Intercept Announces New OCA Data to be Presented at The Liver Meeting® 2018

November 5, 2018

NEW YORK, Nov. 05, 2018 (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 multiple obeticholic acid (OCA) abstracts will be presented at The Liver Meeting® 2018, the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), taking place November 9-13 in San Francisco, California.

"At this year's Liver Meeting, we look forward to sharing new data from our innovative clinical programs, which further our understanding of treatment approaches aimed at impacting the lives of patients with progressive non-viral liver diseases," said Christian Weyer, M.D., M.A.S., Intercept's Executive Vice President, Research & Development. "As we approach the read-out from the interim analysis of our Phase 3 REGENERATE trial in the first half of 2019, we are excited to present abstracts that highlight the depth and breadth of our NASH clinical development program."

Select presentations at The Liver Meeting include:

Oral Presentation:

Sunday, November 11, 2018 – 11:30 a.m. PT

"Obeticholic Acid Was Safe and Well Tolerated in Patients with NASH and Compensated Cirrhosis: A Secondary Analysis of the CONTROL Study" (Abstract #0071)
Dina Halegoua-DeMarzio, Paul Thuluvath, Manal F. Abdelmalek, Courtney Van Biene, Reshma Shringarpure, Leigh MacConell

Poster Presentations:

Sunday, November 11, 2018 – 8 a.m. – 5:30 p.m. PT

"CONTROL: A Randomized, Double-Blind, Placebo-Controlled Phase 2 Study Investigating the Effects of Obeticholic Acid and Atorvastatin Treatment on Lipoprotein Metabolism in Patients with Nonalcoholic Steatohepatitis" (Abstract #1672)
Paul J. Pockros, Michael Fuchs, Bradley Freilich, Eugene Schiff, Anita Kohli, Eric J. Lawitz, Paul A. Hellstern, David E. Cohen, Janet Owens-Grillo, Courtney Van Biene, Reshma Shringarpure, Leigh MacConell, David Shapiro

"Efficacy and Safety of Obeticholic Acid in Patients with Nonalcoholic Steatohepatitis and Significant Fibrosis Using Endpoint Definitions and Populations Accepted for Registrational Studies" (Abstract #1673)
Brent A. Neuschwander-Tetri, Kris V. Kowdley, Arun J. Sanyal, Manal F. Abdelmalek, Norah Terrault, Arthur J. McCullough, Peter Wang, Reshma Shringarpure, Leigh MacConell, David A. Shapiro, Rohit Loomba

"Safety, Pharmacokinetics and Pharmacodynamics of Obeticholic Acid in Subjects with Compensated Cirrhosis due to NASH" (Abstract #1709)
Naim Alkhouri, Jeffrey Edwards, Fred Poordad, Eric Lawitz, Lois Lee, Sharon Karan, Jason Campagna, Leigh MacConell

"Beyond Sirius Red: Collagen Isoforms for Quantitative Histological Analysis of Liver Fibrosis in Preclinical Models of Diet-induced and Biopsy-confirmed Nonalcoholic Steatohepatitis" (Abstract #1760)
Thea Johansen, Denise Oró, Sanne S. Veidal, Michael Feigh, Henrik H. Hansen, Niels Vrang, Mark Young, Jacob Jelsing, Jonathan D. Roth

Monday, November 12, 2018 – 8 a.m. – 5:30 p.m. PT

"Hepatic Safety Overview of Obeticholic Acid for the Treatment of Patients with Primary Biliary Cholangitis" (Abstract #1931)
Paul J. Pockros, Mitchell L. Shiffman, Christopher Bowlus, Arun J. Sanyal, Frederik Nevens, Richard Pencek, David Shapiro, Amrik Shah, Leigh MacConell

"PBC Patient Care Pathway" (Abstract #1886)
Gideon M. Hirschfield, Marco Carbone, Helena Cortez-Pinto, Guilherme Macedo, Victor de Lédinghen, Olivier Chazouilleres, Femi Adekunle

"Characterization of Primary Biliary Cholangitis (PBC) in Canadian Patients" (Abstract #1916)
Eric Yoshida, Robert Bailey, Magdy Elkhashab, Dusanka Grbic, Nir Hilzenrat, Euiseok Kim, Gerald Minuk, Meaghan O'Brien, Kevork Peltekian, Marco Puglia, Alnoor Ramji, Mark Swain, Edward Tam, Cynthia Tsien, Catherine Vincent, Vlad Popovic, Jamie Twiselton, Belinda Yap

A full list of sessions at The Liver Meeting is available on the AASLD website at: www.aasld.org/events-professional-development/liver-meeting.

About Primary Biliary Cholangitis

Primary biliary cholangitis (PBC) is a chronic, progressive liver disorder that mostly affects 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 Nonalcoholic Steatohepatitis

Nonalcoholic steatohepatitis (NASH) is a serious progressive liver disease caused by excessive fat accumulation in the liver that induces chronic inflammation, resulting in progressive fibrosis (scarring) that can lead to cirrhosis, eventual liver failure, cancer and death. There are currently no medications approved for the treatment of NASH. The proportion of liver transplants attributable to NASH has increased rapidly in recent years and as

early as 2020 the disease is projected to become the leading cause of liver transplants in the United States.

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. We are conducting a Phase 4 clinical outcomes trial, which we refer to as our COBALT trial, of OCA in patients with PBC with the goal of confirming clinical benefit on a post-marketing 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, conditioned upon us providing further data post-approval to confirm benefit. For detailed safety information for Ocaliva 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 that can be found on www.ema.europa.eu.

U.S. IMPORTANT SAFETY INFORMATION

WARNING: HEPATIC DECOMPENSATION AND FAILURE IN INCORRECTLY DOSED PBC PATIENTS WITH CHILD-PUGH CLASS B OR C OR DECOMPENSATED CIRRHOSIS

- **In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with Primary Biliary Cholangitis (PBC) with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when OCALIVA was dosed more frequently than recommended.**
- **The recommended starting dosage of OCALIVA is 5 mg once weekly for patients with Child-Pugh Class B or C hepatic impairment or a prior decompensation event.**

Contraindications

OCALIVA is contraindicated in patients with complete biliary obstruction.

Warnings and Precautions

Hepatic Decompensation and Failure in Incorrectly-Dosed PBC Patients with Child-Pugh Class B or C or Decompensated Cirrhosis

In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with decompensated cirrhosis or Child-Pugh B or C hepatic impairment when OCALIVA was dosed more frequently than the recommended starting dosage of 5 mg once weekly. Reported cases typically occurred within 2 to 5 weeks after starting OCALIVA and were characterized by an acute increase in total bilirubin and/or ALP concentrations in association with clinical signs and symptoms of hepatic decompensation (e.g., ascites, jaundice, gastrointestinal bleeding, worsening of hepatic encephalopathy).

Routinely monitor patients for progression of PBC disease, including liver-related complications, with laboratory and clinical assessments. Dosage adjustment, interruption or discontinuation may be required. Close monitoring is recommended for patients at an increased risk of hepatic decompensation. Severe intercurrent illnesses that may worsen renal function or cause dehydration (e.g., gastroenteritis), may exacerbate the risk of hepatic decompensation. Interrupt treatment with OCALIVA in patients with laboratory or clinical evidence of worsening liver function indicating risk of decompensation, and monitor the patient's liver function. Consider discontinuing OCALIVA in patients who have experienced clinically significant liver-related adverse reactions. Discontinue OCALIVA in patients who develop complete biliary obstruction.

Liver-Related Adverse Reactions

Dose-related, liver-related adverse reactions including jaundice, worsening ascites and primary biliary cholangitis flare have been observed in clinical trials, as early as one month after starting treatment with OCALIVA 10 mg once daily up to 50 mg once daily (up to 5-times the highest recommended dosage). Monitor patients during treatment with OCALIVA for elevations in liver biochemical tests and for the development of liver-related adverse reactions.

Severe Pruritus

Severe pruritus was reported in 23% of patients in the OCALIVA 10 mg arm, 19% of patients in the OCALIVA titration arm, and 7% of patients in the placebo arm in a 12-month double-blind randomized controlled trial of 216 patients. Severe pruritus was defined as intense or widespread itching, interfering with activities of daily living, or causing severe sleep disturbance, or intolerable discomfort, and typically requiring medical interventions. Consider clinical evaluation of patients with new onset or worsening severe pruritus. Management strategies include the addition of bile acid resins or antihistamines, OCALIVA dosage reduction, and/or temporary interruption of OCALIVA dosing.

Reduction in HDL-C

Patients with PBC generally exhibit hyperlipidemia characterized by a significant elevation in total cholesterol primarily due to increased levels of high-density lipoprotein-cholesterol (HDL-C). Dose-dependent reductions from baseline in mean HDL-C levels were observed at 2 weeks in OCALIVA-treated patients, 20% and 9% in the 10 mg and titration arms, respectively, compared to 2% in the placebo arm. Monitor patients for changes in serum lipid levels during treatment. For patients who do not respond to OCALIVA after 1 year at the highest recommended dosage that can be tolerated (maximum of 10 mg once daily), and who experience a reduction in HDL-C, weigh the potential risks against the benefits of continuing treatment.

Adverse Reactions

The most common adverse reactions from subjects taking OCALIVA were pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality, and eczema.

Drug Interactions

Bile Acid Binding Resins

Bile acid binding resins such as cholestyramine, colestipol, or colesevelam adsorb and reduce bile acid absorption and may reduce the absorption, systemic exposure, and efficacy of OCALIVA. If taking a bile acid binding resin, take OCALIVA at least 4 hours before or 4 hours after taking the bile acid binding resin, or at as great an interval as possible.

Warfarin

The International Normalized Ratio (INR) decreased following coadministration of warfarin and OCALIVA. Monitor INR and adjust the dose of warfarin, as needed, to maintain the target INR range when coadministering OCALIVA and warfarin.

CYP1A2 Substrates with Narrow Therapeutic Index

Obeticholic acid, the active ingredient in OCALIVA, may increase the exposure to concomitant drugs that are CYP1A2 substrates. Therapeutic monitoring of CYP1A2 substrates with a narrow therapeutic index (e.g. theophylline and tizanidine) is recommended when coadministered with OCALIVA.

Inhibitors of Bile Salt Efflux Pump

Avoid concomitant use of inhibitors of the bile salt efflux pump (BSEP) such as cyclosporine. Concomitant medications that inhibit canalicular membrane bile acid transporters such as the BSEP may exacerbate accumulation of conjugated bile salts including taurine conjugate of obeticholic acid in the liver and result in clinical symptoms. If concomitant use is deemed necessary, monitor serum transaminases and bilirubin.

Please see **Full Prescribing Information, including Boxed WARNING** and **Medication Guide** for OCALIVA.

To report SUSPECTED ADVERSE REACTIONS, contact Intercept Pharmaceuticals, Inc. at 1-844-782-ICPT or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 has operations in the United States, Europe and Canada. For more information, please visit www.interceptpharma.com or connect with the company on Twitter and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements regarding the progress, timing and results of our clinical trials, including our clinical trials for the treatment of nonalcoholic steatohepatitis (“NASH”), the safety and efficacy of our approved product, Ocaliva (obeticholic acid or “OCA”), the potential approval of OCA for indications other than primary biliary cholangitis (“PBC”), the timing and potential commercial success of OCA and any other product candidates we may develop and our strategy, future operations, future financial position, future revenue, projected costs, financial guidance, prospects, plans, objectives of management and expected market growth.

These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “possible,” “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 we undertake no obligation to update any forward-looking statement except as required by law. These forward-looking statements are based on estimates and assumptions by our 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 our forward-looking statements: our ability to successfully commercialize Ocaliva for PBC; our ability to maintain our regulatory approval of Ocaliva for PBC in the United States, Europe, Canada, Israel, Australia and other jurisdictions in which we have or may receive marketing authorization; the initiation, timing, cost, conduct, progress and results of our research and development activities, preclinical studies and clinical trials, including any issues, delays or failures in identifying patients, enrolling patients, treating patients or completing and timely reporting the results of our NASH or PBC clinical trials; our ability to timely and cost-effectively obtain regulatory approval of our product candidates, including OCA for NASH; conditions that may be imposed by regulatory authorities on our marketing approvals for our 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 contained in the label of any of our products or product candidates; any potential side effects associated with Ocaliva for PBC, OCA for NASH or our other product candidates that could delay or prevent approval, require that an approved product be taken off the market, require the inclusion of safety warnings or precautions or otherwise limit the sale of such product or product candidate; our ability to maintain our relationships with, and the performance of, third-party vendors upon whom we are substantially dependent, including contract research organizations for our clinical trials and our third-party suppliers and manufacturers; our ability to identify, develop and commercialize our products and product candidates; our ability to obtain and maintain intellectual property protection for our products and product candidates; our ability to successfully commercialize our product candidates, if approved; the size and growth of the markets for our products and product candidates and our ability to serve those markets; the degree of market acceptance of Ocaliva for PBC and, if approved, OCA for NASH or our other product candidates, which may be affected by the ability of patients and healthcare providers to obtain coverage or reimbursement from payors for our products and the extent to which such coverage or reimbursement is provided; our ability to establish and maintain an effective sales and marketing infrastructure directly or through collaborations with third parties; competition from existing drugs or new drugs that become available; our ability to prevent system failures, data breaches or violations of data protection laws; costs and outcomes relating to any disputes, governmental inquiries or investigations, legal proceedings or litigation, including any securities, intellectual property, employment, product liability or other litigation; our collaborators’ election to pursue research, development and commercialization activities; our ability to attract and

maintain collaborators with development, regulatory and commercialization expertise; our need for and ability to obtain additional financing; our estimates regarding expenses, revenues and capital requirements and the accuracy thereof; our use of cash and short-term investments; our ability to acquire, license and invest in businesses, technologies, product candidates and products; our ability to attract and retain key personnel to manage our business effectively; our ability to manage the growth of our operations, infrastructure, personnel, systems and controls; our ability to obtain and maintain adequate insurance coverage; and the other risks and uncertainties identified in our periodic filings filed with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2017.

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