

## Investigational anti-diabetic may offer potential for management of non-alcoholic fatty liver

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Data presented today at The International Liver Congress 2015 demonstrates that remogliflozin etabonate, an investigational drug in type 2 diabetes, is a potential treatment option for the management of patients with non-alcoholic steatohepatitis (NASH) and non-alcoholic fatty liver disease (NAFLD).

In clinical studies, remogliflozin etabonate was shown to significantly improve insulin sensitivity and beta cell function, as well as reduce body weight and levels of alanine aminotransferase (ALT). In pre-clinical studies, remogliflozin etabonate significantly reduces fat accumulation in the liver and causes a marked reduction in the levels of circulating markers of oxidative stress. Unlike other drugs of its class (SGLT2 inhibitors), remogliflozin etabonate has intrinsic anti-oxidant activity, which may reverse the steatohepatitis and oxidative stress associated with the maintenance and progression of NASH.

The clinical study consisted of 336 treatment-naive subjects with type 2 diabetes and an HbA1c between 7.0% and 9.5%. Subjects were equally randomised to each of the remogliflozin etabonate treatments (50, 100, 250, 500 or 1000 mg twice daily), matching placebo or 30 mg pioglitazone (once daily). At Week 12, remogliflozin etabonate improved insulin sensitivity by 6-33% and beta cell function by 23-43%. Patients receiving remogliflozin etabonate also had significant weight loss (1.4-3.6 kg vs placebo). Importantly, post-hoc analysis of changes in



ALT indicated that remogliflozin etabonate-treated subjects with elevated ALT showed statistically significant (p

"In multiple trials to date, remogliflozin etabonate has been shown to be a safe and potent anti-diabetic compound. In addition to its ability to reverse insulin resistance and cause weight loss, it also uniquely offers intrinsic anti-oxidant activity, which may prove useful in the treatment of patients with NAFLD and NASH," said William Wilkison, Ph.D., COO, Islet Sciences, Inc.

"NAFLD and NASH are both closely associated with diabetes and obesity, and together are now considered the number one cause of liver disease in Western countries. Consequently there is an urgent need for effective treatment options for these diseases. We know that NASH is due, in part, to insulin resistance and oxidative stress resulting from steatosis. Given the mode of action of remogliflozin etabonate, it could potentially offer benefits when treating patients with both NASH and NAFLD," said Professor Markus Peck, Secretary General, European Association for the Study of the Liver.

Provided by European Association for the Study of the Liver

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