Steglatro™ (ertugliflozin), Steglujan™ (ertugliflozin/sitagliptin), Segluromet™ (ertugliflozin/metformin) – New drug approval

- On December 19, 2017, the FDA approved Merck's Steglatro (ertugliflozin), Steglujan (ertugliflozin/sitagliptin), and Segluromet (ertugliflozin/metformin) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
    - Steglujan is indicated when treatment with both ertugliflozin and sitagliptin is appropriate.
    - Segluromet is indicated when patients are not adequately controlled on a regimen containing ertugliflozin or metformin, or in patients who are already treated with both ertugliflozin and metformin.
    - These drugs are not recommended in patients with type 1 diabetes mellitus (T1DM) or for the treatment of diabetic ketoacidosis.
    - Steglujan has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Steglujan.

- Ertugliflozin is the fourth sodium-glucose co-transoporter-2 (SGLT2) inhibitor approved by the FDA. Other marketed SGLT2 inhibitors include Jardiance® (empagliflozin), Farxiga® (dapagliflozin), and Invokana® (canagliflozin).

- The efficacy and safety of ertugliflozin were evaluated in multiple clinical studies involving patients with T2DM. Ertugliflozin was studied as monotherapy and in combination with metformin and/or a dipeptidyl peptidase 4 (DPP-4) inhibitor. Ertugliflozin was also studied in combination with other antidiabetic medications, including insulin and a sulfonylurea, and in T2DM patients with moderate renal impairment.
    - In patients with T2DM, treatment with ertugliflozin, ertugliflozin + sitagliptin, and ertugliflozin + metformin reduced hemoglobin A1c (HbA1c) vs. placebo or the active comparator.
    - In patients with T2DM and moderate renal impairment, treatment with ertugliflozin did not result in a reduction in HbA1c vs. placebo.

- Segluromet carries a boxed warning for lactic acidosis.

- Ertugliflozin is contraindicated in patients with severe renal impairment, end-stage renal disease, or dialysis. Segluromet is contraindicated in patients with metabolic acidosis, including diabetic ketoacidosis.

- Warnings and precautions of ertugliflozin include hypotension, ketoacidosis, acute kidney injury and impairment in renal function, urosepsis and pyelonephritis, lower limb amputation, hypoglycemia with concomitant use with insulin and insulin secretagogues, genital mycotic infections, increases in low-density lipoprotein cholesterol, and macrovascular outcomes.
    - Segluromet also includes vitamin B_{12} levels in the *Warnings and Precautions* section.
    - Steglujan also includes pancreatitis, heart failure, severe and disabling arthralgia, and bullous pemphigoid in the *Warnings and Precautions* section.

- The most common adverse reactions (≥ 5%) associated with ertugliflozin use were female genital mycotic infections.

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- The recommended doses of Steglatro, Steglujan, and Segluromet are as follows:

Product	Starting dose	Titration Schedule*
Steglatro	5 mg once daily	Increase to 15 mg once daily
Steglujan	5 mg ertugliflozin/100 mg sitagliptin once daily	Increase to 15 mg ertugliflozin/100 mg sitagliptin once daily
Segluromet	Individualize based on current regimen†; Dosed twice daily with meals	Dose should not exceed the maximum dose of ertugliflozin 15 mg and metformin 2000 mg

*In those tolerating ertugliflozin and needing additional glycemic control
†Refer to the Segluromet drug label for additional dosing recommendations

- Merck plans to launch Steglatro, Steglujan, and Segluromet in early 2018. Steglatro will be available as 5 mg and 15 mg tablets. Steglujan will be available as ertugliflozin/sitagliptin 5 mg/100 mg and 15 mg/100 mg tablets. Segluromet will be available as ertugliflozin/metformin 2.5 mg/500 mg, 2.5 mg/1000 mg, 7.5 mg/500 mg, and 7.5 mg/1000 mg tablets.