December 17, 2015

FDA Extends PDUFA Date for Obeticholic Acid for the Treatment of PBC

NEW YORK, Dec. 17, 2015 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT), a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic, underserved liver diseases, today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) date for its Priority Review of obeticholic acid (OCA) in primary biliary cirrhosis, recently renamed primary biliary cholangitis (PBC). In response to an information request from the FDA, additional clinical data analyses have been submitted. To provide time for a full review of the submission, the original PDUFA date of February 29, 2016 has been extended by three months, resulting in a new PDUFA date of May 29, 2016. The FDA has also notified Intercept of a planned advisory committee meeting date of April 7, 2016.

Intercept is seeking approval of OCA for the treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

About Primary Biliary Cirrhosis, also known as 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 chronic underserved 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 clinical, preclinical and regulatory developments for Intercept's product candidates; Intercept's potential development and regulatory milestones and the timeframes under which it anticipates such milestones may be achieved, such as the anticipated tentative Advisory Committee meeting date or the approvability of OCA in PBC by the newly designated PDUFA date; the utility of surrogate endpoints and other markers in predicting outcomes in PBC; the ability of past results to predict future results; the clinical utility of our selected endpoint and any potential consensus relating thereto; the sufficiency of our FDA submission package for approval of OCA in PBC; and Intercept's 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 Intercept's development activities, preclinical studies and clinical trials; the timing of and Intercept's ability to obtain and maintain regulatory approval of OCA, INT-767 and any other product candidates it 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; Intercept's plans to research, develop and commercialize its product candidates; the election by Intercept's collaborators to pursue research, development and commercialization activities; Intercept's ability to attract collaborators with development, regulatory and commercialization expertise; Intercept's ability to obtain and maintain intellectual property protection for its product candidates; Intercept's ability to successfully commercialize its product candidates; the size and growth of the markets for Intercept's product candidates and its ability to serve those markets; the rate and degree of market acceptance of any future products; 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; Intercept's need for and ability to obtain additional financing; Intercept's estimates regarding expenses, future revenues and capital requirements and the accuracy thereof; Intercept's ability to retain key scientific or management personnel; and other factors discussed under the heading "Risk Factors" contained in Intercept's annual report on Form 10-K for the year ended December 31, 2014 filed on March 2, 2015 as well as any updates to these risk factors filed from time to time in 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.

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