Norliqva® (amlodipine) – New drug approval

- On February 24, 2022, the FDA approved CMP Pharma's Norliqva (amlodipine) oral solution, for:
    - Treatment of hypertension, to lower blood pressure in adults and children 6 years of age and older
    - Symptomatic treatment of chronic stable angina
    - Treatment of confirmed or suspected vasospastic angina
    - Patients with recently documented coronary artery disease by angiography and without heart failure or an ejection fraction < 40%, to reduce the risk of hospitalization for angina and to reduce the risk of a coronary revascularization procedure.
- Amlodipine is also available as a tablet (Norvasc®; generics available) and as an oral suspension (Katerzia®).
- Warnings and precautions for Norliqva include hypotension, increased angina or myocardial infarction, and patients with hepatic failure.
- The most common adverse reactions with amlodipine use were edema, dizziness, flushing and palpitation which occurred in a dose related manner. Other adverse reactions not clearly dose related but reported with an incidence > 1.0% are fatigue and nausea.
- In adults, the usual initial antihypertensive dose of Norliqva is 5 mg orally once daily, and the maximum dose is 10 mg orally once daily. The recommended dose for chronic stable or vasospastic angina is 5 mg to 10 mg orally once daily and most patients will require 10 mg orally once daily for adequate effect. The recommended dose range for patients with coronary artery disease is 5 mg to 10 mg orally once daily and in clinical studies, the majority of patients required 10 mg.
- The effective antihypertensive oral dose in pediatric patients ages 6 years of age and older is 2.5 mg to 5 mg orally once daily. Doses in excess of 5 mg daily have not been studied in pediatric patients.
- CMP Pharma's launch plans for Norliqva are pending. Norliqva will be available as a 1 mg/mL oral solution.