

Intercept Pharmaceuticals to Collaborate with NIDDK on Study of Obeticholic Acid (INT-747) in Nonalcoholic Steatohepatitis (NASH)

NEW YORK, July 28, 2010 /PRNewswire/ -- Intercept Pharmaceuticals, Inc., a clinical stage biopharmaceutical company developing novel therapeutics for chronic fibrotic and metabolic diseases, today announced the signing of a cooperative research and development agreement (CRADA) with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health to conduct a double blind, multi-center, study to evaluate the effects of obeticholic acid in patients with nonalcoholic steatohepatitis (NASH). Obeticholic acid is the generic name for INT-747, Intercept's first-in-class FXR agonist.

The planned study will enroll 280 patients at the eight U.S. centers constituting the NIDDK-sponsored NASH clinical research network (CRN), which will make it the largest study conducted in this disease. The objectives of the 72 week study will be to assess whether obeticholic acid improves histological disease activity and other disease markers, along with the safety of the drug in this patient population. The study is expected to begin in the fourth quarter of 2010 and the NIDDK will provide a majority of the funding needed under the CRADA.

NASH is a more serious form of nonalcoholic fatty liver disease (NAFLD) and occurs in patients who drink little or no alcohol. The disease is believed to be caused by abnormal metabolism of fats and, although it is often associated with obesity and insulin resistance, it also occurs in lean individuals. NASH is associated with fibrosis (scarring) in the liver that may lead to cirrhosis, liver cancer and death, and the disease also carries an additional risk of death due to heart disease. NASH is now the most common liver disease in the developed world, affecting at least 3 percent of the U.S. population, and there is no approved treatment for the disease.

Mark Pruzanski, MD, founder, President and CEO of Intercept, commented, "We are excited to collaborate with the NIDDK and CRN to test our drug in such a robust NASH study. Last year we presented data showing that obeticholic acid improved insulin sensitivity, lowered liver enzymes and induced weight loss in type 2 diabetic patients with NAFLD. These results and the novel mechanism of action of our drug are a promising basis for pursuing NASH".

Pat Robuck, PhD, MPH, the senior advisor for clinical trials in digestive and liver diseases, in the NIDDK's Division of Digestive Diseases and Nutrition, stated, "There is a huge unmet medical need in this patient population. The NIDDK, working together with our NASH CRN investigators, is committed to discovering effective and safe treatments for this serious disease. The preclinical and clinical data obtained so far with obeticholic acid suggest that it has beneficial effects on glucose metabolism and the liver, and the NASH CRN steering committee thinks it warrants rigorous clinical evaluation in NASH".

About Obeticholic Acid (INT-747)

Obeticholic acid is a potent, first-in-class farnesoid X receptor (FXR) agonist derived from the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist. Previously known as INT-747, the drug was recently given the generic name of obeticholic acid. In 2009, the company announced two sets of positive Phase II results from studies in type 2 diabetics with NAFLD and in patients with refractory primary biliary cirrhosis (PBC). These data support obeticholic acid's potential as a novel, hepatoprotective agent in a broad range of chronic liver diseases. Intercept currently plans to advance obeticholic acid into Phase III for PBC, while pursuing additional studies in other indications such as NASH and portal hypertension.

About Intercept Pharmaceuticals

Intercept is a 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 modified bile acids that are selective for FXR, a nuclear receptor, and TGR5, a G protein-coupled receptor. Bile acid signaling through these receptors regulates key aspects of lipid, glucose and overall energy metabolism, while also serving to maintain the functional integrity of the liver, intestine and kidneys, organs that are exposed to bile acid flux.

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