Pfizer Provides Update on Oral GLP-1 Receptor Agonist Danuglipron

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NEW YORK--(BUSINESS WIRE)-- <u>Pfizer Inc.</u> (NYSE: PFE) today announced the decision to discontinue development of danuglipron (PF-06882961), an oral glucagon-like peptide-1 (GLP-1) receptor agonist, which was being investigated for chronic weight management.

Pfizer's dose-optimization studies of once-daily formulations of danuglipron (NCT06567327 and NCT06568731) met key pharmacokinetic objectives and confirmed a formulation and dose with the potential to deliver a competitive efficacy and tolerability profile in Phase 3 testing, based on earlier studies of twice-daily danuglipron. While the overall frequency of liver enzyme elevations across the over 1,400 participant safety database of danuglipron is in-line with approved agents in the class, a single asymptomatic participant in one of the dose-optimization studies experienced potential drug-induced liver injury which resolved after discontinuation of danuglipron. After a review of the totality of information, including all clinical data generated to date for danuglipron and recent input from regulators, Pfizer has decided to discontinue development of the molecule.

"Cardiovascular and metabolic diseases including obesity remain important areas of unmet medical need, and we plan to continue applying our global capabilities to advance a pipeline of investigational treatments that have the potential to fill critical gaps in patient care, including continued development of our oral GIPR antagonist candidate and other earlier obesity programs," said Chris Boshoff, MD, PhD, Chief Scientific Officer and President, Research and Development at Pfizer. "While we are disappointed to discontinue the development of danuglipron, we remain committed to evaluating and advancing promising programs in an effort to bring innovative new medicines to patients."

Data from the danuglipron clinical development program will be presented at a scientific forum or submitted for publication in a peer-reviewed journal in the future.

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 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.news, LinkedIn, YouTube and like us on Facebook at

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Disclosure Notice

The information contained in this release is as of April 14, 2025. 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, among other topics, Pfizer's plans and pipeline of investigational products, including Pfizer's plans for continued development of its oral GIPR antagonist candidate and other earlier obesity programs and 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 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 Pfizer's oral GIPR antagonist candidate, other earlier obesity programs or any other product candidates, including whether or when Pfizer's oral GIPR antagonist candidate, other earlier obesity programs or any such other product candidates will advance to future studies or phases of development; 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 Pfizer's oral GIPR antagonist candidate, other earlier obesity programs or any other product candidates 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 Pfizer's oral GIPR antagonist candidate, other earlier obesity programs or any such other product candidates 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 Pfizer's oral GIPR antagonist candidate, other earlier obesity programs or any such other product candidates; 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, 2024 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 w

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