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## A Look at Diabetes Drugs That Reduce the Risk of Cardiovascular Disease

Announcer:

You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:

Welcome to *The Drug Report*. I'm Dr. Linda Bernstein.

On today's episode, we'll focus on some diabetes medications that have achieved or are pending approval for new indications pertaining to cardiovascular disease risk reduction.

Recently, the FDA approved a label expansion based upon a supplemental New Drug Application for Ozempic, a once weekly semaglutide injection. Semaglutide, an analogue of the naturally occurring hormone glucagon-like peptide-1, or GLP-1, is indicated along with diet and exercise to improve blood sugar levels in adults with type 2 diabetes mellitus, and now to reduce cardiovascular disease risk as well. This new indication is for reducing the risk of major adverse cardiovascular events, called MACE, which includes cardiovascular death, non-fatal heart attack, or non-fatal stroke in adults with type 2 diabetes and known heart disease. Todd Hobbs, vice president and U.S. chief medical officer of Novo Nordisk stated, "Today's milestone establishes Ozempic® as an option for patients to help address two critical aspects of managing type 2 diabetes, blood sugar control and cardiovascular risk reduction, in those with known heart disease."

The approval stems from the two-year SUSTAIN 6 cardiovascular outcomes trial which showed that Ozempic significantly lowered the risk of the three-component MACE endpoint, cardiovascular death, non-fatal heart attack or non-fatal stroke, with a relative risk reduction of 26% over placebo when added to standard of care. During the trial, gastrointestinal adverse events occurred more frequently in the Ozempic® group than in the placebo group, but the majority of these side effects were mild to moderate in severity and occurred during the first 30 weeks.

Ozempic was initially approved in December 2017 as a diabetes treatment, entered the market in early 2018, and has since achieved blockbuster status. In the first nine months of 2019, Ozempic reached a billion dollars in global sales. This drug now joins other diabetes medications that carry similar labels indicating cardiovascular risk reduction, including Eli Lilly and Boehringer Ingelheim's Jardiance (or empagliflozin) and AstraZeneca's Farxiga (or dapagliflozin).

AstraZeneca announced in early January that the FDA has accepted a supplemental New Drug Application and granted Priority Review for Farxiga to reduce the risk of cardiovascular death or disease worsening in adults with heart failure and reduced ejection fraction, with and without type-2 diabetes. Farxiga is a first-in-class, oral once-daily selective inhibitor of SGLT2. If granted approval, Farxiga could raise the stakes even further for diabetes medications as a reducer of cardiovascular risk in patients with or without Type 2 diabetes. This submission is based upon the findings of the Phase III DAPA-HF trial published in September 2019 in the *New England Journal of Medicine*, which demonstrated a reduced incidence of cardiovascular death or the worsening of heart failure versus placebo when Farxiga was added to standard of care for heart failure patients.

An oral semaglutide formulation is also making news. Novo Nordisk announced that the prescribing information for oral Rybelsus (or semaglutide) tablets was being updated to include an analysis from the PIONEER 6 cardiovascular outcomes trial, demonstrating cardiovascular safety by meeting the primary endpoint of non-inferiority for MACE. 3.8% of patients experienced at least one MACE with Rybelsus vs. 4.8% with placebo. The cardiovascular risk reduction profile of Rybelsus is under continuing study in the cardiovascular

outcomes trial, SOUL.

Novo Nordisk also revealed that Rybelsus will be covered by Express Scripts, one of the largest US pharmacy benefit managers.

For *The Drug Report*, I'm Pharmacist, Dr. Linda Bernstein.

Announcer:

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