April 7, 2016

FDA Advisory Committee Unanimously Recommends Accelerated Approval of Ocaliva™ (obeticholic acid) for the Treatment of PBC

PDUFA Date is May 29, 2016

Intercept to host investor conference call today at 5:30 p.m. ET

NEW YORK, April 07, 2016 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT), a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases, today announced that the U.S. Food and Drug Administration (FDA)'s Gastrointestinal Drugs Advisory Committee voted 17 to 0 to recommend accelerated approval of Ocaliva™ (obeticholic acid) for the treatment of patients with primary biliary cirrhosis, recently renamed primary biliary cholangitis (PBC). The target date for the FDA to take action under the Prescription Drug User Fee Act (PDUFA) is May 29, 2016. The FDA is not bound by the Advisory Committee's guidance, but takes its advice into consideration when reviewing investigational medicines. If approved, Ocaliva would be the first new treatment for PBC in nearly 20 years.

"We're pleased that the Advisory Committee strongly supported the approval of Ocaliva for people living with PBC. Today's positive recommendation is an encouraging step for the PBC community," said Mark Pruzanski, M.D., Chief Executive Officer and President of Intercept. "We'd like to thank the many patients and physicians who took part in the research discussed in today's meeting, as their participation and dedication has been — and remains — instrumental in evolving the treatment paradigm for PBC."

Intercept is seeking accelerated approval of Ocaliva for the treatment of PBC in patients with an inadequate response to, or who are unable to tolerate, ursodeoxycholic acid (UDCA), the only approved therapy for this disease. While UDCA has a marked impact on clinical outcomes in PBC, a substantial percentage of UDCA-treated patients have a suboptimal response or are intolerant to treatment, leaving them at significantly increased risk of an adverse outcome.

The Advisory Committee's recommendation is based on data from the clinical development program for Ocaliva in PBC, including the Phase 3 POISE trial, which assessed the safety and efficacy of Ocaliva in 216 PBC patients who had an inadequate therapeutic response to, or were unable to tolerate, UDCA. Intercept's New Drug Application (NDA) includes data for 432 PBC patients who have received Ocaliva with an amassed total of 675 patient years of exposure and some patients on therapy for over five years. In accordance with the FDA guidelines for accelerated approval, Intercept is currently enrolling COBALT, a global Phase 4 long-term outcomes trial to confirm the clinical benefit of Ocaliva in people living with PBC.

PBC is a rare chronic liver disease, and if patients are left untreated or have an inadequate response to UDCA therapy, the disease typically progresses to hepatic fibrosis, cirrhosis, liver failure and death unless they receive a liver transplant.

The brand name Ocaliva has been provisionally approved by the FDA and European Medicines Agency, but Ocaliva is an investigational medicine that has not been granted marketing authorization or approval from any regulatory authority.

Conference Call Information
Intercept will host a conference call today, Thursday, April 7, 2016, at 5:30 p.m. ET to discuss the outcome of the Gastrointestinal Drugs Advisory Committee meeting. The live event will be available on the investor page of the Intercept website at http://ir.interceptpharma.com or by calling (855) 232-3919 (toll-free domestic) or (315) 625-6894 (international) five minutes prior to the start time (no passcode required). A replay of the call will be available on the Intercept website approximately two hours after the completion of the call and will be archived for two weeks.

About Primary Biliary Cirrhosis, recently renamed Primary Biliary Cholangitis
PBC is a rare liver disease that primarily results from autoimmune destruction of the bile ducts that transport bile acids out of the liver, resulting in cholestasis. It is primarily a disease of women, afflicting approximately one in 1,000 women over the age of 40. Since 1988, PBC has been the second-leading overall cause of liver transplant in women in the United States, behind hepatitis C. In Europe, the disease accounts for approximately half of liver transplants due to cholestatic diseases and 6% of all liver transplants.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat non-viral, progressive liver diseases. The Company's lead product candidate, obeticholic acid (OCA), is an agonist of the farnesoid X receptor (FXR). OCA is being developed for a variety of chronic liver diseases, including primary biliary cirrhosis, recently renamed primary biliary cholangitis (PBC), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC) and biliary atresia. The FDA has granted OCA breakthrough therapy designation for the treatment of NASH with liver fibrosis and granted OCA fast track designation for the treatment of patients with PBC. OCA has also received orphan drug designation in both the United States and Europe for the treatment of PBC and PSC. Intercept owns worldwide rights to OCA outside of Japan, China and Korea, where it has out-licensed the product candidate to Sumitomo Dainippon Pharma. Intercept's pipeline of product candidates includes other novel bile acid analogs such as INT-767, which is in clinical development. For more information about Intercept, please visit the Company's website at: www.interceptpharma.com.

Safe Harbor Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the anticipated approval and launch of OCA in PBC and the timelines related thereto, the clinical relevance and utility of the endpoints used in the Phase 3 POISE trial, the anticipated prevalence of PBC, the continued development of OCA and Intercept's other product candidates, and our strategic directives under the caption "About Intercept." These "forward-looking statements" are based on management's current expectations of future events and are subject to a number of important risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the initiation, cost, timing, progress and results of our development activities, preclinical studies and clinical trials; the timing of and our ability to obtain and maintain regulatory approval of OCA, INT-767 and any other product candidates we may develop, particularly the possibility that regulatory authorities may require clinical outcomes data (and not just results based on achievement of a surrogate endpoint) as a condition to any marketing approval for OCA, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; our plans to research, develop and commercialize our product candidates; our ability to obtain and maintain intellectual property protection for its product candidates; our ability to successfully commercialize our product candidates; the size and growth of the markets for our product candidates and our ability to serve those markets; the rate and degree of market acceptance of any future products, which may be affected by the reimbursement that our products receive from payors; the success of competing drugs that are or become available; regulatory developments in the United States and other countries; the performance of third-party suppliers and manufacturers; our collaborators' election to pursue research, development and commercialization activities; our ability to attract collaborators with development, regulatory and commercialization expertise; our need for and ability to obtain additional financing; our estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; our ability to retain key scientific or management personnel; and other factors discussed under the heading "Risk Factors" contained in our annual report on Form 10-K for the year ended December 31, 2015 filed on February 29, 2016 as well as any updates to these risk factors filed from time to time in our other filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Intercept undertakes no duty to update this information unless required by law.

Contact
For more information about Intercept Pharmaceuticals, please contact:

Mark Vignola
+1-646-747-1000
investors@interceptpharma.com

Christopher Frates
+1-646-757-2371
media@interceptpharma.com