ZTlido™ (lidocaine topical system) – New drug approval

- On February 28, 2018, Sorrento Therapeutics and Scilex Pharmaceuticals announced the FDA approval of ZTlido (lidocaine topical system) 1.8% for the relief of pain associated with post-herpetic neuralgia (PHN).

- Because of the difference in bioavailability of ZTlido compared to Lidoderm® (lidocaine patch) 5%, a different dosage strength is required to be administered to the patient. One ZTlido 1.8% topical system provides equivalent lidocaine exposure to one Lidoderm 5% patch.

- The efficacy of ZTlido was demonstrated in two clinical studies comparing lidocaine patch to vehicle patch in patients with PHN.

    - A study of 35 patients demonstrated that treatment with a single dose of lidocaine patch had improvements in pain intensity from 4 to 12 hours vs. those treated with vehicle patch.
    - A multi-dose study of 32 patients demonstrated that treatment with lidocaine patch had statistically significant differences in terms of time to exit from the trial (14 vs. 3.8 days, $p < 0.001$), daily average pain relief, and patient's preference of treatment vs. those treated with vehicle patch.
- ZTlido adhesion performance was demonstrated in a clinical study of 54 patients, where 87% had adhesion scores of 0 (≥ 90% adhered) for all evaluations performed every 3 hours during the 12 hours of administration, and 13% had adhesion scores of 1 (≥ 75% to < 90% adhered) for at least one evaluation, and no subjects had scores of ≥ 2 (< 75% adhered).

- ZTlido is contraindicated in patients with a known history of sensitivity to local anesthetics of the amide type, or to any other component of the product.

- Warnings and precautions of ZTlido include accidental exposure, excessive dosing/overexposure to lidocaine, application site reactions, and eye exposure.

- Common adverse reactions associated with ZTlido use were application site reactions, such as irritation, erythema, and pruritus.

- The prescribed number of ZTlido topical systems should be applied to intact skin to cover the most painful area. A maximum of 3 topical systems may be used once for up to 12 hours within a 24-hour period (12 hours on and 12 hours off).

    - When ZTlido is used concomitantly with other products containing local anesthetic agents, the total amount of drug absorbed from all formulations must be considered.
    - Smaller areas of treatment are recommended in a debilitated patient, or a patient with impaired elimination.
    - Refer to the ZTlido prescribing information for further storage, application, removal, and disposal instructions.

- Sorrento Therapeutics and Scilex Pharmaceuticals plan to launch ZTlido in 2018. ZTlido will be available as a 1.8% topical system.