Ozobax™ (baclofen) – New drug approval

- On September 18, 2019, the FDA approved Metacel Pharmaceuticals' Ozobax (baclofen), for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Ozobax may also be of some value in patients with spinal cord injuries and other spinal cord diseases.
    - Ozobax is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.
- Baclofen is also available generically as an oral tablet. The oral tablet formulation shares the same indication as Ozobax.
- The efficacy of Ozobax is based upon a bioavailability study in healthy adults comparing baclofen oral tablets to Ozobax.
- Warnings and precautions for Ozobax include adverse reactions from abrupt withdrawal of Ozobax; 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 Ozobax use were drowsiness, dizziness, and weakness.
- Ozobax 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:
    - 5 mL (5 mg) three times a day for three days
    - 10 mL (10 mg) three times a day for three days
    - 15 mL (15 mg) three times a day for three days
    - 20 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 (20 mg four times a day).
- Metacel Pharmaceuticals' launch plans for Ozobax are pending. Ozobax will be available as a 5 mg/5 mL oral solution.