Intercept Receives Complete Response Letter from FDA for Obeticholic Acid as a Treatment for Pre-Cirrhotic Fibrosis due to NASH

June 22, 2023

- ***Company to discontinue all NASH-related investment and restructure the Company's operations to strengthen its focus on rare and serious liver diseases***
- ***Company anticipates achieving profitability in 2024 as a result of planned actions***
- ***Conference call scheduled for Friday, June 23, 2023, at 8:30 a.m. ET***

MORRISTOWN, N.J., June 22, 2023 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat rare and serious liver diseases, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) in response to the Company's New Drug Application (NDA) for obeticholic acid (OCA) for the treatment of pre-cirrhotic fibrosis due to nonalcoholic steatohepatitis (NASH).

The FDA indicated in the CRL that it has completed its review of the NDA and determined that it cannot be approved in its present form. Based on the content of the CRL, any resubmission of an NDA for OCA in NASH would require, at a minimum, successful completion of the long-term outcomes phase of the REGENERATE study. As a result of the CRL, Intercept has decided to discontinue all NASH-related investment, restructure the Company's operations to strengthen its focus on rare and serious liver diseases, and drive an accelerated path to profitability beginning in 2024.

"While this is clearly not the outcome that we have worked toward, I'm proud of the impact that Intercept has made to move the science of NASH forward and bring the field closer to a treatment option," said Jerry Durso, President and Chief Executive Officer of Intercept. "Intercept thanks the scientists, clinicians and patients whose contributions to the clinical development of OCA in NASH have significantly advanced the understanding of this deadly disease."

Durso continued, "We believe that taking decisive action to reshape Intercept will improve our long-term ability to grow our business, innovate for patients, and create value for shareholders. We remain committed to the liver community and will continue to advance our leadership in rare and serious liver diseases where Intercept has deep expertise and a recognized dedication to therapeutic innovation."

Conference Call on Friday, June 23, 2023, at 8:30 a.m. ET
The Company will host a conference call on Friday, June 23, 2023, at 8:30 a.m. ET to address the restructuring and provide updated financial guidance. 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 rare and serious liver diseases, including primary biliary cholangitis (PBC) 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 news release contains forward-looking statements ("FLS"), including regarding a planned corporate restructuring, corporate strategy and priorities, corporate financial performance and profitability, and timing of profitability. Important factors could cause actual results to differ materially from the FLS. For example, we may be less effective than expected in implementing strategic changes, restructuring and clinical trial wind-down may be slower and have greater costs than expected, and we may fail to achieve profitability due to lower revenues or higher expenses than expected.

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Source: Intercept Pharmaceuticals, Inc.