Ozempic® (semaglutide) – New drug approval

- On December 5, 2017, Novo Nordisk announced the FDA approval of Ozempic (semaglutide), as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
    - Ozempic is not recommended as first-line therapy for patients inadequately controlled on diet and exercise because of the uncertain relevance of rodent C-cell tumor findings to humans.
    - Ozempic has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy.
    - Ozempic is not a substitute for insulin. Ozempic is not indicated for use in type 1 DM or treatment of diabetic ketoacidosis, as it would not be effective in these settings.

- Ozempic is a glucagon-like peptide (GLP-1) receptor agonist that reduces blood glucose through a mechanism where it stimulates insulin secretion and lowers glucagon secretion, both in a glucose-dependent manner. The mechanism of blood glucose lowering also involves a minor delay in gastric emptying in the early postprandial phase.

- Ozempic has been studied as monotherapy and in combination with metformin, metformin and sulfonylureas, metformin and/or thiazolidinedione, and basal insulin in patients with T2DM. The efficacy of Ozempic was compared with placebo, Januvia® (sitagliptin), exenatide extended-release (Bydureon®, Bydureon BCise™), and Lantus® (insulin glargine).
    - Ozempic showed clinically meaningful and statistically significant reductions in HbA_{1c} vs. placebo, sitagliptin, exenatide extended-release and insulin glargine.
    - In addition, a cardiovascular outcomes study (SUSTAIN 6) demonstrated no increased risk for major adverse cardiovascular (CV) events (CV death, non-fatal myocardial infarction or non-fatal stroke) with Ozempic vs. placebo (6.6% vs. 8.9%, respectively).

- There are other approved GLP-1 receptor agonists: Trulicity® (dulaglutide), Bydureon, Bydureon BCise, Byetta® (exenatide), Victoza® (liraglutide), and Adlyxin™ (lixisenatide).
    - Byetta is given twice daily.
    - Adlyxin and Victoza are given once daily.
    - Trulicity, Bydureon, and Bydureon BCise are given once weekly.

- Ozempic carries a boxed warning for risk of thyroid C-cell tumors.

- Ozempic is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2 and known hypersensitivity to Ozempic or any of the product components.

- Other warnings and precautions of Ozempic include pancreatitis, diabetic retinopathy complications, never share an Ozempic pen between patients, hypoglycemia with concomitant use of insulin secretagogues or insulin, acute kidney injury, hypersensitivity, and macrovascular outcomes.

- The most common adverse reactions (≥ 5%) with Ozempic use were nausea, vomiting, diarrhea, abdominal pain, and constipation.

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- The recommended starting dose of Ozempic is 0.25 mg subcutaneously (SC) once weekly for 4 weeks. The 0.25 mg dose is intended for treatment initiation and is not effective for glycemic control. After 4 weeks on the 0.25 mg dose, increase the dosage to 0.5 mg SC once weekly.

    — If additional glycemic control is needed after at least 4 weeks on the 0.5 mg dose, the dosage may be increased to the maximum recommended dose of 1 mg once weekly.
    — Administer Ozempic SC to the abdomen, thigh, or upper arm. Instruct patients to use a different injection site each week when injecting in the same body region.

- Novo Nordisk plans to launch Ozempic in the first quarter of 2018. Ozempic will be available as a pre-filled pen-injector containing 2 mg of semaglutide per 1.5 mL. There will be two different pens: one will deliver doses of 0.25 mg or 0.5 mg and the other will deliver doses of 1 mg.