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# Pfizer Provides Update on GLP-1-RA Clinical Development Program for Adults with Obesity and Type 2 Diabetes Mellitus

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- Pfizer is continuing to advance the first full agonist oral GLP-1-RA candidate danuglipron toward late-state development
- Danuglipron is the largest oral, small molecule GLP-1-RA clinical development program underway with over 1,400 participants enrolled for the treatment of obesity and T2DM
- Ongoing danuglipron Phase 2b study in obesity is fully enrolled
- Second GLP-1-RA candidate lotiglipron to be discontinued

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced its decision to continue to progress one oral late-stage glucagon-like peptide-1 receptor agonist (GLP-1-RA) candidate toward further clinical development for the potential treatment of adults with obesity and Type 2 diabetes mellitus (T2DM). Moving forward, the company will continue advancing the clinical program for danuglipron (PF-06882961), subject to results from the ongoing Phase 2 trial, and discontinue the clinical development of lotiglipron (PF-07081532). The company expects to finalize plans for the danuglipron late-stage program by the end of 2023 and also is developing a once-daily modified release version.

“Building on Pfizer’s small molecule design expertise, we were developing two promising GLP-1-RAs that have shown proof of concept, with the intent of selecting one to advance into further clinical studies. We look forward to analyzing the danuglipron Phase 2 results and selecting the dose and titration schedule that will maximize the therapeutic benefit and safety and tolerability,” said William Sessa, Ph.D., Senior Vice President and Chief Scientific Officer, Internal Medicine, Pfizer. “If successful in clinical trials and approved, danuglipron could be in a prime position to differentiate based on profile, including full receptor agonism, which we believe has the potential to translate to robust efficacy.”

Results previously published in the *Journal of the American Medical Association Network Open* from the Phase 2 study (NCT03985293) of danuglipron in T2DM showed dose-dependent placebo-adjusted reductions (doses ranging from 2.5 mg through 120 mg for 16 weeks) 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. The most common adverse events were nausea, vomiting and diarrhea. The Phase 2b study of danuglipron in non-diabetic obesity participants is currently ongoing (doses ranging from 40 mg through 200 mg for up to 32 weeks) and expected to complete by end of year. The safety profile of danuglipron to date, including transaminase changes, appears to be similar to the peptidic GLP-1R agonist class.

The decision to terminate the clinical development of lotiglipron is based on pharmacokinetic data from Phase 1 drug-drug-interaction studies (C3991040 – NCT05671653 and C3991047 – NCT05788328) and laboratory

measurements of elevated transaminases in these Phase 1 studies as well as the ongoing Phase 2 study C3991004 (NCT05579977). None of these participants reported liver related symptoms or side effects, there was no evidence of liver failure, and none needed treatment.

Such transaminase elevations have not been observed in the over 1,400 patients enrolled in the danuglipron program. Data from these studies evaluating lotiglipron will be presented at a scientific conference or published in peer-reviewed journal(s).

**About Danuglipron and Lotiglipron**

Danuglipron (PF-06882961) and lotiglipron (PF-07081532) are experimental medicines that are not approved for use by health authorities at this time. Both danuglipron and lotiglipron are taken as a tablet by mouth and are a type of medicine known as GLP-1-RA. These medicines are 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. They also slow down the digestion of food and increase 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 June 26, 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 Pfizer's GLP-1RA program and its investigational GLP-1 receptor agonist, danuglipron, including their potential benefits, potential profile, an ongoing Phase 2 trial, plans to continue advancing the clinical program for danuglipron, expectations to finalize the plans for the danuglipron late-stage program by the end of 2023 and a potential once-daily modified release version, 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; 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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