Rapivab™ (peramivir) – Expanded indication

- On September 20, 2017, BioCryst announced the FDA approval of Rapivab (peramivir) injection, for the treatment of acute uncomplicated influenza in patients ≥ 2 years age who have been symptomatic for no more than 2 days.
    - Previously, Rapivab was only approved for use in patients ≥ 18 years of age.
    - The 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 (for example, 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 approval of Rapivab in pediatric patients (2 – 17 years of age) was based on an active-controlled trial comparing Rapivab vs. oral oseltamivir. The primary endpoint was the safety of Rapivab compared to oseltamivir as measured by adverse events, laboratory analysis, vital signs and physical exams.
    - The safety profile of Rapivab in pediatric subjects was generally similar to that observed in adults.
    - Specific adverse reactions reported in pediatric subjects treated with Rapivab and not reported in adults included: vomiting (3% vs. 9% for oseltamivir), fever and tympanic membrane erythema (2% vs. 0% for oseltamivir, respectively, for each of these events).
    - The only clinically significant laboratory abnormality occurring in ≥ 2% of pediatric subjects treated with Rapivab was proteinuria (3% vs. 0% for oseltamivir).
    - 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.

- The recommended dosage of Rapivab in pediatric patients (2 – 12 years old) with acute uncomplicated influenza is a single 12 mg/kg dose (up to a maximum dose of 600 mg) via intravenous (IV) infusion administered within 2 days of onset of symptoms of influenza.

- The recommended dosage of Rapivab in adults and adolescents (≥ 13 years old) with acute uncomplicated influenza is a single 600 mg dose via IV infusion administered within 2 days of onset of symptoms of influenza.