

MEDIA UPDATE • MEDIA UPDATE • MEDIA UPDATE**Novartis data show tropifexor (LJN452) significantly improves several key biomarkers of NASH in patients with moderate to severe fibrosis**

- *The FLIGHT- FXR phase IIb study showed tropifexor, a highly potent non-bile acid FXR agonist, produces robust and dose-dependent reductions in hepatic fat and alanine aminotransferase compared to placebo at 12 weeks¹*
- *These data from the final part of the study (part C) confirm previous interim results and demonstrate the favorable safety profile of tropifexor. Full 48-week biopsy data from the study are expected in Q2 2020¹*
- *It is estimated non-alcoholic steatohepatitis (NASH) affects up to 5% of the population worldwide,^{2,3} but with currently no approved pharmacological treatments, there is a major unmet need*

Basel, November 11, 2019 – Novartis announced positive interim results from the final part of its phase IIb FLIGHT-FXR adaptive design study, assessing the safety, tolerability, and efficacy of tropifexor in patients with biopsy-confirmed stage 2-3 fibrotic non-alcoholic steatohepatitis (NASH). This interim analysis showed higher doses of tropifexor (140 µg and 200 µg) resulted in improvements in several key biomarkers of NASH, including hepatic fat fraction, alanine aminotransferase and body weight, with favorable safety after 12 weeks of treatment. The data will be presented during The Liver Meeting 2019 in Boston this week.

“NASH is a complex disease with currently no approved pharmacological treatments,” said Eric Hughes, Global Development Unit Head, Immunology, Hepatology and Dermatology. “We are encouraged by the results tropifexor has shown in monotherapy while we continue to investigate its potential as a backbone therapy in combination treatments for NASH.”

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