# Discussion Guide

# Lioresal® Intrathecal (baclofen injection)

Communication between you and your treatment team is vital to ensure an optimal outcome. Asking questions to obtain a full understanding of Intrathecal Baclofen (ITB) Therapy℠ with Lioresal® Intrathecal (baclofen injection) and long-term management of severe spasticity is crucial. Starting and maintaining a dialogue between you and your treatment team can help.

1. Have you treated previous patients with Lioresal® Intrathecal and have prior treatments been successful?

2. What are the risks of treatment with Lioresal® Intrathecal?

3. What does the screening trial consist of and what kind of goals should I set for the trial?

4. What should I expect my condition to be like after receiving Lioresal® Intrathecal during a screening test?

5. What does the implant procedure consist of, and will I be able to feel the implanted pump?

6. How will my day-to-day life be affected by treatment with Lioresal® Intrathecal (baclofen injection)?

7. Are there activities I won't be able to do with Lioresal® Intrathecal?

8. What are the potential complications that can occur after implant?

9. Does the pump have to be refilled, and how will I know when it gets empty?

10. Do I need to do any additional therapy after I receive the implant?

# Important Safety Information
## for ITB Therapy℠ with Lioresal® Intrathecal (baclofen injection)

ITB Therapy℠ (Intrathecal Baclofen Therapy) is indicated for use in the management of severe spasticity. Patients should first respond to a screening dose of intrathecal baclofen prior to consideration for long term infusion via an implantable pump. For spasticity of spinal cord origin, ITB Therapy℠ via an implantable infusion system should be reserved for patients unresponsive to oral baclofen or those who experience intolerable CNS side effects at effective doses. Patients with spasticity due to traumatic brain injury should wait at least one year after the injury before consideration of long term intrathecal baclofen therapy.

**Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.**

**Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g., spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional postimplant clinician and patient information (see WARNINGS).**

This therapy is contraindicated in patients who are hypersensitive to baclofen. Implantation of the infusion system is contraindicated if the patient is of insufficient body size, requires a pump implant deeper than 2.5 cm, or, in the presence of spinal anomalies or active infection.

The most frequent drug adverse events vary by indication but include: hypotonia (34.7%), somnolence (20.9%), headache (10.7%), convulsion (10.0%), dizziness (8.0%), urinary retention (8.0%), nausea (7.3%), and paresthesia (6.7%). Pump system component failures leading to pump stall, or dosing/programming errors may result in clinically significant overdose or underdose. Acute massive overdose may result in coma and may be life-threatening.

The most frequent and serious adverse events related to device and implant procedures are catheter dislodgement from the intrathecal space, catheter break/cut, and implant site infection including meningitis. Electromagnetic interference (EMI) and magnetic resonance imaging (MRI) may cause patient injury, system damage, operational changes to the pump, and changes in flow rate.

Please refer to the full Lioresal® Intrathecal prescribing information, located in the booth, and the SynchroMed™ infusion system information for details.

For more information, including **BOX WARNING**, refer to Lioresal® Intrathecal (baclofen injection) prescribing information located on www.lioresalrx.com.

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SAOL THERAPEUTICS