Fleqsuvy™ (baclofen) – New drug approval

- On February 7, 2022, Azurity Pharmaceuticals announced the FDA approval of Fleqsuvy (baclofen) oral suspension, for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.
    - Fleqsuvy may also be of some value in patients with spinal cord injuries and other spinal cord diseases.
    - Fleqsuvy is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.
- Baclofen is currently available orally as a generic tablet and as a brand oral solution (Ozobax®).
- The efficacy of Fleqsuvy is based upon a bioavailability study in healthy adults comparing baclofen oral tablets to Fleqsuvy.
- Warnings and precautions for Fleqsuvy include adverse reactions from abrupt withdrawal of Fleqsuvy; neonatal withdrawal symptoms; drowsiness and sedation; poor tolerability in stroke patients; exacerbation of psychotic disorders, schizophrenia, or confusional states; exacerbation of autonomic dysreflexia; exacerbation of epilepsy; posture and balance effects and ovarian cysts.
- The most common adverse reactions (up to 15% or more) with Fleqsuvy use were drowsiness, dizziness, and weakness.
- Fleqsuvy should be initiated with a low dosage, preferably in divided doses, administered orally. The following gradually increasing dosage regimen is suggested, but should be adjusted based on clinical response and tolerability:
    - 1 mL (5 mg) three times a day for three days
    - 2 mL (10 mg) three times a day for three days
    - 3 mL (15 mg) three times a day for three days
    - 4 mL (20 mg) three times a day for three days
    - Additional increases may be necessary up to the maximum recommended dosage of 80 mg daily (4 mL [20 mg] four times a day).
- Azurity Pharmaceuticals' launch plans for Fleqsuvy are pending. Fleqsuvy will be available as a 25 mg/5 mL oral suspension.