April 4, 2014

Data From Intercept's Pivotal Phase 3 POISE Trial of Its FXR Agonist Obeticholic Acid to Treat Primary Biliary Cirrhosis and Other Key Obeticholic Acid Data to be Presented at EASL 2014

NEW YORK, April 4, 2014 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT), a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic liver diseases, today announced presentations of key data at the International Liver Congress 2014, the 49th Annual Meeting of the European Association for the Study of the Liver (EASL), being held in London, UK, at the ExCel Centre from April 9-13, 2014. Intercept will be exhibiting at booth #715 throughout the Congress.

Obeticholic Acid (OCA), Intercept's lead product candidate, is a bile acid analog and first-in-class agonist of the farnesoid X receptor (FXR) in development for primary biliary cirrhosis (PBC), nonalcoholic steatohepatitis (NASH) and other liver and intestinal diseases.

A schedule highlighting key OCA presentations and relevant symposia at and around EASL 2014 follows:

Oral Presentations

- "Obeticholic Acid, A Farnesoid-X Receptor Agonist, Reduces Bacterial Translocation and Restores Intestinal Permeability in a Rat Model of Cholestatic Liver Disease" - Thursday, April 10 at 14:15 in the ICC Auditorium during the General Session I & Opening.

  Len Verbeke, M.D., Department of Hepatology, University Hospital Gasthuisberg, Leuven, Belgium

- "The First Primary Biliary Cirrhosis (PBC) Phase 3 Trial in Two Decades - an International Study of the FXR Agonist Obeticholic Acid in PBC Patients" - Saturday, April 12 at 16:45 in the ICC Auditorium during the Late Breaker Session.

  Frederick Nevens, M.D., Department of Hepatology, University Hospital Gasthuisberg, Leuven, Belgium

  This late breaker presentation will provide new data from the Phase 3 POISE clinical trial. Top-line results, announced on March 16, 2014, showed that OCA met the study's primary endpoint and produced clinically meaningful improvements across a broad range of biochemical liver function parameters.

Poster Presentations

- "Long-Term Treatment of Primary Biliary Cirrhosis with the FXR Agonist Obeticholic Acid Shows Durable Efficacy" - Thursday, April 10, in the Autoimmune and Chronic Cholestatic Liver Disease section.

  Kris Kowdley, M.D., Department of Gastroenterology and Hepatology, Virginia Mason Medical Center

- "The FXR Agonist Obeticholic Acid Improves a Transplant-Free Survival-Proven Biochemical Response Criterion in Placebo Controlled Primary Biliary Cirrhosis Studies" - Thursday, April 10, from 9:00 - 16:00 in the Autoimmune and Chronic Cholestatic Liver Disease section.

  Velimir Luketic, M.D., Department of Gastroenterology, Virginia Commonwealth University Medical Center

Symposia

- "PBC: Past, Present and Future" - Tuesday, April 8, 13:00 - 17:30 at the Royal College of Physicians of London.

  Program includes, Alan Hofmann, M.D., Professor Emeritus University of California San Diego; David E. J. Jones, Newcastle University; Dean of Research and Innovation, Keith Lindor M.D., Executive Vice Provost and Dean, Arizona State University; Henk van Buuren, M.D. Ph.D., Erasmus Medical Center, The Netherlands; Gideon Hirschfield M.D., Senior Lecturer, University of Birmingham, UK.

  This program is hosted by UK-PBC Consortium. For more information and to register, please visit

www.profbriefings.co.uk/ukpbc2014/ukpbcprog.html. Admission is free, if registered.

- "Changing Dynamics in the Science and Clinical Management of Primary Biliary Cirrhosis: What They Mean for Us, What They Mean for Our Patients" - Saturday, April 12, at 18:00 in the Capital Suite 2-3-4.

  Program includes: David E. J. Jones, M.D., Ph.D. Dean of Research and Innovation Newcastle University Newcastle upon Tyne, UK; Ulrich H. W. Beuers, M.D. Professor Department of Gastroenterology & Hepatology Tytgat Institute for Liver and Intestinal Research University of Amsterdam, The Netherlands

  This symposium is supported by an educational grant from Intercept Pharmaceuticals. For more information and to register, please visit www.projectsinknowledge.com. Registration is free.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat orphan and more prevalent liver and intestinal 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 being developed for a variety of chronic liver diseases and patient populations including primary biliary cirrhosis (PBC), nonalcoholic steatohepatitis (NASH), cirrhosis, portal hypertension, alcoholic hepatitis, primary sclerosing cholangitis (PSC) and bile acid diarrhea. OCA has 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 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.

About Primary Biliary Cirrhosis

PBC is an autoimmune liver disease that may progress to cirrhosis and liver failure, and it is currently the fifth leading indication for liver transplant in the United States. It is primarily a disease of women, afflicting approximately one in 1,000 women over the age of 40. Clinically, the progress of the disease is assessed by measuring the blood levels of alkaline phosphatase (ALP) and bilirubin, which have been shown to correlate with risk of adverse outcomes. Ursodiol is the only approved drug treatment for PBC and studies have shown that up to 50% of PBC patients fail to respond adequately, thereby remaining at risk of adverse outcomes.

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, the utility of the selected endpoint for POISE; the acceptance by regulatory authorities of the POISE trial endpoint or results; clinical and regulatory developments for OCA; 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 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 use of the proceeds from its initial public offering in October 2012 and follow-on offering in June 2013; 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, 2013 filed on March 14, 2014 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.

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