Korsuva™ (difelikefalin) – New drug approval

- On August 23, 2021, Vifor Pharma and Cara Therapeutics announced the FDA approval of Korsuva (difelikefalin), for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD).
    - Korsuva has not been studied in patients on peritoneal dialysis and is not recommended for use in this population.
- Korsuva is a novel kappa opioid receptor agonist and the first approved treatment for CKD-aP.
- The efficacy of Korsuva was established in two randomized, double-blind, placebo-controlled studies that enrolled a total of 851 patients 18 years of age and older undergoing HD who had moderate-to-severe pruritus. In both studies, patients received Korsuva or placebo three times per week for 12 weeks. In each study, the primary endpoint was the proportion of patients achieving a 4-point or greater improvement (reduction) from baseline in the weekly mean of the daily 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score at week 12 (0 “no itch” to 10 “worst itch imaginable”).
    - In study 1, 40% of patients met the primary endpoint vs. 21% with placebo (difference of 19, 95% CI: 9, 28).
    - In study 2, 37% of patients met the primary endpoint vs. 26% with placebo (difference of 12, 95% CI: 3, 20).
- Warnings and precautions for Korsuva include dizziness, somnolence, mental status changes, and gait disturbances, and risk of driving and operating machinery.
- The most common adverse reactions (incidence ≥ 2% and ≥ 1% higher than placebo) with Korsuva use were diarrhea, dizziness, nausea, gait disturbances, including falls, hyperkalemia, headache, somnolence, and mental status change.
- The recommended dosage of Korsuva is 0.5 mcg/kg administered by intravenous bolus injection into the venous line of the dialysis circuit at the end of each HD treatment.
    - Refer to the Korsuva drug label for complete dosing and administration recommendations.
- Vifor Pharma and Cara Therapeutics are planning a promotional launch for Korsuva in the first quarter of 2022. Korsuva will be available as a 65 mcg /1.3 mL injection in a single-dose vial.