Elyxyb™ (celecoxib) – New formulation approval

- On May 6, 2020, Dr. Reddy's announced the FDA approval of Elyxyb (celecoxib) oral solution, for the acute treatment of migraine with or without aura in adults.
    - Elyxyb is not indicated for the preventive treatment of migraine.
- Celecoxib is also available as generic oral capsules.
- Celecoxib is indicated for the management of osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, and primary dysmenorrhea.
- The efficacy of Elyxyb was demonstrated in two placebo-controlled studies in patients with acute migraine with or without aura. In study 1 and 2, 631 patients and 622 patients, respectively, were enrolled. Patients with migraines of moderate to severe pain intensity were evaluated for efficacy. The efficacy of Elyxyb was established by an effect on pain freedom at 2 hours post-dose and most bothersome symptom (MBS) freedom at 2 hours post-dose.
    - In study 1, 32.4% of the Elyxyb-treated patients vs. 25.3% of the placebo patients achieved pain freedom at 2 hours post-dose ($p = 0.076$) and 58.0% of the Elyxyb-treated patients vs. 44.4% of placebo patients reported MBS freedom at 2 hours post-dose ($p = 0.003$).
    - In study 2, 35.1% of the Elyxyb-treated patients vs. 21.0% of the placebo patients achieved pain freedom at 2 hours post-dose ($p < 0.001$) and 56.8% of the Elyxyb-treated patients vs. 43.9% of placebo patients reported MBS freedom at 2 hours post-dose ($p = 0.006$).
- Elyxyb carries a boxed warning for the risk of serious cardiovascular and gastrointestinal events.
- Additional warnings and precautions for Elyxyb include hepatotoxicity; hypertension; heart failure and edema; renal toxicity and hyperkalemia; anaphylactic reactions; exacerbation of asthma related to aspirin sensitivity; serious skin reactions; medication overuse headache; premature closure of fetal ductus arteriosus; hematological toxicity; masking of inflammation and fever; laboratory monitoring; and disseminated intravascular coagulation.
- The most common adverse event (≥ 3% and > placebo) with Elyxyb use was dysgeusia.
- The recommended dose of Elyxyb is 120 mg taken orally, with or without food.
    - The maximum dosage in a 24-hour period is 120 mg. The safety and effectiveness of a second dose in a 24-hour period have not been established.
    - Elyxyb should be used for the fewest number of days per month, as needed.
- Dr. Reddy's launch plans for Elyxyb are pending. Elyxyb will be available as a 120 mg/4.8 mL (25 mg/mL) oral solution.