



October 1, 2013

Additional Results of Global Primary Biliary Cirrhosis Study Group Analysis to be Presented at AASLD Annual Meeting

Data Support Strong Statistical Association of PBC Biochemical Endpoint with Clinical Outcomes

NEW YORK, Oct. 1, 2013 /PRNewswire/ -- Intercept Pharmaceuticals, Inc. (NASDAQ: ICPT)(Intercept), a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver diseases such as primary biliary cirrhosis, today announced that two analyses by the Global Primary Biliary Cirrhosis (PBC) Study Group (also known as the PBC Supergroup) have been accepted for oral presentation at the 64th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), taking place November 1 — 5 in Washington, D.C.

Data from over 3,895 PBC patients collected and pooled by an independent group of 15 academic medical centers across eight countries have been analyzed by the Global PBC Study Group. These analyses are expected to further confirm that the surrogate biochemical endpoint used by Intercept in its ongoing Phase 3 POISE trial (i.e., alkaline phosphatase (ALP) < 1.67x upper limit of normal and normal bilirubin) is strongly predictive of adverse clinical outcomes in PBC patients.

"This international collaboration has assembled data from the largest group of PBC patients to have ever been evaluated since PBC was first described over 150 years ago," commented Dr. Henk van Buuren, one of the principal investigators at Erasmus University Medical Centre. "The data show that abnormal biochemical values predict a higher risk of adverse clinical outcomes. We believe that our results will facilitate the development of new drugs by clearly establishing meaningful biochemical goals for therapy and enable physicians to determine if a given treatment is effective. PBC is a rare disease and we are very grateful to our colleagues at the many participating institutions around the world for sharing their data."

The two abstracts from the Global PBC Study Group can be accessed through the AASLD website, www.aasld.org.

Primary Biliary Cirrhosis and the Global PBC Study Group

PBC is an autoimmune chronic liver disease that typically affects women. The disease progresses in those patients who have an inadequate response to therapy and may require a liver transplant or die. Biochemical assessments of liver function, particularly by measuring plasma levels of ALP and bilirubin, are typically used by physicians to diagnose and manage PBC patients. There is a log-linear relationship between ALP levels and transplant-free survival; higher levels are associated with a worse prognosis. Accordingly, the relationship between these biochemical assessments of liver function and adverse clinical outcomes is highly important in the selection of appropriate endpoints in therapeutic clinical trials.

Data from the Global PBC Study Group are being analyzed under the direction of Dr. Bettina Hansen, Dr. Henk van Buuren and colleagues at Erasmus University Medical Centre in Rotterdam, The Netherlands. Intercept is sponsoring this independent academic research program but is not involved in the data collection and analysis. In April 2013, the Global PBC Study Group presented an analysis of data from over 2,100 patients at the annual meeting of the European Association for the Study of the Liver (EASL). These preliminary data demonstrated that the primary endpoint being used in Intercept's Phase 3 POISE trial is highly statistically predictive of liver transplant-free survival in PBC patients.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat orphan and more prevalent liver diseases utilizing its expertise in bile acid chemistry. The company's lead product candidate, obeticholic acid (OCA), is a bile acid analog and first-in-class agonist of the farnesoid X receptor (FXR). OCA is initially being developed for the second line treatment of primary biliary cirrhosis (PBC) in patients with an inadequate response to, or who are unable to tolerate, ursodiol, the only approved therapy for this indication. OCA has received orphan drug designation in both the United States and Europe for the treatment of PBC. Intercept owns worldwide rights to OCA outside of Japan and China, where it has out-licensed the product candidate to Dainippon Sumitomo Pharma. For more information about Intercept, please visit the Company's website at: www.interceptpharma.com.

Safe Harbor Statement

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 analyses of the Global PBC Study Group data and the results thereof, the relationship between ALP and bilirubin and adverse clinical outcomes, the clinical utility of the POISE trial selected endpoints and any potential consensus relating thereto, clinical, preclinical and regulatory developments for our product

candidates, the anticipated results of our clinical and preclinical trials and other development activities, 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 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 and any other product candidates it may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; Intercept's plans to research, develop and commercialize future 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 ability to obtain additional financing; Intercept's use of the proceeds from its recently completed initial public offering; the accuracy of Intercept's estimates regarding expenses, future revenues, capital requirements and the need for additional financing; the loss of 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 2012, as well as any updates to these risk factors filed from time to time in Intercept's 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.

For more information about Intercept, please contact Barbara Duncan or Senthil Sundaram, both of Intercept Pharmaceuticals, at 1-646-747-1000.

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