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Pfizer Announces Topline Phase 2b Results of Oral GLP-1R Agonist, Danuglipron, in Adults with Obesity

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- *Danuglipron demonstrated mean placebo-adjusted weight reductions ranging from -8% to -13% at 32 weeks and -5% to -9.5% at 26 weeks*
- *While most common adverse events were mild and gastrointestinal in nature consistent with the mechanism, high rates were observed; no new safety signals were observed*
- *High discontinuation rates, greater than 50%, were seen across all doses compared to approximately 40% with placebo*
- *Ongoing pharmacokinetic study of once-daily formulation of danuglipron will continue, the outcome of which will inform a path forward*
- *At this time, twice-daily danuglipron formulation will not advance into Phase 3 studies*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced topline data from the Phase 2b clinical trial (NCT04707313) investigating its oral Glucagon-like peptide-1 receptor agonist (GLP-1RA) candidate, danuglipron (PF-06882961), in adults with obesity and without type 2 diabetes. The study met its primary endpoint demonstrating statistically significant change in body weight from baseline.

Twice-daily dosing of danuglipron showed statistically significant reductions from baseline in body weight for all doses, with mean reductions ranging from -6.9% to -11.7%, compared to +1.4% for placebo at 32 weeks, and -4.8% to -9.4%, compared to +0.17% for placebo at 26 weeks. Placebo-adjusted reductions in mean body weight ranged from -8% to -13% at 32 weeks and -5% to -9.5% at 26 weeks. Depending on titration schedule, participants were at target dose levels for 6 to 24 weeks.

While the most common adverse events were mild and gastrointestinal in nature consistent with the mechanism, high rates were observed (up to 73% nausea; up to 47% vomiting; up to 25% diarrhea). High discontinuation rates, greater than 50%, were seen across all doses compared to approximately 40% with placebo. No new safety signals were reported and treatment with danuglipron was not associated with increased incidence of liver enzyme elevation compared to placebo. Data from this study will be presented at a future scientific conference or published in a peer-reviewed journal.

“We believe an improved once-daily formulation of danuglipron could play an important role in the obesity treatment paradigm, and we will focus our efforts on gathering the data to understand its potential profile,” said Mikael Dolsten, MD., PhD., Chief Scientific Officer & President, Pfizer Research and Development. “Results from ongoing and future studies of the once-daily danuglipron modified release formulation will inform a potential path forward with an aim to improve the tolerability profile and optimize both study design and execution.”

Future development of danuglipron will be focused on a once-daily formulation, with pharmacokinetic data anticipated in the first half of 2024.

Results previously published in the *Journal of the American Medical Association Network Open* from the Phase 2 study (NCT03985293) of danuglipron in type 2 diabetes showed dose-dependent placebo-adjusted reductions in HbA1c of up to -1.16%; fasting plasma glucose of -33.24 mg/dL; and body weight of -4.17 kg over 16 weeks. Additionally, the Phase 2a study (NCT04617275) of danuglipron in patients with type 2 diabetes who are treated with metformin and in non-diabetic adults with obesity showed robust declines in HbA1c, fasting plasma glucose (FPG) and body weight. In both populations, danuglipron demonstrated a safety and tolerability profile consistent with the mechanism of action.

About Phase 2b Study Design (NCT04707313)

The Phase 2b randomized, double-blind, placebo-controlled, parallel group, dose-ranging study evaluated the efficacy and safety of danuglipron (PF-06882961) administration in adults with obesity and without type 2 diabetes. The study evaluated three cohorts across different fixed titration schedules and target doses. Cohorts 1 and 2 (n=497) evaluated one-week and two-week titration steps over 26 weeks with target doses at 40mg, 80mg, 120mg, 160mg and 200mg twice-daily. Cohort 3 (n=129) evaluated four-week titration steps over 32 weeks with target doses at 80mg, 140mg and 200mg twice-daily. The study utilized a titration protocol where participants were required to follow a fixed titration scheme, according to their randomized treatment group.

About Danuglipron

Danuglipron (PF-06882961) is an experimental 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 medicine known as a GLP-1RA. This medicine is intended to keep blood sugar at healthy levels and work by increasing the amount of insulin released and lowering the amount of glucagon released into the blood. It also slows down the digestion of food and increases the feeling of fullness after eating.

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 170 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 Twitter 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 December 1, 2023. 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 topline data from the Phase 2b clinical trial investigating Pfizer's oral Glucagon-like peptide-1 receptor agonist candidate, danuglipron, in adults with obesity and without Type 2 diabetes, Pfizer's plans to not advance the twice-daily danuglipron formulation into Phase 3 studies at this time and the potential future development of the once-daily danuglipron formulation, 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, 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; 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, 2022 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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