Brenzavvy™ (bexagliflozin) – New drug approval

- On January 23, 2023, TheracosBio announced the FDA approval of Brenzavvy (bexagliflozin), as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
    - Brenzavvy is not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Brenzavvy is a sodium-glucose co-transporter 2 (SGLT2) inhibitor.
- The efficacy of Brenzavvy was established as monotherapy (Trial 1), in combination with metformin in adults with type 2 diabetes mellitus (Trials 2, 3, and 4), and in adults with type 2 diabetes mellitus with established cardiovascular disease (CVD) or at increased risk for CVD (Trial 6).
    - Treatment with Brenzavvy reduced hemoglobin A1c (HbA1c) compared to placebo and efficacy was noninferior to glimepiride (up-titrated to a maximum dose of 6 mg) and Januvia® (sitagliptin) 100 mg once daily.
    - For complete study details, refer to the Brenzavvy drug label.
- Brenzavvy is contraindicated in patients:
    - With hypersensitivity to bexagliflozin or any excipient in Brenzavvy. Anaphylaxis and angioedema have been reported with SGLT2 inhibitors.
    - On dialysis
- Warnings and precautions for Brenzavvy include ketoacidosis, lower limb amputation, volume depletion, urosepsis and pyelonephritis, hypoglycemia with concomitant use with insulin and insulin secretagogues, necrotizing fasciitis of the perineum (Fournier's Gangrene), and genital mycotic infections.
- The most common adverse reactions (> 5%) with Brenzavvy use were female genital mycotic infections, urinary tract infection and increased urination.
- The recommended dosage of Brenzavvy is 20 mg orally taken once daily in the morning.
- TheracosBio's launch plans for Brenzavvy are pending. Brenzavvy will be available as a 20 mg tablet.