

First study in decade provides hope for patients suffering from primary biliary cirrhosis

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Results from an international study presented today at the International Liver Congress have shown Obeticholic Acid (OCA) is a safe and effective treatment in patients suffering from Primary Biliary Cirrhosis (PBC) as demonstrated by substantial decreases in the levels of alkaline phosphatase (AP) enzyme in the blood, a key marker for PBC.

In this double blind parallel group study, 59 patients received 10 or 50mg of OCA or a placebo once a day for 12 weeks. After 12 weeks the 10mg group showed the greatest reduction in AP levels.

PBC is a chronic disease that slowly destroys some of the tubes (bile ducts) linking the liver to the gut. PBC predominantly affects females at a ratio of approximately nine women to every one man. Bile ducts carry bile to the gut but in patients with PBC, bile can no longer flow through effectively and instead builds up in the liver, damaging the <u>liver cells</u> and causing inflammation and scarring. Long-term damage over the years can result in cirrhosis and <u>liver failure</u>.

Daniele Prati, EAS's Scientific Committee Member and Press Committee Chairman commented: "It is extremely encouraging to see that OCA seems to be effective in patients from a variety of countries. This is the first treatment trial in many years for patients with PBC that has shown such promising results. Further studies are needed to evaluate the action of this therapy compared to existing therapies and in larger



patient populations."

OCA, 6-ethyl chenodeoxycholic acid (CDCA) or INT-747, is a novel derivative of CDCA, the natural ligand for the farnesoid-X receptor, a bile acid receptor which is found in the <u>liver</u>.

More information: References

- 1. Kowdley V.K et al. An International Study Evaluating the Farnesopid X Receptor Agonist Obeticholic Acid as Monotherapy in PBC. Presented at The International Liver Congress 2011
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