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Dainippon Sumitomo Pharma Co., Ltd.
Intercept Pharmaceuticals, Inc.

Dainippon Sumitomo Pharma and Intercept Pharmaceuticals Announce Agreement to Develop and Commercialize Obeticholic Acid (INT-747) for Chronic Liver Disease

OSAKA and NEW YORK, March 30, 2011 /PRNewswire/ -- Dainippon Sumitomo Pharma Co, Ltd. (DSP) and Intercept Pharmaceuticals, Inc. (Intercept) today announced that they have entered into an exclusive licensing agreement for the development and commercialization of Intercept's first-in-class FXR agonist obeticholic acid (OCA, also known as INT-747). DSP will advance OCA in Japan and China for the treatment of chronic liver diseases, with an initial focus on primary biliary cirrhosis (PBC) and nonalcoholic steatohepatitis (NASH). Intercept is currently preparing for the initiation of a Phase III PBC program in the US and Europe and, under the company's cooperative research and development agreement (CRADA) with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a large placebo-controlled trial of OCA in NASH patients recently started enrolling in the US.

Under the terms of the licensing agreement, Intercept will receive an initial payment from DSP of $15 million and will be eligible to receive approximately $300 million in additional milestone payments associated with the successful development and commercialization of OCA. Upon launch of OCA, Intercept will be entitled to receive tiered double-digit royalties from DSP based on sales in its territory. DSP has the exclusive option to add several other Asian countries to its territory, including Korea and Taiwan, and to pursue additional indications. DSP will be responsible for the costs of developing and commercializing OCA in its territory.

"OCA is an important strategic addition to our growing pipeline of hepatology drugs and reflects DSP's strong commitment to specialty therapeutic areas," said Masayo Tada, President and CEO of DSP. "There is a very high unmet medical need in the hepatology area in Asia and DSP's marketed products SUMIFERON®, a natural alpha interferon, and MIRIPLA®, a therapeutic agent for hepatocellular carcinoma, benefit many thousands of liver patients in Japan. We strongly believe that OCA has the potential to significantly add to the treatment options DSP can make available to these patients and are looking forward to working with Intercept to bring OCA to the market as an important new therapy for PBC and the first drug approved for NASH."

"This agreement is an important milestone for our OCA program and provides additional confirmation of our drug's potential," said Mark Pruzanski, MD, President and CEO of Intercept. "We are excited to be partnering in Asia with DSP, given its proven track record in the development and commercialization of drugs in the hepatology area. This collaboration with DSP will provide important development support as we advance OCA in parallel for PBC, NASH and possibly other indications."

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 previously announced positive Phase II results from randomized clinical trials in patients with primary biliary cirrhosis (PBC) and in type 2 diabetics with nonalcoholic fatty liver disease. The clinical data and mechanism of action support OCA's potential as a novel, hepatoprotective agent in a broad range of chronic liver diseases.

About Primary Biliary Cirrhosis (PBC)

PBC is the most common autoimmune chronic liver disease that primarily afflicts women over the age of 40. PBC causes substantial loss of intrahepatic bile ducts, resulting in impaired bile flow (cholestasis) and progressive fibrosis that leads eventually to cirrhosis. It is estimated that there are approximately 50,000 PBC patients in Japan and more than 400,000 in China. Given inadequate treatment options, up to 50% of such patients worldwide continue to be at significant risk of progression to liver transplant or death.

About Nonalcoholic Steatohepatitis (NASH)

NASH is a more serious form of nonalcoholic fatty liver disease (NAFLD) and occurs in patients who drink little or no alcohol. NASH occurs most commonly in obese and insulin resistant patients, but is also seen in lean individuals. In a report of a 5-10 year follow-up study, up to 25% of NASH patients progressed to cirrhosis of the liver. The prevalence of NASH in Japan is estimated to be at least 1% of the adult population and pediatric disease is also becoming more common, while in the US it is estimated that 3-5% of the population has the disease in association with higher obesity rates. There is currently no approved treatment for NASH.

About Intercept Pharmaceuticals, Inc.

Intercept is a biotechnology 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. 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.

About Dainippon Sumitomo Pharma Co., Ltd. (DSP)

DSP is a multi-billion dollar, top-ten listed pharmaceutical company in Japan with a diverse portfolio of pharmaceutical products. DSP aims to produce innovative pharmaceutical products in the central nervous system (CNS) field and other specialty areas. Today, DSP has more than 7,000 employees worldwide. Additional information about DSP is available through its corporate website at http://www.ds-pharma.com/