



# Pfizer Announces Clinical Development 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

NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE:PFE) announced today that it has entered into a non-exclusive clinical development agreement with Novartis (NYSE: NVS) to investigate one or more combination therapies for the treatment of non-alcoholic steatohepatitis (NASH). 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.”

## About 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.

Pfizer Inc: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at [www.pfizer.com](http://www.pfizer.com). In addition, to learn more, please visit us on [www.pfizer.com](http://www.pfizer.com) and follow us on Twitter at @Pfizer and @Pfizer\_News, LinkedIn, YouTube and like us on Facebook at [Facebook.com/Pfizer](https://www.facebook.com/Pfizer).

**DISCLOSURE NOTICE:** The information contained in this release is as of October 29, 2018. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer’s investigational programs in non-alcoholic steatohepatitis (NASH) and a non-exclusive clinical development

agreement with Novartis to investigate one or more combination therapies for the treatment of NASH, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any jurisdictions for any investigational therapies for the treatment of NASH; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted, and, if approved, whether any such investigational therapies will be commercially successful; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of any investigational therapies for NASH; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at [www.sec.gov](http://www.sec.gov) and [www.pfizer.com](http://www.pfizer.com).

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