



Intercept Announces Multiple New Ocaliva® (obeticholic acid) Data Presentations at the International Liver Congress™ 2018

March 23, 2018

Late-breaking presentation will feature the first clinical data from a biopsy-based substudy supporting obeticholic acid's ability to reverse or stabilize fibrosis and cirrhosis in primary biliary cholangitis (PBC) patients

NEW YORK, March 23, 2018 (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 (OCA) abstracts, including a late-breaking poster, "Long-Term Obeticholic Acid Treatment Associated with Reversal or Stabilization of Fibrosis/Cirrhosis in Patients with Primary Biliary Cholangitis," will be presented at the International Liver Congress™ 2018, the 53rd Annual Meeting of the European Association for the Study of the Liver (EASL), in Paris, France, from April 11-15, 2018.

"We're very excited to share the first biopsy-based clinical data supporting OCA's ability to reverse or stabilize fibrosis and cirrhosis in patients with PBC," said Christian Weyer, M.D., M.A.S., Intercept's Executive Vice President of Research & Development. "In addition to this important late-breaking poster, the International Liver Congress will also feature new safety analyses from the OCA clinical development program in NASH, the first real-world OCA data from the TARGET-PBC registry, changes in bilirubin and markers of cholestasis following long-term OCA treatment in PBC, and OCA dose selection in pediatric patients with biliary atresia. Finally, a preclinical oral presentation will provide new insights into the effects of steroidal and non-steroidal FXR agonists on cholesterol metabolism."

Congress attendees can visit Intercept at booth 810 (primary booth) and 430 (Medical Affairs booth) throughout the meeting. Presentations at the International Liver Congress include:

Late-Breaking Poster Presentation

"Long-Term Obeticholic Acid Treatment Associated with Reversal or Stabilization of Fibrosis/Cirrhosis in Patients with Primary Biliary Cholangitis"

Christopher Bowlus, Paul Pockros, Andreas Kremer, Albert Parés, Lisa Forman, Joost Drenth, Steve Ryder, Elizabeth Smoot Malecha, Richard Pencek, Uchenna Iloeje, Leigh MacConell, David Shapiro, Pierre Bedossa

Oral Presentation

"Steroidal and Non-Steroidal FXR Agonists Elicit Clinically Relevant Lipoprotein Profiles in Mice with Chimeric Humanized Livers"

Romeo Papazyan, Kristoffer Rigbolt, Rasmus Lind, Michael Feigh, Jingwen Liu, Bin Dong, Emily M. Plummer, Ronald D. Lewis II, Jonathan Roth, Mark Young

Clinical Poster Presentations

"Treatment with Obeticholic Acid in Patients with NASH Does Not Show Increased Markers of Liver Toxicity Based on Evaluation of Drug-Induced Serious Hepatotoxicity (eDISH)"

Arun Sanyal, Paul Pockros, Amrik Shah, Reshma Shringarpure, David Shapiro, Leigh MacConell

"Primary Biliary Cholangitis in the U.S.: Real World Effectiveness of Obeticholic Acid in TARGET-PBC"

Cynthia Levy, Christopher Bowlus, Elizabeth J. Carey, George DeMuth, Karen Deane, Marilyn J. Mayo, W. Ray Kim, Bruce R. Bacon, David Bernstein, PJ Thuluvath, L. Michael Weiss, Uchenna Iloeje, Mary Erickson, Marcie Strauss, Michael W. Fried

"Durable Response in the Markers of Cholestasis through 36 Months of Open-Label Extension Study of Obeticholic Acid in Primary Biliary Cholangitis"

Michael Trauner, Mitchell Shiffman, Joost Drenth, Christopher Bowlus, Victor Vargas, Pietro Andreone, Richard Pencek, Elizabeth Smoot Malecha, Leigh MacConell, David Shapiro

"Change in Bilirubin with Obeticholic Acid Treatment in Primary Biliary Cholangitis Patients with High Baseline Bilirubin: A Retrospective Analysis of POISE, 201, and 202"

Gideon M. Hirschfield, Mitchell Shiffman, Albert Parés, Elizabeth Smoot Malecha, Richard Pencek, Leigh MacConell, David Shapiro

"Disease Severity, Obeticholic Acid Disposition and Dose Selection in Patients with Biliary Atresia"

Jeffrey E. Edwards, Carl LaCerte, Yuanyuan Zhang, Saul J. Karpen, Janet Owens-Grillo, Leigh MacConell

Preclinical Poster Presentations

"Combined Administration of Obeticholic Acid and GFT-505: Additive Histological Improvements in Mice with Diet-induced and Biopsy-confirmed Non-alcoholic Steatohepatitis"

Jonathan Roth, Sanne Veidal, Romeo Papazyan, Kristoffer Rigbolt, Michael Feigh, Mark Young

"Fibrosis Involves Increased Fibroblast and Hepatocyte Collagen Species, Reflecting the Interstitial and Basement Membrane Matrix: Restoration of the Local Tissue Milieu with FXR Agonism"

Jonathan Roth, Sanne Veidal, Romeo Papazyan, Kristoffer Rigbolt, Michael Feigh, Morten Karsdal, Diana Leeming, Mark Young

A full list of sessions at the International Liver Congress 2018, 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 is indicated in the United States 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.

This indication is approved under accelerated approval based on a reduction in alkaline phosphatase (ALP), as a surrogate endpoint which is reasonably likely to predict clinical benefit, including an improvement in liver transplant free-survival. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Intercept is currently enrolling COBALT, a Phase 4 clinical outcomes trial of Ocaliva in patients with PBC with the goal of confirming clinical benefit on a postmarketing basis.

In December 2016, Ocaliva received conditional marketing authorization in Europe 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, conditional to the company providing further data post-approval to confirm benefit. Ocaliva received conditional approval from Health Canada in May 2017.

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. For more information about Intercept, please visit www.interceptpharma.com or connect with the company on [Twitter](#) and [LinkedIn](#).

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements regarding the progress, timing and results of Intercept's clinical trials, including its clinical trials for the treatment of nonalcoholic steatohepatitis ("NASH"), the safety and efficacy of Intercept's approved product, Ocaliva (obeticholic acid or "OCA"), the potential approval of OCA in indications other than primary biliary cholangitis ("PBC") and the timing and potential commercial success of OCA and any other product candidates Intercept may develop.

These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and Intercept undertakes no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by Intercept's management that, although believed to be reasonable, are inherently uncertain and subject to a number of risks. The following represent some, but not necessarily all, of the factors that could cause actual results to differ materially from historical results or those anticipated or predicted by Intercept's forward-looking statements: Intercept's ability to successfully commercialize Ocaliva in PBC; Intercept's ability to maintain its regulatory approval of Ocaliva in PBC in the United States, Europe, Canada and other jurisdictions in which it has or may receive marketing authorization; the initiation, cost, timing, progress and results of Intercept's development activities, preclinical studies and clinical trials, including its clinical trials for the treatment of NASH; the timing of and Intercept's ability to obtain regulatory approval of OCA in indications other than PBC and regulatory approval of any other product candidates it may develop; 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 products or product candidates; Intercept's plans to research, develop and commercialize its products and 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 Intercept's third-party suppliers and manufacturers; Intercept's collaborators' election 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 the other risks and uncertainties identified in Intercept's periodic filings, including Intercept's Annual Report on Form 10-K for the year ended December 31, 2017.

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