## Lyvispah™ (baclofen) – New drug approval

- On November 22, 2021, the FDA approved Saol Therapeutics' Lyvispah (baclofen), for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Lyvispah may also be of some value in patients with spinal cord injuries and other spinal cord diseases.
    - Lyvispah 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 Lyvispah is based upon a bioavailability study in healthy adults comparing baclofen oral tablets to Lyvispah.
- Warnings and precautions for Lyvispah include adverse reactions from abrupt withdrawal of Lyvispah; 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 Lyvispah use were drowsiness, dizziness, and weakness.
- The recommended initial dose of Lyvispah is 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 mg three times a day for three days
    - 10 mg three times a day for three days
    - 15 mg three times a day for three days
    - 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). Multiple packets or multiple strengths can be used to achieve the prescribed dosage.
- Saol Therapeutics' launch plans for Lyvispah are pending. Lyvispah will be available as 5 mg, 10 mg, or 20 mg oral granules in packets.