Intercept Pharmaceuticals Announces Positive Phase II Results for Obeticholic Acid (INT-747) as Monotherapy in Primary Biliary Cirrhosis

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NEW YORK, March 31, 2011 /PRNewswire/ -- Intercept Pharmaceuticals, Inc., today announced positive results from a 59 patient, placebo controlled, double-blind Phase II clinical trial of obeticholic acid (OCA) given as monotherapy to patients with primary biliary cirrhosis (PBC). The study evaluated the effects of 10 mg and 50 mg of OCA compared with placebo in patients with elevated alkaline phosphatase (AP). AP is a liver enzyme routinely used to evaluate the clinical status and disease progression of PBC patients.

At the end of the 12 week treatment period, both doses of OCA produced statistically highly significant reductions in AP, the primary endpoint, compared with the patients receiving placebo (changes: 10mg: -45%; 50mg: -38%; placebo: 0%; $p < 0.0001$ both doses versus placebo). There were also significant improvements in other liver enzymes, including gamma-glutamyl transferase. In addition, serum markers of inflammation and immunity also improved with significant reductions of C-reactive protein (CRP), and immunoglobulin M (IgM), which is closely associated with the autoimmune dysfunction in PBC. Pruritus (itch) was seen more commonly in the OCA treated patients and increased with dose; otherwise, all other adverse events were generally similar across the groups.

PBC is a chronic autoimmune disease of the liver marked by the slow progressive destruction of the small bile ducts within the liver which may lead to liver failure and the need for liver transplantation. PBC primarily afflicts women with up to 300,000 patients estimated in developed countries. There is only one drug approved to treat the disease, ursodeoxycholic acid (UDCA), and up to 50% of PBC patients on UDCA therapy continue to be at significant risk of progression to cirrhosis.

Kris V. Kowdley, MD, Director of the Center for Liver Disease at Virginia Mason Medical Center, in Seattle, Washington and a princ
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