



Constipation drug Amitiza improves hepatic markers in NAFLD

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VIENNA — Amitiza was tolerable and improved hepatic markers among patients with nonalcoholic fatty liver disease, according to data presented at the International Liver Congress 2019.

"Lubiprostone (Amitiza, Takeda) is a chloride channel activator <u>approved for</u> <u>the treatment of chronic constipation</u>," **Takaomi Kessoku, MD,** of Yokohama City University in Japan said during his presentation. "Previous human studies have shown that lubiprostone ameliorated gut-permeability induced by NSAIDS in healthy volunteers."

Kessoku and colleagues enrolled 150 patients with NAFLD in the randomized control trial. Patients received 12 g of lubiprostone (n = 47), 24 g of the therapeutic (n = 51), or placebo (n = 41) for 12 weeks.

After 12 weeks of treatment, patients who received 12 g of lubiprostone (P = .0096) and 24 g of lubiprostone (P = .0025) showed significant improvements in mean alanine aminotransferase compared with placebo.

Compared with placebo, treated patients also had significant improvements in lactulose-mannitol ratio (12 g, P = .0125; 24 g, P = .0017), blood endotoxin activity (12 g, P = .0008; 24 g, P = .0002), MRI-PDFF (12 g, P < .001; 24 g, P = .001) and liver stiffness (12 g, P = .0207; 24 g, P = .0002).

In the <u>safety and tolerability analysis</u>, 5% of patients in the placebo group, 0% in the 12 g lubiprostone group, and 9% in the 24 g group had dropped out of the study, which "showed that 24 g of lubiprostone had significantly higher rates of adverse events," Kessoku said (P = .0025), especially diarrhea compared with the other groups.

"These results suggest that manipulating gut permeability may be a promising

novel treatment target for the treatment of NAFLD." - by Talitha Bennett

Reference:

Kessoku T. Abstract GS-01. Presented at: International Liver Congress; April 10-14, 2019; Vienna, Austria.

Disclosures: Kessoku reports financial connections with Mylan EPD.

