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Intercept-Sumitomo completes liver cirrhosis drug's phase II trials

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Tokyo: Intercept Pharmaceuticals Inc has announced the results of a 72-week phase II dose ranging trial of obeticholic acid (OCA), a lead FXR agonist, in adult patients with nonalcoholic steatohepatitis (NASH) in Japan. The trial was conducted by Intercept's collaborator, Sumitomo Dainippon Pharma.

The company indicates that this trial is the first to evaluate the safety and efficacy of OCA in Japanese NASH patients.

The primary efficacy analysis was conducted on an intention to treat (ITT) basis, testing the dose dependent effects of once daily OCA (10mg, 20mg and 40mg) versus placebo on the primary endpoint of a two point improvement in the NAFLD Activity Score (NAS) with no worsening of fibrosis.

The ITT analysis included all randomized patients who received treatment (50 per group), and patients who discontinued or did not have a repeat biopsy were treated as non-responders. A pre-specified completer analysis was conducted on the patients who had biopsies at both baseline and 72 weeks.

The company has observed that the ITT results show a dose dependent increase in the percentage of OCA treated patients compared to placebo who achieved the primary endpoint (p=0.053, not significant).

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The 40mg OCA dose group achieved statistical significance on the primary endpoint compared to placebo (p=0.0496). Dose-dependent trends not reaching statistical significance were also observed for several other pre-specified histologic endpoints, including the proportion of patients with steatosis and inflammation improvement, ballooning resolution and NASH resolution.

NASH is a serious chronic liver disease caused by excessive fat accumulation in the liver that induces chronic inflammation, resulting in progressive fibrosis (scarring) that can lead to cirrhosis, eventual liver failure, cancer and death. There are currently no drug therapies approved for the treatment of NASH. Patients with early disease but with risk factors such as

diabetes, obesity or elevated ALT are at increased risk of progression to cirrhosis.

The proportion of liver transplants attributable to NASH has increased rapidly in past years and by 2020 the disease is projected to become the leading indication for liver transplant ahead of chronic hepatitis C and alcoholic liver disease.