## Xofluza® (baloxavir marboxil) – Expanded indications

- On August 11, 2022, Genentech announced the FDA approval of Xofluza (baloxavir marboxil), for the treatment of acute uncomplicated influenza in patients who have been symptomatic for no more than 48 hours and who are otherwise healthy adults and pediatric patients 5 years of age and older.
    - Xofluza was previously approved for this use in otherwise healthy patients 12 years of age and older.
    - Xofluza is also approved for this use in adults and pediatric patients 12 years of age and older who are at high-risk of developing influenza-related complications.
- The approval of Xofluza for the expanded indication was based on a randomized, double-blind, active-controlled study in 118 otherwise healthy pediatric patients ages 5 to < 12 years of age, with influenza-like symptoms. Patients received a single-dose of Xofluza or oseltamivir for 5 days. The primary objective was to compare the safety of Xofluza with oseltamivir. The secondary endpoint included time to alleviation of influenza signs and symptoms.
    - The median time to alleviation of influenza was 138 hours in the Xofluza arm (95% CI: 117, 163) and 126 hours in the oseltamivir arm (95% CI: 96, 166).
- Genentech also announced the approval of Xofluza for post-exposure prophylaxis of influenza in persons 5 years of age and older following contact with an individual who has influenza.
    - Xofluza was previously approved for this use in patients 12 years of age and older.
- The approval of Xofluza for the expanded indication was based on a randomized, double-blind, placebo-controlled study that included 108 patients 5 to less than 12 years of age. Patients who were household contacts of influenza-infected patients in Japan received a single oral dose of Xofluza or placebo. The primary endpoint was the proportion of household patients who were infected with influenza virus and presented with fever and at least one respiratory symptom from day 1 to day 10.
    - In this age group, the proportion of patients with laboratory-confirmed clinical influenza was 4% in the Xofluza group and 14% in the placebo group.
- The most common adverse reactions (≥ 5%) with Xofluza use in pediatric patients 5 years to less than 12 were vomiting and diarrhea.
- The recommended dose of Xofluza for the treatment of influenza or post-exposure prophylaxis is a single weight-based oral dosage.
    - Oral tablet formulation dosing: for patients 20 kg to less than 80 kg, the dose is one 40 mg tablet; for patients at least 80 kg, the dose is one 80 mg tablet.
    - Oral suspension formulation dosing: for patients less than 20 kg, the dose is 2 mg/kg; for patients 20 kg to less than 80 kg, the dose is 40 mg (20 mL); for patients at least 80 kg, the dose is 80 mg (40 mL).