June 12, 2017

Intercept Announces New Data Analysis From FLINT Trial of OCA in NASH Patients with Type 2 Diabetes

- *Post-hoc analysis showed that patients with both type 2 diabetes and NASH had high rates of advanced fibrosis*
- *OCA-treated patients achieved statistically significant improvements in all histologic measures, including fibrosis*
- *New findings presented at the American Diabetes Association's Scientific Sessions*

NEW YORK, June 12, 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 a retrospective analysis of the Phase 2 FLINT trial in patients who had a diagnosis of nonalcoholic steatohepatitis (NASH) and type 2 diabetes. The poster entitled "Improvements in Liver Histology with Obeticholic Acid in Patients with Nonalcoholic Steatohepatitis and Type 2 Diabetes Mellitus" was presented at the American Diabetes Association's 77th Scientific Sessions in San Diego, California. Obeticholic acid (OCA) is an investigational therapy for the treatment of NASH.

Both type 2 diabetes and advanced fibrosis are associated with lower transplant-free survival in patients with NASH. In FLINT, 149 NASH patients (53%) had type 2 diabetes and, within this population, 45% (67/149) had advanced bridging fibrosis (≥F3).

In a retrospective analysis of FLINT patients with a diagnosis of NASH and type 2 diabetes at baseline, a greater percentage of OCA-treated patients achieved the primary endpoint of the trial, a ≥2-point improvement in NAFLD activity score (NAS) without worsening of fibrosis, at week 72 as compared to placebo (57% vs. 21%, $p<0.01$). More than twice as many OCA-treated patients with fibrosis (F1-F3) experienced ≥1 stage of fibrosis improvement as compared to patients in the placebo group (41% vs. 19%, $p<0.05$). This benefit was observed for every fibrosis stage.

OCA treatment resulted in a mean 3.3 kg reduction in body weight from baseline compared to a 0.3 kg increase in the placebo group ($p<0.01$). Most patients (83-89%) were taking concomitant anti-diabetic medications and were generally well controlled at baseline (HbA1c of 7.0-7.2%). OCA administration did not impact glycemic control over the 72-week treatment period (HbA1c unchanged). Changes in liver and lipid biochemistry were similar to findings previously reported in FLINT.

In FLINT the incidence of adverse events in the OCA and placebo arms were similar except for pruritus (23% vs. 6%, $p< 0.0001$). OCA-associated pruritus was mostly mild or moderate and resulted in only one patient discontinuation. The incidence of severe or life-threatening events was not different between the two treatment groups.

"NASH is expected to become the leading indication for liver transplant by 2020, but we currently lack approved treatments to manage the disease," said Arthur J. McCullough, M.D., Department of Gastroenterology and Hepatology, Cleveland Clinic. "These data from the FLINT trial add to our understanding of OCA's potential to help those in the NASH patient population with diabetes who are at the highest risk of progressing to cirrhosis and adverse outcomes."

About FLINT
The Farnesoid X Receptor Ligand Obeticholic Acid in Nonalcoholic Steatohepatitis Treatment (FLINT) trial was sponsored by the National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK). FLINT enrolled 283 adult NASH patients at eight U.S. centers comprising the NIDDK's NASH clinical research network (CRN). Patients were randomized to receive either a 25-mg dose of OCA or placebo for 72 weeks. Patients enrolled in the trial were qualified based on a diagnosis determined by liver biopsy at the start of the trial with a NAFLD Activity Score (NAS) of four or greater and with a score of at least one in each component of the NAS eight point scale (steatosis 0-3, lobular inflammation 0-3, ballooning 0-2). End of trial biopsies were conducted in patients after the 72-week treatment period, with all biopsies centrally scored in a blinded fashion. The results from the FLINT trial were published in *The Lancet* in November 2014.

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 prevalence of NASH and NAFLD, the association of type 2 diabetes and fibrosis with increased risk in NASH patients, the potential utility of the histological primary and secondary endpoints used in FLINT, 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: 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.

Contact
For more information about Intercept Pharmaceuticals, please contact:

Mark Vignola
+1-646-747-1000
investors@interceptpharma.com

Christopher Frates
+1-646-757-2371
media@interceptpharma.com