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

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NEW YORK, July 28 /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.

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[1] http://www.bio-medicine.org/medicine-technology-1/Intercept-Pharmaceuticals-to-Collaborate-With-NIDDK-on-Study-of-Obeticholic-Acid--28INT-747-29-in-Nonalcoholic-Steatohepatitis--28NASH-29-9970-1/