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Pfizer enters into an agreement with Novartis to advance the treatment of NASH

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Joint studies will evaluate one or more of Pfizer's investigational NASH therapies in combination with Novartis's FXR agonist for the treatment of the progressive liver disease

Pfizer Inc. has announced that it has entered into a non-exclusive clinical development agreement with Novartis to investigate one or more combination therapies for the treatment of non-alcoholic steatohepatitis (NASH).

Non-alcoholic steatohepatitis (NASH) is a serious, progressive form of non-alcoholic fatty liver disease caused by a buildup of fat in the liver accompanied by inflammation, liver cell scarring and damage. Due to its lack of symptoms, NASH is often unrecognized and underdiagnosed, but it is believed to affect at least three to five percent of the global adult population. With no currently available treatments, NASH is expected to be the leading cause of liver transplants within the next decade. Pfizer is committed to researching multiple pathways to treat NASH at different stages of its progression with monotherapies, or combinations of medicines, to address different aspects of the disease.

The companies will conduct both non-clinical and Phase 1 clinical studies of Pfizer's investigational therapies, including an Acetyl CoA-Carboxylase (ACC) Inhibitor (PF-05221304, currently in Phase 2), a Diacylglycerol O-Acyltransferase 2 (DGAT2) Inhibitor (PF-06865571, Phase 1) and a Ketohexokinase (KHK) Inhibitor (PF-06835919, Phase 2), together with Novartis's tropifexor, a non-bile acid, Farnesoid X receptor (FXR) agonist.

With three assets in development, and several first-in-class pre-clinical candidates under investigation, Pfizer is building a robust NASH program, which was entirely developed in-house and targets NASH through multiple, diverse pathways of the disease. The collaboration with Novartis helps Pfizer to explore combination approaches at an early stage.

"This is an exciting collaboration with Novartis that furthers our approach to this complex disease by exploring different and potentially complementary mechanisms of action," said Morris Birnbaum, MD, PhD, Senior Vice President and Chief Scientific Officer, Pfizer Internal Medicine. "Our research in NASH dates back more than a decade and stems directly from how we have developed medicines to address conditions that put patients at risk for NASH, including Type 2 diabetes and cardiovascular disease. We are confident that by drawing from our history and deep understanding of the close interplay between metabolic, inflammatory and cardiovascular conditions, we can potentially uncover treatments that truly meet patient

needs.”