July 31, 2017

CONTROL Trial Shows Statin Therapy Reversed LDL Increases to Below Baseline Levels in NASH Patients Treated with OCA

- *Low dose atorvastatin rapidly reversed OCA associated LDL changes*

Conference call scheduled for 8:30 am ET

NEW YORK, July 31, 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 results from CONTROL, a placebo-controlled trial to prospectively characterize the lipid metabolic effects of obeticholic acid (OCA) and concomitant statin administration in patients with nonalcoholic steatohepatitis (NASH) with fibrosis or cirrhosis. The CONTROL trial met its primary objective by showing that newly initiated treatment with atorvastatin rapidly reversed OCA-associated increases in LDL to below baseline levels. Most of the effect was observed four weeks after initiation of the lowest available dose of atorvastatin and was sustained throughout the study period.

CONTROL is a 16-week double-blind, placebo-controlled, dose-ranging study of 84 NASH patients with fibrosis and compensated cirrhosis, followed by a two-year long term safety extension (LTSE) open label phase which is currently ongoing. Lipid changes were assessed every four weeks over the course of the double-blind phase. Details of the study design are as follows:

- Statin-naïve or washout patients were randomized to receive one of three doses of OCA (5 mg, 10 mg or 25 mg) or placebo.
- At week four, the lowest approved dose of atorvastatin (10 mg) was added in all patients.
- At week eight, patients were titrated to the next highest prescribed dose of atorvastatin (20 mg).
- At week 12, further titration of atorvastatin (up to 40 mg) was permitted at investigators' discretion.

The study was designed to measure treatment differences within each group relative to baseline. The intent-to-treat (ITT) analysis is shown below and includes all patients who received at least one dose of study medication.

At week four, mean LDL levels increased in each of the OCA treatment groups, while remaining relatively unchanged in the placebo group. The addition of 10 mg of atorvastatin rapidly reversed mean LDL to below baseline levels in all OCA treatment groups at the first assessed time point (week eight), and this effect was sustained through week 16. The observed mean LDL reductions in the OCA groups were approximately 40 — 45 mg/dL while placebo was 48 mg/dL.

(mg/dL)	Placebo (N=21)	OCA 5 mg (N=20)	OCA 10 mg (N=21)	OCA 25 mg (N=22)
Mean LDL at Baseline	118	135	122	126
Mean LDL at Week 4	113	153	141	158
Mean LDL at Week 8 (+ atorvastatin 10 mg)	75	96	91	93
Mean LDL at Week 16 (+ atorvastatin 10 — 40 mg)	70	95	82	85
Mean LDL Change from Baseline at Week 16	-48	-40	-40	-45

The primary efficacy analysis was based on the efficacy evaluable (EE) population, defined as those patients who completed the double-blind phase and received all doses of OCA and atorvastatin (n=67). The overall results for the ITT population were similar to those in the EE population.

Lipid sub-fraction analysis showed that OCA-related increases in LDL were primarily driven by an increase in large buoyant LDL particles rather than small dense LDL particles. Changes in other lipid parameters were similar to those previously reported with OCA therapy in patients with NASH.

Mild to moderate pruritus was the most common adverse event in patients treated with OCA, occurring in 5%, 5%, 10% and 55% in placebo, 5 mg, 10 mg and 25 mg OCA groups, respectively. Two patients discontinued treatment in the 25 mg OCA treatment arm due to pruritus. Co-administration of atorvastatin and OCA was generally well tolerated and did not result in any unexpected safety observations.

The proportion of patients completing the double-blind period was similar across treatment groups (100%, 95%, 90% and 91% for placebo, OCA 5 mg, OCA 10 mg and OCA 25 mg, respectively). Of these patients, 77 of 79 (97%) chose to participate in the LTSE phase.

During the ongoing LTSE phase, there has been one patient death due to acute renal and liver failure. While Intercept determined it could not be ruled out that this was possibly related to treatment, the principal investigator and the independent Data Safety Monitoring Committee determined the death was unlikely related to OCA.

"The majority of NASH patients in CONTROL were statin eligible according to AHA treatment guidelines, and statins are recommended for patients with NASH in both AASLD and EASL treatment guidelines," said David Shapiro, M.D., Chief Medical Officer of Intercept. "In CONTROL, we have shown that statin therapy can have an important role in managing LDL when co-administered with OCA in NASH patients with fibrosis and cirrhosis."

Conference Call on July 31st at 8:30 a.m. ET
Intercept will discuss the CONTROL results during its second quarter 2017 financial results conference call and webcast on July 31st at 8:30 a.m. ET. The live event will be available on the investor page of Intercept's website at http://ir.interceptpharma.com or by calling (855) 232-3919 (toll-free domestic) or (315) 625-6894 (international) five minutes prior to the start time (no passcode is required). A replay of the call will be available on Intercept's website approximately two hours after the completion of the call and will be archived for two weeks.

About CONTROL
CONTROL is a randomized, double-blind, placebo-controlled trial to characterize the lipid metabolic effects of OCA and cholesterol management effects of concomitant statin administration in NASH patients. CONTROL enrolled 84 NASH patients who were naïve to statin therapy or underwent a statin washout, and includes a 16-week double-blind phase followed by an optional two-year long-term safety extension phase.

About 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 past years and by 2020 the disease is projected to become the leading indication for liver transplant.

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.

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 effective management of LDL increases in NASH from OCA treatment with the use of statins, the potential utility of the results from CONTROL, the prevalence of NASH and NAFLD, the association of type 2 diabetes and fibrosis with increased risk in NASH patients, the potential of OCA to treat patients with NASH, 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 potential benefit and commercial potential of 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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