Trial of fibrate therapy in primary biliary cholangitis shows treatment is well tolerated

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The results of the BEZURSO study, presented today, found that bezafibrate in combination with UDCA normalised prognostic markers of liver disease in patients with primary biliary cholangitis (PBC) with an inadequate response to UDCA. The study, presented at The International Liver Congress 2017 in Amsterdam, The Netherlands, showed that the bezafibrate and UDCA combination therapy was well tolerated, normalised prognostic biochemical parameters, improved fatigue and itching, and prevented progression of liver stiffness and ELF score, which are predictors of liver failure and mortality.1,2

PBC is a chronic autoimmune disease that can damage and eventually destroy bile ducts.3 It is an inflammatory condition which can lead to cirrhosis, liver failure and cancer.3 PBC affects mostly middle-aged women and may progress silently for years; over time, symptoms such as fatigue and itching (pruritus) emerge, often resulting in poor quality of life for patients.3 PBC is a disease that cannot be cured: there is no therapy that can stop its progression. A large proportion of patients respond to the administration of UDCA, which can significantly improve liver function tests, and slow the destruction of bile ducts as well as disease progression.4,5 However, more than 30% of patients do not respond adequately to UDCA treatment, and thus remain at high risk of disease progression which may require a liver transplant, as well as reduced survival rates.6 Additional treatments for these patients are urgently needed.4,5

"This study is the first large randomised trial of fibrates in patients with

PBC who had responded inadequately to UDCA," said Dr Christophe Corpechot, head of the Reference Center for Inflammatory Biliary Diseases, Paris, France, and lead author of the study. "The study provides evidence supporting the use of a combination of fibrates and UDCA in this population, with normalisation of liver function tests, improved symptoms and prevention of liver disease progression."

The BEZURSO study (Bezafibrate in Combination with Ursodeoxycholic Acid in Primary Biliary Cirrhosis) was a randomised, double-blind, placebo-controlled trial of bezafibrate for the treatment of PBC in 100 patients with an incomplete response to UDCA.7 Patients with an inadequate biochemical response to UDCA, as defined by the Paris-2 criteria, were randomised to two years of either bezafibrate 400 mg/day or placebo, in combination with UDCA 13-15 mg/kg/day. Normalisation of liver function tests was the primary endpoint.

The primary endpoint was reached in 15 (30%) patients in the bezafibrate group compared with no patients in the placebo group (p