Xofluza® (baloxavir marboxil) – New indication, new formulation approval

- On November 23, 2020, Genentech announced the FDA approval of Xofluza (baloxavir marboxil), for post-exposure prophylaxis of influenza in persons 12 years of age and older following contact with an individual who has influenza.
    - Influenza viruses change over time, and factors such as the virus type or subtype, emergence of resistance, or changes in viral virulence could diminish the clinical benefit of antiviral drugs. Available information on drug susceptibility patterns for circulating influenza virus strains should be considered when deciding whether to use Xofluza.
- Xofluza is also approved for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are:
    - Otherwise healthy, or
    - At high risk of developing influenza-related complications.
- In addition to the new indication, the FDA approved a new oral suspension formulation (40 mg/20 mL) of Xofluza. It was previously only available as 20 mg and 40 mg oral tablets.
- The approval of Xofluza for the new indication was based on a randomized, double-blind, placebo-controlled study evaluating Xofluza in the prevention of influenza in 607 subjects who were household contacts of influenza-infected patients in Japan. The primary efficacy endpoint was the proportion of household subjects who were infected with influenza virus and presented with fever and at least one respiratory symptom from day 1 to day 10.
    - There was a statistically significant reduction in the proportion of household contacts with laboratory-confirmed clinical influenza from 13% (95% CI: 10, 17) in the placebo group vs. 1% (95% CI: 0, 3) in the Xofluza group.
- Xofluza should be taken orally as a single dose as soon as possible and within 48 hours of influenza symptom onset for treatment of acute uncomplicated influenza or following contact with an individual who has influenza.
    - In patients less than 80 kg, the recommended dosage is two 20 mg tablets taken at the same time (blister card contains two 20 mg tablets) or one 40 mg/20 mL bottle for a total single dose of 40 mg.
    - In patients at least 80 kg, the recommended dosage is two 40 mg tablets taken at the same time (blister card contains two 40 mg tablets) or two 40 mg/20 mL bottles for a total single dose of 80 mg.
- Genentech's launch plans for Xofluza 40 mg/20 mL oral suspension are pending.