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Intercept's Ocaliva® (obeticholic acid) Receives 2017 Galien Chemical Synthesis Drug Award in Italy

NEW YORK, June 22, 2017 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced that Ocaliva® (obeticholic acid) has been granted the 2017 Premio Galeno Italia (Prix Galien) Chemical Synthesis Drug Award.

The Premio Galeno Italia is one of the most recognized honors in the Italian life sciences industry, and this award reflects the innovation Ocaliva represents as a novel treatment for primary biliary cholangitis (PBC). PBC is a rare autoimmune liver disease that, if left untreated, can progress to hepatic fibrosis, cirrhosis, liver failure, and death unless a patient receives a liver transplant.

For almost 20 years ursodeoxycholic acid (UDCA) was the only approved treatment for PBC; however, a substantial proportion of patients do not adequately respond to UDCA or are intolerant to UDCA. Ocaliva, which is a farnesoid X receptor (FXR) agonist, is indicated to address these patients with high unmet need.

The Scientific Board that awarded the prize stated that Ocaliva is "very innovative both from the point of view of patients and therapeutically" and noted that the mechanism of action is both different and complementary to UDCA, allowing Ocaliva to more directly, and effectively, modulate the molecular and cellular mechanisms which underlie the disease.

The Ocaliva story began in Italy. Professor Roberto Pellicciari and a team of researchers at the University of Perugia pioneered research in the field of bile acid chemistry in the 1990s, which led to the discovery of obeticholic acid. Professor Pellicciari helped found Intercept in 2002 to advance obeticholic acid and discover other molecules under an ongoing collaboration that has underpinned the innovation recognized today.

In May 2016, the U.S. Food and Drug Administration granted accelerated approval to Ocaliva for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA. This was followed in December 2016 by conditional marketing authorization in the European Union and conditional approval in Canada in May 2017 for the same indication.

"We are honored that Ocaliva has been recognized with the 2017 Premio Galeno Italia Chemical Synthesis Drug Award," said Lisa Bright, Intercept's President, International. "This is particularly meaningful for us because the discovery of Ocaliva happened in Italy. We would like to take the opportunity to thank the scientific researchers, clinical investigators, and of course the members of the PBC community for their longstanding partnership and support over the years that successfully brought Ocaliva from bench to bedside."

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 Premio Galeno Italia
In 2017 the Premio Galeno celebrates 25 years in Italy. Springer is the official partner for Premio Galeno Italia since 2012.

The Premio Galeno includes two awards: The Award for Clinical or Experimental Research and The Award for Drug Innovation. The Award for Drug Innovation is assigned to a company that has developed a drug, approved by the European Medicines Agency (EMA) or the Italian Drug Agency AIFA not prior to 2013 (except for the "Special 25th anniversary" award).

The 2017 edition of the Galien Award Italy for Drug Innovation includes the following categories:
1.Chemical synthesis drug award
2.Biological drug award
3.Immunologic drug award
4.Orphan drug award
5.Real-World Evidence (RWE) award — Special 25th anniversary

About Ocaliva® (obeticholic acid)
Ocaliva (obeticholic acid) is an 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. Where approved, Ocaliva is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.

In May 2016, the U.S. Food and Drug Administration granted accelerated approval to Ocaliva for the treatment of PBC. In December 2016, Ocaliva received conditional marketing authorization in the European Union from the European Medicines Authority. In May 2017, Ocaliva was issued a marketing authorization with conditions from Health Canada, pending the results of trials to verify its clinical benefit.

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 with 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 activities anticipated to be undertaken by Intercept regarding Ocaliva® in PBC; the acceptance of Ocaliva as a treatment for PBC by healthcare providers, patients and payors; the anticipated prevalence of and other epidemiological estimates and market data related to PBC, including those related to disease progression; 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: 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; 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 its products and 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 received 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; 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 need for and ability to obtain additional financing; Intercept's estimates regarding expenses, revenues and capital requirements and the accuracy thereof; Intercept's use of cash and short-term investments; 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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