Intercept Pharmaceuticals' FXR Agonist INT-747 Meets Primary Endpoint in a Phase II Clinical Trial in Type 2 Diabetic Patients with Nonalcoholic Fatty Liver Disease

Company to Present Data at EASD Plenary Session

NEW YORK, Oct. 1 /PRNewswire/ -- Intercept Pharmaceuticals, Inc., has announced that its first-in-class farnesoid X receptor (FXR) agonist INT-747 has met the primary endpoint of improved insulin sensitization in a 6 week double blind, placebo controlled trial in type 2 diabetic patients with nonalcoholic fatty liver disease (NAFLD).

By employing a euglycemic insulin clamp procedure, the study demonstrated that a single oral daily dose of INT-747 statistically significantly improved glucose disposal rate, consistent with improved hepatic and peripheral insulin sensitivity. Furthermore, patients treated with INT-747 demonstrated statistically significant weight loss and improved biochemical markers of liver function. The compound was well tolerated at the doses tested, with side effects similar to placebo.

Intercept's Chief Medical Officer, David Shapiro, MD, commented, "INT-747 therapy generated several clinically meaningful signals in this first proof of concept study, validating the mechanism of action of FXR activation that we and other groups have described preclinically." Dr. Shapiro is presenting the results of the trial on Friday, Oct. 2, in a plenary session at the European Association for the Study of Diabetes (EASD) annual meeting.

Insulin resistance is an important driver of liver fibrosis, the progressive scarring that can lead to cirrhosis. Based on INT-747's ability to improve insulin sensitivity and other important parameters of liver function in this patient population, Intercept is planning to initiate a Phase II trial in patients with nonalcoholic steatohepatitis (NASH) in 2010. There are an estimated 5 million or more NASH patients in the United States alone with no effective therapeutics currently available.

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 modified bile acids that are selective for FXR, a nuclear receptor, and TGR5, a G protein-coupled receptor. Intercept's lead drug candidate, the FXR agonist INT-747, is currently being advanced for chronic liver disease indications. The company's next candidate in the pipeline, INT-777, is a selective TGR5 agonist being advanced to an IND, projected for the second quarter of 2010.

For more information about Intercept, please go to www.interceptpharma.com, and for information about Intercept's lead investor, Genextra S.p.A., please go to www.genextra.it.

CONTACT: Mark Pruzanski, M.D. or Barbara Duncan, both of Intercept Pharmaceuticals, +1-646-747-1000