Adlyxin™ (lixisenatide) – New Drug Approval

- On July 28, 2016, the FDA announced the approval of Sanofi and Zealand Pharma's Adlyxin (lixisenatide) injection, as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
    - Adlyxin has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
    - Adlyxin is not a substitute for insulin. Adlyxin is not indicated for use in patients with type 1 diabetes mellitus or for treatment of diabetic ketoacidosis.
    - The concurrent use of Adlyxin with short-acting insulin has not been studied and is not recommended.
    - Adlyxin has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.
- Adlyxin contains lixisenatide, a glucagon-like peptide-1 (GLP-1) receptor agonist, which increases glucose-dependent insulin release, decreases glucagon secretion, and slows gastric emptying.
    - Other GLP-1 receptor agonists for T2DM include Tanzeum® (albiglutide), Trulicity® (dulaglutide), Byetta® (exenatide), Bydureon® (exenatide extended-release), and Victoza® (liraglutide).
- The safety and efficacy of Adlyxin were evaluated in 10 clinical trials enrolling 5,400 patients with T2DM. Adlyxin was evaluated both as monotherapy and in combination with other FDA-approved diabetic medications, including metformin, sulfonylureas, pioglitazone, and basal insulin.
    - Adlyxin improved average blood glucose levels (hemoglobin A1c) in these trials.
- In addition, more than 6,000 patients with T2DM at risk for atherosclerotic cardiovascular disease were treated with either Adlyxin or a placebo in a cardiovascular outcomes trial. Use of Adlyxin did not increase the risk of cardiovascular adverse events in these patients.
- Adlyxin is contraindicated in patients with known hypersensitivity to lixisenatide or to any component of Adlyxin. Hypersensitivity reactions, including anaphylaxis, have occurred with Adlyxin.
- Other warnings and precautions of Adlyxin include pancreatitis, never share Adlyxin pen between patients, hypoglycemia with concomitant use of sulfonylurea or basal insulin, acute kidney injury, immunogenicity, and macrovascular outcomes.
- The most common adverse events (≥ 5%) with Adlyxin were nausea, vomiting, headache, diarrhea, dizziness, and hypoglycemia.
- The recommended starting dose of Adlyxin is 10 mcg subcutaneously once daily for 14 days. On day 15, patients may increase to 20 mcg once daily.
    - Patients should administer Adlyxin within one hour before the first meal of the day, preferably the same meal each day.
    - Discard the pen 14 days after first use.

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- Sanofi's launch plans for Adlyxin are pending. Adlyxin will be available as prefilled pens containing 3 mL of solution. Each pen contains either 50 mcg/mL or 100 mcg/mL and delivers 14 pre-set doses of 10 mcg/dose or 14 pre-set doses of 20 mcg/dose, respectively.

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