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Session SAPP16-2 - Regional Anesthesia and Acute Pain II - Paper Posters (Non-CME)

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A2074. A Phase 3, Single-Arm Study of Suzetrigine, a Non-Opioid, Pain Signal Inhibitor For Treatment of Acute Pain From Surgical and Non-surgical Conditions

October 19, 2024, 10:00 AM - 11:30 AM | Exhibit Hall

Authors

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Abstract

Background: Moderate to severe acute pain is a common condition that arises from multiple causes (e.g., injury, illness, surgery), yet there are currently limited treatment options with a favorable benefit-risk profile. A potential therapeutic target for moderate to severe acute pain is the voltage-gated sodium channel 1.8 ($Na_V1.8$), which plays a key role in pain signaling based on its selective expression on the peripheral nociceptors and within dorsal root ganglia. Suzetrigine (SUZ; VX-548) is an oral, small molecule that is a potent and highly selective inhibitor of $Na_V1.8$ with no misuse potential. In two phase 3, randomized, placebo-controlled trials, SUZ demonstrated statistically

significant improvements in pain compared to placebo and clinically meaningful reductions in pain from baseline in the 48 hours following abdominoplasty and bunionectomy. To expand on these findings, we further evaluated the safety and effectiveness of SUZ for moderate or severe acute pain in a broad population including postoperative surgical patients and non-surgical patients with painful medical conditions.

Methods: This phase 3, single-arm study enrolled adults (18 to 80 years) with moderate or severe acute pain on the verbal categorical rating scale (VRS) and ≥4 on the numeric pain rating scale (NPRS; range, 0 to 10) following a scheduled surgical procedure or after presenting to a medical facility with moderate to severe acute pain of new origin (occurring within the prior 48 hours and not related to a prior known condition). Participants received SUZ (100 mg first dose, then 50 mg every 12 hours) for 14 days or until their pain resolved, whichever occurred first. The primary objective was to evaluate safety. The secondary objective was to evaluate the effectiveness of SUZ in treating acute pain at the end of treatment using a patient global assessment (PGA).

Results: A total of 256 participants (surgical: n = 222; non-surgical: n = 34) received SUZ. The most common surgical procedures were orthopedic (41.9%), plastic (37.4%), and otorhinolaryngologic (10.8%); the most common non-surgical conditions were sprains and strains of upper and lower extremities. SUZ was generally safe and well tolerated in participants with surgical and non-surgical acute pain. The majority of AEs were mild or moderate in severity; the only AE occurring in ≥5% of participants was headache (incidence: 7.0%). There were no serious AEs related to SUZ. Most participants (83.2%) rated the effectiveness of SUZ for treating pain on a PGA as good, very good, or excellent at the end of treatment.

Conclusions: These results demonstrate the safety and effectiveness of SUZ, a pain signal inhibitor that selectively inhibits $Na_V1.8$, for the treatment of a broad range of surgical and non-surgical acute pain conditions. SUZ has the potential to be a safe and effective non-opioid treatment option for various causes of moderate to severe acute pain and the potential to be the first drug in a new class of pain medicines in ~20 years.
