Journavx™ (suzetrigine) – New drug approval

- On January 30, 2025, the FDA announced the approval of Vertex's Journavx (suzetrigine), for the **treatment of moderate to severe acute pain in adults**.

- Journavx is a **first-in-class, non-opioid analgesic**. Journavx reduces pain by targeting a pain-signaling pathway involving sodium channels (NaV1.8) in the peripheral nervous system, before pain signals reach the brain.

- Journavx could be attractive to both prescribers and patients because it is not a controlled substance and has low potential for abuse. It would be an alternative to opioids for short-term acute pain, even though it has not demonstrated superiority vs. opioids for pain relief.

- The efficacy of Journavx was established in two randomized, double-blind, placebo and active-controlled studies of acute pain, one following full abdominoplasty (Trial 1) and the other following bunionectomy (Trial 2). Patients were randomized to receive Journavx, placebo, or hydrocodone bitartrate/acetaminophen (HB/APAP) for a duration of 48 hours. In each study, pain intensity was measured using a patient-reported 11-point numeric pain rating scale (NPRS), ranging from 0 to 10, where zero corresponds to no pain and 10 corresponds to the worst pain imaginable. Efficacy was evaluated by the time-weighted sum of the pain intensity difference from 0 to 48 hours (SPID48) in the Journavx group compared to the placebo group and then to the HB/APAP group. A larger SPID48 value represents better efficacy.

    - **In Trial 1, the least squares (LS) mean SPID48 was 118.4 with Journavx, 70.1 with placebo, and 111.8 with HB/APAP**. The LS mean difference vs. placebo was 48.4 (95% CI: 33.6, 63.1; $p < 0.0001$). The LS mean difference vs. HB/APAP was 6.6 (95% CI: -5.4, 18.7).
    - **In Trial 2, the LS mean SPID48 was 99.9 with Journavx, 70.6 with placebo, and 120.1 with HB/APAP**. The LS mean difference vs. placebo was 29.3 (95% CI: 14.0, 44.6; $p = 0.0002$). The LS mean difference vs. HB/APAP was -20.2 (95% CI: -32.7, -7.7).

- Journavx is contraindicated in patients with concomitant use of strong CYP3A inhibitors.

- Warnings and precautions for Journavx include increased risk of adverse reactions with concomitant use with strong or moderate CYP3A inhibitors; risk of drug interactions with certain CYP3A substrates; risk of drug interactions with certain hormonal contraceptives; and risk of adverse reactions in patients with moderate and severe hepatic impairment.

- The most common adverse reactions (greater incidence in Journavx-treated patients compared to placebo-treated patients) with Journavx use were pruritis, muscle spasms, increased creatine phosphokinase, and rash.

- The recommended **starting dose of Journavx is 100 mg orally**. **Starting 12 hours after the initial dose, the dose is 50 mg orally every 12 hours**.

    - Journavx should be used for the shortest duration, consistent with individual patient treatment goals.
    - **Use of Journavx for the treatment of moderate to severe acute pain has not been studied beyond 14 days**.

- The wholesale acquisition cost (WAC) for Journavx is **$15.50 per 50 mg tablet**.

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- Vertex's launch plans for Journavx are pending. Journavx will be available as a 50 mg tablet.
- More information on Journavx can be found in the prescribing information.