Ingrezza® Sprinkle (valbenazine) – New formulation approval

- On April 30, 2024, Neurocrine Biosciences announced the FDA approval of Ingrezza Sprinkle (valbenazine) capsules, for the treatment of adults with:
    - Tardive dyskinesia
    - Chorea associated with Huntington's disease.
- Ingrezza Sprinkle is a new oral granules formulation of Ingrezza capsules. Ingrezza Sprinkle provides an alternative administration option for those who experience dysphagia or have difficulty swallowing.
- Ingrezza Sprinkle carries a boxed warning for depression and suicidal ideation and behavior in patients with Huntington's disease.
- Additional warnings and precautions for Ingrezza Sprinkle include hypersensitivity reactions; somnolence and sedation; QT prolongation; neuroleptic malignant syndrome; and parkinsonism.
- The most common adverse reactions (≥ 5% and twice the rate of placebo) with Ingrezza Sprinkle use for tardive dyskinesia was somnolence and for chorea were somnolence/ lethargy/sedation, urticaria, rash, and insomnia.
- For tardive dyskinesia, the initial dosage for Ingrezza and Ingrezza Sprinkle is 40 mg once daily. After one week, the dose should be increased to the recommended dosage of 80 mg once daily. A dosage of 40 mg or 60 mg once daily may be considered depending on response and tolerability.
- For chorea associated with Huntington's disease, the initial dosage for Ingrezza and Ingrezza Sprinkle is 40 mg once daily. The dose should be increased in 20 mg increments every two weeks to the recommended dosage of 80 mg once daily. A dosage of 40 mg or 60 mg once daily may be considered depending on response and tolerability.
- Neurocrine Biosciences' launch plans for Ingrezza Sprinkle are pending. Ingrezza Sprinkle will be available as a 40 mg, 60 mg, and 80 mg capsule.