complete response letter of June 2020 responding to our earlier submission; and there could be efficacy, safety, or tolerability concerns about our product candidate.

**Contacts**

For more information about Intercept, please contact:

For investors:
Nareg Sagherian, Executive Director, Global Investor Relations
investors@interceptpharma.com

For media:
Karen Preble, Executive Director, Global Corporate Communications
media@interceptpharma.com

Source: Intercept Pharmaceuticals, Inc.