Rapivab® (peramivir) – Expanded indication

- On January 28, 2021, the FDA approved Biocryst's Rapivab (peramivir), for the treatment of acute uncomplicated influenza in patients 6 months and older who have been symptomatic for no more than 2 days.
    - Rapivab was previously approved for this indication in patients 2 years and older.
    - Efficacy of Rapivab is based on clinical trials of naturally occurring influenza in which the predominant influenza infections were influenza A virus; a limited number of subjects infected with influenza B virus were enrolled.
    - Influenza viruses change over time. Emergence of resistance substitutions could decrease drug effectiveness. Other factors (eg, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use Rapivab.
    - The efficacy of Rapivab could not be established in patients with serious influenza requiring hospitalization.

- The efficacy of Rapivab in pediatric patients was evaluated in a randomized, open-label, active-controlled study in 97 patients 6 months to 17 years of age with acute uncomplicated influenza. Patients were randomized to receive a single intravenous (IV) dose of Rapivab or oral oseltamivir for 5 days. The primary endpoint was the safety of Rapivab compared to oseltamivir as measured by adverse events, laboratory analysis, vital signs and physical exams. Secondary endpoints included efficacy outcomes such as time to resolution of influenza symptoms and time to resolution of fever; however, the trial was not powered to detect statistically significant differences in these secondary endpoints.
    - Patients receiving Rapivab experienced a median time to alleviation of their combined influenza symptoms of 79 hours (interquartile range: 31 to 126 hours) vs. 100 hours (interquartile range: 57 to 145 hours) in patients receiving oseltamivir.
    - The median time to recovery to normal temperature (less than 37°C) was 40 hours (interquartile range: 21 to 68 hours) and 35 hours (interquartile range: 16 to 42 hours) in patients receiving Rapivab and oseltamivir, respectively.

- The recommended dosage of Rapivab in pediatric patients 6 months to 12 years of age with acute uncomplicated influenza is a single 12 mg/kg dose (up to a maximum dose of 600 mg), administered via IV infusion for 15 to 30 minutes.
    - Rapivab should be administered as a single dose within 2 days of onset of influenza symptoms.
    - Refer to the Rapivab drug label for adult and adolescent dosing.