

## **Initiation of FLINT Announced by NIDDK: Study of Intercept Pharmaceuticals Obeticholic Acid**

### **(INT-747) in NASH**

NEW YORK, March 29, 2011 /PRNewswire/ -- Intercept Pharmaceuticals, Inc., has been informed by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health that patient enrollment has started in a new clinical trial in patients with nonalcoholic steatohepatitis (NASH), which will evaluate Intercept's first-in-class farnesoid X receptor (FXR) agonist obeticholic acid (OCA) as a novel therapy for NASH. The FXR Ligand NASH Treatment (FLINT) trial is a double blind, placebo controlled, multi-center clinical study that will evaluate the effects of OCA compared with placebo in adult NASH patients.

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 mortality risk due to heart disease. NASH is now the most common liver disease in the developed world, affecting at least 3-5% of the U.S. population and up to 50% of patients with morbid obesity. There is currently no approved treatment for the disease.

FLINT will enroll 280 patients at the eight U.S. centers comprising the NIDDK-sponsored NASH Clinical Research Network. The primary endpoint in the 72 week study will be determined by liver biopsy and is defined as an improvement in the NAFLD activity score with no worsening of liver fibrosis. NIDDK is providing the majority of funding for the study and is partnering with Intercept under a cooperative research and development agreement (CRADA).

"It is a privilege to be collaborating with this group of leading NASH investigators and the NIDDK," commented David Shapiro, MD, Chief Medical Officer of Intercept. "FLINT has been carefully designed to evaluate the efficacy of OCA in NASH patients and we believe it will be the largest clinical trial conducted to date in this large untreated patient population."

"Past clinical trials of marketed drugs in NASH have been disappointing and an effective therapy is urgently needed," added Mark Pruzanski, MD, Intercept's founder and CEO. "We believe that OCA's mechanism of action as an FXR agonist makes it a very promising candidate and we are excited that the FLINT study has started enrolling patients."

See <http://www.clinicaltrials.gov/ct2/show/NCT01265498?term=NCT01265498&rank=1> for additional information about FLINT.

### **About Obeticholic Acid (OCA or INT-747)**

OCA 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. Intercept has announced positive Phase II results from randomized clinical trials in type 2 diabetics with NAFLD and in patients with primary biliary cirrhosis (PBC), the most common autoimmune liver disease. These clinical data and OCA's mechanism of action support its potential as a novel, hepatoprotective agent in a broad range of chronic liver diseases. Intercept is currently preparing for the initiation of a Phase III PBC program in the U.S. and Europe, 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 liver 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](http://www.interceptpharma.com). CONTACT: Mark Pruzanski, M.D. or Barbara Duncan, both of Intercept, +1-646-747-1000. For information about Intercept's majority shareholder Genextra S.p.A., please go to [www.genextra.it](http://www.genextra.it).