Pfizer Advances Development of Once-Daily Formulation of Oral GLP-1 Receptor Agonist Danuglipron

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Clinical evaluation of several modified release once-daily formulations of danuglipron resulted in encouraging pharmacokinetic data for several candidates with one showing the most favorable profileThe company plans to conduct dose optimization studies with a focus on the preferred formulation to inform the registration enabling studies

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced that based on results from the ongoing pharmacokinetic study (NCT06153758), the company has selected its preferred once-daily modified release formulation for danuglipron, an oral glucagon-like peptide-1 (GLP-1) receptor agonist. Pfizer plans to conduct dose optimization studies in the second half of 2024 evaluating multiple doses of the preferred modified release formulation to inform the registration enabling studies.

“Obesity is a key therapeutic area for Pfizer, and the company has a robust pipeline of three clinical and several pre-clinical candidates. The most advanced of them, danuglipron, has demonstrated good efficacy in a twice-daily formulation, and we believe a once-daily formulation has the potential to have a competitive profile in the oral GLP-1 space,” said Mikael Dolsten, MD., PhD., Chief Scientific Officer & President, Pfizer Research and Development. “Following a thorough analysis of our previous Phase 2b data and trial design, we believe that with the preferred modified release formulation and future trial design optimization, we can advance a competitive oral GLP-1 molecule into registration enabling studies, with the goal of addressing the present and persistent medical needs of people living with obesity.”

The ongoing open-label, randomized study is evaluating the pharmacokinetics and safety of immediate- and modified release formulations of danuglipron administered orally in healthy adults 18 years or older. To date, study results have demonstrated a pharmacokinetic profile supportive of once-daily dosing. with a safety profile consistent with prior danuglipron studies including no liver enzyme elevations observed in more than 1,400 study participants.

About Danuglipron

Danuglipron (PF-06882961) is an investigational medicine that is taken as a tablet by mouth and is not approved for use by health authorities at this time. Danuglipron, which was discovered and developed in-house at Pfizer, is a type of investigational medicine known as a GLP-1 receptor agonist. This investigational medicine is intended to keep blood sugar at healthy levels and work by increasing the amount of insulin released. Other potential effects include slowing down the digestion of food and increasing the feeling of fullness after eating, which may be associated with weight loss.

About Pfizer: Breakthroughs That Change Patients' Lives

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, including innovative medicines and vaccines. 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 175 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. In addition, to learn more, please visit us on www.Pfizer.com and follow us on X at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Disclosure Notice

The information contained in this release is as of July 11, 2024. 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 potential future development of once-daily formulation of danuglipron, an investigational oral GLP-1 receptor agonist, including its potential benefits and a planned dose optimization study of the preferred formulation to inform the registration enabling studies, as well as Pfizer’s pipeline of clinical and pre-clinical candidates in the obesity space, 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 endpoints, commencement and/or completion dates for clinical trials (including the planned dose optimization study), regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; uncertainties regarding the future development of danuglipron, including whether or when danuglipron will advance to future studies or phases of development (including the registration enabling studies); the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from the clinical studies; whether and when drug applications for any potential indications for danuglipron may be filed in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications, which will depend on a myriad of factors, including making a determination as to whether the product’s benefits outweigh its known risks and determination of the product’s efficacy and, if approved, whether danuglipron will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety, and/or other matters that could affect the availability or commercial potential of danuglipron; uncertainties regarding the impact of COVID-19 on Pfizer’s business, operations and financial results; 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, 2023 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 and www.pfizer.com.

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