Zituvio™ (sitagliptin) – New drug approval

- On October 20, 2023, Zydus Lifesciences announced the FDA approval of Zituvio (sitagliptin), as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
    - Zituvio is not recommended in patients with type 1 diabetes mellitus.
    - Zituvio 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 Zituvio.
- Sitagliptin is a dipeptidyl peptidase-4 (DPP-4) inhibitor and is also available under the brand name Januvia®. Zituvio shares the same indication as Januvia.
- Warnings and precautions for Zituvio include pancreatitis; heart failure; acute renal failure; hypoglycemia with concomitant use with insulin or insulin secretagogues; hypersensitivity reactions; severe and disabling arthralgia; and bullous pemphigoid.
- The most common adverse reactions (≥ 5%) with Zituvio use were upper respiratory tract infection, nasopharyngitis and headache. In the add-on to sulfonylurea and add-on to insulin studies, hypoglycemia was also more commonly reported in patients treated with Zituvio compared to placebo.
- The recommended dose of Zituvio is 100 mg orally once daily.
- Zydus Lifesciences' launch plans for Zituvio are pending. Zituvio will be available as 25 mg, 50 mg, and 100 mg tablets.