Brynovin™ (sitagliptin) – New drug approval

- On January 16, 2025, the FDA approved Azurity Pharmaceuticals' Brynovin (sitagliptin) oral solution, as an adjunct to diet and exercise to **improve glycemic control in adults with type 2 diabetes mellitus**.
    - Brynovin is not recommended in patients with type 1 diabetes.
    - Brynovin 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 Brynovin.
- Brynovin is the **first oral solution formulation of sitagliptin**. Sitagliptin is also available generically as an oral tablet.
- The effectiveness of Brynovin has been established for glycemic control in patients with type 2 diabetes mellitus based on adequate and well-controlled trials of sitagliptin tablets.
- Warnings and precautions for Brynovin 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 Brynovin use are upper respiratory tract infection, nasopharyngitis and headache. In the add-on to sulfonylurea and add-on to insulin trials, hypoglycemia was also more commonly reported in patients treated with sitagliptin compared to placebo.
- The recommended dose of Brynovin is **100 mg (4 mL) taken orally once daily**.
- Azurity Pharmaceuticals' launch plans for Brynovin are pending. Brynovin will be available as a 25 mg/mL oral solution.