Intercept Pharmaceuticals Presents Positive Phase II Results from Study of INT-747 Therapy in Primary Biliary Cirrhosis at EASL

Company Also Presents Data on Novel Dual FXR/TGR5 Agonist INT-767

NEW YORK, April 13, 2010 /PRNewswire/ -- Intercept Pharmaceuticals, Inc., today announced the presentation of the results from its recently completed Phase II clinical trial of INT-747 (obeticholic acid) in patients with primary biliary cirrhosis (PBC). The oral presentation will take place during the Opening Session of the 45th Annual Meeting of the European Association for the Study of the Liver **(**EASL 2010**)** on April 15, 2010.

About the INT-747 Phase II Clinical Trial in Patients with PBC

This double blind, placebo controlled, dose response study evaluated INT-747's ability to lower serum alkaline phosphatase (AP) after 12 weeks of treatment in patients with an inadequate response to ursodeoxycholic acid (UDCA) treatment. AP is a validated marker of PBC disease progression and clinical outcome that is routinely used to evaluate the status of PBC patients and response to therapy. The study assessed the efficacy of INT-747 added to ongoing UDCA therapy in patients with AP values ≥1.5x the upper limit of normal (ULN = 117 U/L). Other liver enzymes such as gamma glutamyl transferase (GGT) and alanine aminotransferase (ALT) – general indicators of liver injury and function – were also measured.

The study was conducted at more than 30 centers in eight countries across North America and Europe, the largest PBC study group assembled to date. 165 patients were randomized to one of three doses of INT-747 (10 mg, 25 mg or 50 mg) or placebo taken once daily for 12 weeks with a two-week follow up.

Highlights of the study results are as follows:

- All three doses of INT-747 significantly lowered AP by 21-24.7% with absolute values decreasing by 66-77 U/L compared to a 2.6% (5 U/L) reduction in the placebo group ($p<0.0001$ for all three doses).

- INT-747 reduced GGT by 48-63% in the three treatment groups compared to a 7% increase in the placebo group ($p<0.0001$ for all three doses); similarly, ALT was reduced by 21-35% in the treatment groups with no change for placebo ($p<0.005$ for all three doses).

- Pruritus, a very common symptom in PBC patients, was the notable adverse event with a reported incidence in more than half of all the patients (placebo: 50%, 10 mg: 47%, 25 mg: 85%, 50 mg: 80%); severe pruritus and associated discontinuation rate (placebo: 0%, 10 mg: 8%, 25 mg: 8%, 50 mg: 24%) was dose related and appeared soon after initiation of dosing in susceptible patients.

- In summary, the 10 mg lowest dose of INT-747 showed good efficacy and was well tolerated.

Andrew Mason, MD, the lead investigator in the PBC study and an Associate Professor of Gastroenterology at the University of Alberta, commented, “The consensus of the investigators participating in this study was that a 10% or greater reduction in alkaline phosphatase compared to placebo in these patients would be clinically meaningful. INT-747 more than achieved this at each dose tested within the first two weeks. There is a significant unmet medical need in this disease and INT-747 is the first truly exciting new drug with the potential to make a real difference in the lives of the majority of PBC patients at risk of disease progression.”

Intercept is planning for an end of Phase II meeting with FDA with the goal of initiating a Phase III program in PBC thereafter.

About the Presentations on the Dual FXR/TGR5 Agonist INT-767

In addition, the company will disclose data for its novel dual FXR/TGR5 agonist INT-767 in two poster presentations at the conference. The first, entitled "Functional Characterization of the Semi-synthetic Bile Acid Derivative INT-767, a Dual FXR and TGR5 Agonist", reports INT-767’s characteristics as a potent agonist of FXR and TGR5 that modulates lipid and glucose metabolic pathways via both receptors. The other, “Therapeutic Effects of FXR and TGR5 Activation in the MDR2 (ABCBR) Mouse Model of Sclerosing Cholangitis”, presents evidence of INT-767’s antifibrotic and other hepatoprotective effects in an animal model of primary sclerosing cholangitis, another orphan cholestatic liver disease for which there are no approved drug therapies.

About Primary Biliary Cirrhosis

PBC is a chronic autoimmune liver disease that primarily afflicts Caucasian women (1 in 1,000 women over the age of 40) with an estimated worldwide prevalence of up to 300,000 patients. PBC is a slowly progressive disease that causes substantial loss of intrahepatic bile ducts, resulting in impaired bile flow (cholestasis) and progressive fibrosis that may lead to cirrhosis and liver failure. Despite widespread use of the generic bile acid UDCA to treat PBC, approximately two thirds of patients continue to experience elevated AP levels and the disease remains an important cause of liver transplantation.

About INT-747 (Obeticholic acid, first-in-class FXR agonist)

INT-747 (obeticholic acid) is a potent, first-in-class FXR agonist that is a small molecule bile acid derivative of chenodeoxycholic acid (CDCA), a primary human bile acid and natural endogenous FXR agonist. INT-747 is formulated as an oral drug given once daily. Bile acid signaling through FXR has been shown to regulate the regenerative properties of the liver. In numerous animal models of liver disease INT-747 treatment prevents, and even reverses, liver damage caused by progressive fibrosis (scarring). FXR is also expressed in the intestine and kidney and INT-747 exhibits similar protective antifibrotic effects in animal models of inflammatory bowel disease and diabetic nephropathy.

About Intercept Pharmaceuticals

Intercept is a clinical stage biopharmaceutical company focused on discovering and developing small molecule drugs for the treatment of chronic fibrotic and metabolic diseases. The company's most advanced programs are focused on the development of bile acid derived small molecules that are

selective for FXR, a nuclear receptor, and TGR5, a G protein-coupled receptor. Bile acid signaling via these receptors has been shown to regulate bile, lipid and glucose metabolism, as well as inflammatory and immune responses, suggesting their broad therapeutic potential as novel targets.

For more information about Intercept, please go to www.interceptpharma.com. CONTACT: Mark Pruzanski, M.D., or Barbara Duncan, both of Intercept Pharmaceuticals, +1-646-747-1000