January 9, 2014

Intercept Provides 2013 Year-End Update and 2014 Anticipated Milestones

NEW YORK, Jan. 9, 2014 (GLOBE NEWSWIRE) -- Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT) (Intercept), today provided a clinical update on obeticholic acid (OCA), a novel bile acid analog and first-in-class agonist of the farnesoid X receptor (FXR), currently being developed in a Phase 3 trial for primary biliary cirrhosis (PBC), as well as Phase 2 trials for several chronic indications including nonalcoholic steatohepatitis (NASH), portal hypertension and bile acid diarrhea (BAD), together with projected 2014 anticipated milestones. Intercept will hold a conference call and audio webcast today at 4:30 p.m. ET to review this information with details provided below.

"2013 was an important year for Intercept as we continued to advance OCA in PBC, NASH and other indications with promising clinical data suggesting that, in keeping with its potent FXR agonist properties, OCA could potentially be used to treat a number of chronic liver and intestinal diseases," said Mark Pruzanski, M.D., Chief Executive Officer of Intercept. "We recently finished the double-blind phase of our Phase 3 POISE trial in PBC and are happy to see that a vast majority of the patients completing the 12 months have opted to cross over to the five year long term safety extension open-label phase of the trial. Together with the FLINT results announced earlier today, Intercept has obtained positive clinical data in all six Phase 2 clinical trials completed to date in five different indications. We're looking forward to a pivotal year in 2014, with clinical data awaited from POISE and FLINT, followed by the anticipated completion of the NDA and MAA filings for PBC by year end."

Summary of Recent Program Updates and 2014 Anticipated Milestones

-- PBC Program:

- POISE Double-Blind Phase Completed; Top-line Results Expected in 2Q 2014
- More than 95% Enrollment into Long-Term Safety Extension of POISE Trial
- Supergroup Final Data Support Utility of POISE Surrogate Endpoint; Phase 3 Confirmatory Trial to be Initiated in 2Q 2014
- NDA and MAA Filings for OCA in PBC Anticipated End of 2014

-- Proof of Concept Trials in Portal Hypertension (PESTO) and Bile Acid Diarrhea (OBADIAH) Completed; Double-Blind Phase 2b Trial in Each Indication to be Initiated in 2H 2014

-- Double-Blind Phase 2 Trial to be Initiated in Primary Sclerosing Cholangitis in 2H 2014

-- Phase 1 Trial for INT-767, Dual FXR and TGR5 Agonist, to be Initiated in 4Q 2014

POISE: Phase 3 Trial in Primary Biliary Cirrhosis

Double-Blind Phase Completed with Strong Enrollment into Long-Term Safety Extension Phase

POISE is a double-blind, placebo-controlled Phase 3 trial evaluating the safety and efficacy of a once daily dose of OCA in PBC patients with an inadequate therapeutic response to, or who are unable to tolerate, ursodiol. In December 2013, the last patient follow-up visit was completed, marking the conclusion of the double-blind phase of the POISE trial. Of the 217 patients randomized, 19 patients (approximately 9%) discontinued early, including seven patients (approximately 3%) who did so due to pruritus. Top-line results from the double-blind phase of the POISE trial are expected to be available in the second quarter of 2014.

Patients completing the double-blind phase have had the option to continue in an open-label, long-term safety extension (LTSE) phase for another five years, during which all patients will receive OCA treatment with daily doses starting at 5 mg and potentially titrating up to 25 mg a day, as clinically indicated. Of the 198 patients who completed the double-blind phase, more than 95% continued in the LTSE phase of the trial.

Global PBC Study Group (Supergroup)

Data from over 6,100 PBC patients collected and pooled by an independent group of 15 academic medical centers across eight countries have been analyzed by the Global PBC Study Group, or Supergroup, and key data were presented at the 2013

AASLD conference by the Supergroup. These and additional analyses confirm that the surrogate biochemical endpoint used in POISE (i.e., alkaline phosphatase (ALP) < 1.67x upper limit of normal (ULN) and normal bilirubin) is strongly predictive of clinical outcomes in PBC patients. Specifically, the analyses demonstrated that patients who failed to meet the POISE trial primary endpoint after one year of ursodeoxycholic acid (UDCA) treatment had approximately two times greater chance of dying or requiring a liver transplant.

Based on these additional analyses, Intercept has submitted a design for its anticipated confirmatory trial to FDA for review. If subsequent discussions result in general agreement concerning the appropriate design of the trial without undue delay, Intercept intends to initiate the confirmatory trial in the second quarter of 2014.

PESTO: Phase 2a Trial in Portal Hypertension

Recently Completed Open-Label Trial Supports Initiation of Double-Blind Trial in Portal Hypertension

PESTO is an open-label, multi-center Phase 2a trial evaluating the safety and efficacy of OCA administered to alcoholic cirrhotic patients for approximately seven days at daily doses of 10 mg and 25 mg for the treatment of portal hypertension. The rationale for the PESTO trial is based on previously published results in animal models of cirrhosis, demonstrating that short term OCA therapy can reverse portal hypertension via a local nitric oxide induced mechanism with no concomitant change in systemic blood pressure.

Preliminary data from PESTO indicate that approximately 50% of patients evaluated for efficacy in the combined dose groups demonstrated a clinically significant reduction in hepatic venous pressure gradient (HVPG) reflective of a lowered risk of variceal bleeds. Systemic mean arterial blood pressure, already adversely low in cirrhotic patients, was unchanged at the end of therapy.

Detailed results obtained by the lead investigator, Raj Mookerjee, M.D., at the primary center (University College London) conducting the PESTO trial have been submitted for presentation at the upcoming International Liver Congress of the European Association for the Study of the Liver (EASL) in April 2014.

Intercept plans to initiate a multi-center, double-blind, placebo-controlled, randomized Phase 2b clinical trial focusing on HVPG as an endpoint in patients with liver cirrhosis and portal hypertension in the second half of 2014.

OBADIAH: Phase 2a Trial in Primary and Secondary Bile Acid Diarrhea

Recently Completed Open-Label Trial Supports Initiation of Double-Blind Trial in Secondary BAD

OBADIAH is an investigator-initiated open-label Phase 2a trial evaluating the safety and efficacy of OCA in the treatment of primary and secondary bile acid diarrhea, with Professor Julian Walters at Imperial College London acting as Principal Investigator. The trial demonstrated that OCA increased levels of fibroblast growth factor 19 (FGF19) with concomitant clinical improvement over a two-week treatment period in patients with primary BAD (pBAD) and in patients with secondary bile acid diarrhea due to Crohn's disease (sBAD), with no response shown in a control group consisting of IBS-D patients with normal FGF19 levels. The data also show that increased length of prior ileal resection reduced response to OCA treatment in Crohn's patients suffering from sBAD.

Detailed results from OBADIAH have been submitted for presentation at Digestive Disease Week in May 2014. Intercept plans to initiate a multi-center, double-blind, placebo-controlled, randomized Phase 2b clinical trial of OCA in Crohn's patients with sBAD in the second half of 2014.

Phase 2 Trial in Primary Sclerosing Cholangitis

Intercept plans to initiate a multi-center, double-blind, placebo-controlled, randomized Phase 2 clinical trial of OCA in primary sclerosing cholangitis (PSC) in the second half of 2014. PSC is a chronic autoimmune liver disease that could eventually lead to cirrhosis, liver failure and death. As with PBC, studies have shown that patients with PSC who have reduced or normal levels of ALP have significantly improved long-term clinical outcomes. Although there is no approved treatment of PSC, patients are commonly treated with ursodiol. The prevalence of PSC is estimated to be approximately one-third that of PBC, with approximately 60% of cases occurring in men and typically 75% of PSC patients also having associated ulcerative colitis.

Phase 1 Trial of INT-767

INT-767 is an orally-administered dual FXR and TGR5 agonist that, similar to OCA, is derived from the primary human bile acid chenodeoxycholic acid (CDCA). This product has been tested in numerous animal models of chronic liver, intestinal and kidney diseases and has demonstrated preclinically potent anti-fibrotic and anti-inflammatory properties. Intercept is completing IND-enabling studies for INT-767, with the intention to submit an IND and initiate Phase 1 trials in the fourth quarter of 2014.

Today's Conference Call and Webcast at 4:30 p.m. ET

Intercept will hold a conference call and audio webcast today at 4:30 p.m. ET. The live event will be available on the investor page of the Intercept website at http://ir.interceptpharma.com or by calling (855) 232-3919 (domestic) or (315) 625-6894 (international) five minutes prior to the start time. A replay of the call will be available on the Intercept website approximately two hours after the completion of the call and will be archived for two weeks.

About Intercept

Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat orphan and more prevalent liver diseases utilizing its expertise in bile acid chemistry. The company's lead product candidate, obeticholic acid (OCA), is a bile acid analog and first-in-class agonist of the farnesoid X receptor (FXR). OCA is initially being developed for the second line treatment of primary biliary cirrhosis (PBC) in patients with an inadequate response to, or who are unable to tolerate, ursodiol, the only approved therapy for this indication. OCA has received orphan drug designation in both the United States and Europe for the treatment of PBC. Intercept owns worldwide rights to OCA outside of Japan and China, where it has out-licensed the product candidate to Dainippon Sumitomo Pharma. For more information about Intercept, please visit the Company's website at: *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, the statements regarding the Company's anticipated outlook and milestones for 2014; potential application of OCA in liver, gastrointestinal and other indications; relationship between the endpoints being investigated and adverse clinical outcomes in the related indication; the clinical utility of the selected endpoints and any potential consensus relating thereto; the acceptance by regulatory authorities of the trial endpoint or results; clinical, preclinical and regulatory developments for our product candidates; the anticipated timeframe for the commencement, completion and receipt of results from Intercept's clinical trials and for the making of regulatory submissions; the anticipated results of our clinical and preclinical trials and other development activities; 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 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 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, INT-767 and any other product candidates it may develop, and any related restrictions, limitations, and/or warnings in the label of any approved product candidates; Intercept's plans to research, develop and commercialize future product candidates; 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 ability to obtain and maintain intellectual property protection for its product candidates; Intercept's ability to successfully commercialize its product candidates; the size and growth of the markets for Intercept's product candidates and its ability to serve those markets; the rate and degree of market acceptance of any future products; 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; Intercept's ability to obtain additional financing; Intercept's use of the proceeds from its initial public offering in October 2012 and follow-on offering in June 2013; the accuracy of Intercept's estimates regarding expenses, future revenues, capital requirements and the need for additional financing; the loss of key scientific or management personnel; and other factors discussed under the heading "Risk Factors" contained in Intercept's annual report on Form 10-K for the year ended December 31, 2012 filed on April 1, 2013 as well as any updates to these risk factors filed from time to time in Intercept's 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: Barbara Duncan or Senthil Sundaram

Intercept Pharmaceuticals

1-646-747-1000

Source: Intercept Pharmaceuticals, Inc.