Katerzia™ (amlodipine) – New formulation approval

- On July 8, 2019, the FDA approved Silvergate Pharmaceuticals' Katerzia (amlodipine) oral suspension, for:
    - Treatment of hypertension in adults and children 6 years and older, to lower blood pressure
    - Symptomatic treatment of chronic stable angina
    - Treatment of confirmed or suspected vasospastic angina
    - To reduce the risk of hospitalization for angina and to reduce the risk of a coronary revascularization procedure in patients with recently documented coronary artery disease (CAD) by angiography and without heart failure or an ejection fraction < 40%.
- Amlodipine is also available generically as an oral tablet. The tablet formulation carries the same indications as Katerzia.
- Warnings and precautions for Katerzia include hypotension, increased angina or myocardial infarction, and patients with hepatic failure.
- The most common adverse reaction with amlodipine use is edema which occurs in a dose related manner. Other adverse experiences not dose related but reported with an incidence > 1% are fatigue, nausea, abdominal pain, and somnolence.
- The usual initial antihypertensive oral dose of Katerzia in adult patients is 5 mg orally once daily, and the maximum dose is 10 mg once daily. The recommended dose for adult patients with chronic stable or vasospastic angina or CAD is 5 to 10 mg once daily.
- The effective antihypertensive oral dose in pediatric patients ages 6 to 17 years is 2.5 to 5 mg once daily. Doses in excess of 5 mg daily have not been studied in pediatric patients.
    - Silvergate Pharmaceuticals' launch plans for Katerzia are pending. Katerzia will be available as a 1 mg/mL oral suspension