April 19, 2017

Intercept Announces New Ocaliva® (obeticholic acid) and INT-767 Data to be Presented at EASL 2017

NEW YORK, April 19, 2017 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT) (Intercept), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced that multiple obeticholic acid, INT-767 and preclinical research abstracts will be presented at the International Liver Congress 2017, the 52nd Annual Meeting of the European Association for the Study of the Liver (EASL), in Amsterdam, the Netherlands, from April 19-23, 2017.

"As our first International Liver Congress following the marketing authorization of Ocaliva for PBC, this represents an important and exciting milestone for our team," said David Shapiro, M.D., Intercept's Chief Medical Officer. "The presentations at this year's meeting provide new insights into Ocaliva's potential effects on long term risk in PBC patients, as well as preclinical findings on the drug's potential impact on cognitive impairment in cholestatic liver disease. Additionally, we will be presenting new preclinical research indicating that activation of the farnesoid X receptor by both steroidal and non-steroidal agonists may cause an increase in LDL-cholesterol."

EASL attendees can visit Intercept at booth 127 (primary booth) and 187 (Medical Affairs booth) throughout the meeting. Presentations at the International Liver Congress include:

Clinical Poster Presentations

"Effect of obeticholic acid treatment in patients with primary biliary cholangitis on categorical shifts in GLOBE score" (Abstract LBP-527)
Maren H. Harms, Willem J. Lammers, Bettina E. Hansen, Marlyn Mayo, Albert Parés, Elizabeth Smoot Malecha, Richard Pencek, Leigh MacConell

"Risk reduction with obeticholic acid in patients not achieving the POISE primary endpoint" (Abstract SAT-378)
Maren Harms, Marco Carbone, Bettina Hansen, George Mells, Richard Pencek, Elizabeth Smoot Malecha, Leigh MacConell

Preclinical Poster Presentations

"Effects of obeticholic acid and INT-767: a comparison of hepatic and ileal drug concentration and gene expression" (Abstract FRI-355)
Jonathan Roth, Michael Feigh, Sanne Veidal, Kristoffer Rigbolt, Jacob Jelsing, Niels Vrang, Weslyn Friley, Mark Young

"Obeticholic acid improves histological, biochemical and gene expression profiles in Gubra AMLN mice with biopsy-confirmed NASH" (Abstract FRI-356)
Jonathan Roth, Michael Feigh, Sanne Veidal, Kristoffer Rigbolt, Mark Young

"Obeticholic acid therapy improves cognitive decline in cholestatic liver disease" (Abstract FRI-396)
Ben Millar, Claire Richardson, Kat McKay, Alexandros Pechlivanis, Barbara Innes, John Kirby, David Jones, Elaine Holmes, Fiona Oakley

"Activation of FXR by steroidal or non-steroidal agonists causes an increase in LDL-cholesterol in mice with humanized chimeric liver" (Abstract SAT-363)
Xueqing Liu, Jingwen Liu, Bin Dong, Jonathan Roth, Mark Young

"Evidence of FXR activation with obeticholic acid in an in vitro intestinal model" (Abstract SAT-420)
Yuanyuan Zhang, Carl LaCerte, Kenneth R. Brouwer, Jonathan P. Jackson, Sanjay Kansra, Jeffrey E. Edwards

A full list of sessions at EASL 2017, including symposia, relating to obeticholic acid is available on the International Liver Congress website.

About Primary Biliary Cholangitis
Primary biliary cholangitis (PBC) is a rare, autoimmune cholestatic liver disease that puts patients at risk for life-threatening complications. PBC is primarily a disease of women, afflicting approximately one in 1,000 women over the age of 40. If left untreated, survival of PBC patients is significantly worse than the general population.

About Ocaliva® (obeticholic acid)
Ocaliva (obeticholic acid) is a potent and highly selective agonist of the farnesoid X receptor (FXR), a nuclear receptor

expressed in the liver and intestine. FXR is a key regulator of bile acid, inflammatory, fibrotic and metabolic pathways.

In December 2016, Ocaliva received conditional marketing authorization in Europe 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, conditional to the company providing further data post-approval to confirm benefit. In May 2016, the U.S. Food and Drug Administration granted accelerated approval to Ocaliva for the treatment of PBC. For full prescribing information in the U.S., visit Ocaliva.com.

EU IMPORTANT SAFETY INFORMATION

Contraindications

Hypersensitivity to the active substance or to any of the excipients and complete biliary obstruction.

Warnings and Precautions

Elevations in alanine amino transferase (ALT) and aspartate aminotransferase (AST) have been observed in patients taking obeticholic acid. Clinical signs and symptoms of hepatic decompensation have also been observed. These events have occurred as early as within the first month of treatment. Liver-related adverse events have primarily been observed at doses higher than the maximum recommended dose of 10 mg once daily. Patients should be monitored during treatment with Ocaliva for elevations in liver biochemical tests and for the development of liver-related adverse events. Dosage adjustments are needed for patients with moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment.

Severe pruritus was reported in 23% of patients treated in the Ocaliva 10 mg arm, 19% of patients in the Ocaliva titration arm and 7% of patients in the placebo arms. The median time to onset of severe pruritus was 11, 158 and 75 days for patients in the Ocaliva 10 mg, Ocaliva titration and placebo arms, respectively. Management strategies include the addition of bile acid binding resins or antihistamines, dose reduction, reduced dosing frequency and/or temporary dose interruption.

Adverse Reactions

The most commonly reported adverse reactions were pruritus (63%) and fatigue (22%). Other common adverse reactions observed in clinical trials (> 5%) were abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality and eczema.

Drug Interaction

Bile acid binding resins such as cholestyramine, colestipol or colesevelam adsorb and reduce bile acid absorption and may reduce efficacy of obeticholic acid. When concomitant bile acid binding resins are administered, obeticholic acid should be taken at least 4-6 hours before or 4-6 hours after taking a bile acid binding resin, or at as great an interval as possible.

For detailed safety information for Ocaliva (obeticholic acid) 5 mg and 10 mg tablets including posology and method of administration, special warnings, drug interactions and adverse drug reactions, please see the European Summary of Product Characteristics.

About Intercept
Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, including primary biliary cholangitis (PBC), nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC) and biliary atresia. Founded in 2002 in New York, Intercept now has operations in the United States, Europe and Canada. Intercept's International headquarters are located in London. For more information about Intercept, please visit 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 relevance and utility of the data on OCA and INT-767 to be presented at EASL, the continued development of OCA, INT-767 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: Intercept's ability to successfully commercialize Ocaliva in PBC, and Intercept's ability to maintain its regulatory approval in jurisdictions in which Ocaliva is approved for use in PBC; the initiation, cost, timing, progress and results of Intercept's development activities, preclinical studies and clinical trials, including Intercept's development program in NASH; the timing of and Intercept's ability to obtain and maintain regulatory approval of OCA in PBC in countries outside the ones in which it is approved and in indications other than PBC and any other product candidates it may develop such as INT-767; conditions that may be imposed by regulatory authorities on Intercept's marketing approvals for its products and product candidates such as the need for clinical outcomes data (and not just results based on achievement of a surrogate endpoint), and any related restrictions, limitations, and/or warnings in the label of any approved products and product candidates; Intercept's plans to research, develop and commercialize its product candidates; Intercept's ability to obtain and maintain intellectual property protection for its products and product candidates;

Intercept's ability to successfully commercialize OCA in indications other than PBC and its other product candidates; the size and growth of the markets for Intercept's products and product candidates and its ability to serve those markets; the rate and degree of market acceptance of any of Intercept's products, which may be affected by the reimbursement that it may receive for its products from payors; the success of competing drugs that are or become available; 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; 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 cash, short-term investments and the proceeds from the offering; Intercept's ability to attract and 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, 2016 filed on March 1, 2017 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.

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