Obeticholic acid produces meaningful biochemical and clinical improvements in PBC cirrhosis patients

April 12 2014

Results from an international Phase III study presented today at the International Liver CongressTM 2014 have shown obeticholic acid (OCA) given to patients suffering from Primary Biliary Cirrhosis (PBC) who previously had an inadequate response to, or have been unable to tolerate ursodeoxycholic acid (UDCA), produced meaningful biochemical and clinical improvements. UDCA is the only therapy currently approved to treat PBC.

Obeticholic acid at both a 10 mg dose and a 5 mg dose titrated to 10 mg, met the trial's primary composite endpoint of achieving a serum alkaline phosphatase (ALP) activity of less than 1.67 times the upper limit of normal (ULN), a total bilirubin within normal limits, and at least a 15% decrease in ALP.

The proportion of patients meeting the primary endpoint was: 47% in the 10 mg OCA group and 46% in the 5-10 mg OCA group vs. only 10% in the placebo group (both dose groups p