Xofluza™ (baloxavir marboxil) – New drug approval

- On October 24, 2018, the FDA announced the approval Genentech's Xofluza (baloxavir marboxil), 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.

    — 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.

- Influenza, or flu, is one of the most common yet serious infectious diseases. Since 2010, the CDC estimates that the flu has resulted annually in 9.2 to 35.6 million illnesses, 140,000 to 900,000 hospitalizations, and 12,000 to 80,000 deaths.

    — Current treatments, including existing vaccines and antiviral drugs, have limitations as flu viruses are constantly changing.

- Xofluza is a first-in-class, single-dose oral medicine with a novel proposed mechanism of action that inhibits polymerase acidic endonuclease, an enzyme essential for viral replication.

- The efficacy of Xofluza was assessed in two studies of 1,832 patients in two different influenza seasons in patients with acute uncomplicated influenza. Patients received Xofluza, placebo, or Tamiflu® (oseltamivir). The primary endpoint of both trials, time to alleviation of symptoms, was defined as the time when all seven symptoms (cough, sore throat, nasal congestion, headache, feverishness, myalgia, and fatigue) had been assessed by the patient as none or mild for a duration of at least 21.5 hours.

    — In study 1, the median time to alleviation of symptoms was 50 hours (95% CI: 45 to 64) for Xofluza 40 mg vs. 78 hours (95% CI: 68 to 89) for placebo.
    — In study 2, the median time to alleviation of symptoms was 54 hours (95% CI: 50 to 59) for Xofluza 40 mg or 80 mg vs. 80 hours (95% CI: 73 to 87) for placebo. There was no difference in the time to alleviation of symptoms between patients who received Xofluza (54 hours) and those who received Tamiflu (54 hours).

- A warnings and precaution of Xofluza is bacterial infections.

- The most common adverse reactions (≥ 1%) with Xofluza use were diarrhea, bronchitis, nasopharyngitis, headache, and nausea.

- The recommended dose of Xofluza is an oral single-dose of 40 mg in patients weighing 40 kg to less than 80 kg or a single-dose of 80 mg in patients weighing at least 80 kg.

    — Treatment with Xofluza should be initiated within 48 hours of influenza symptom onset.
    — Xofluza may be taken with or without food; however, co-administration of Xofluza with dairy products, calcium-fortified beverages, polyvalent cation-containing laxatives, antacids or oral supplements (eg, calcium, iron, magnesium, selenium, or zinc) should be avoided.

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- Genentech plans to launch Xofluza during the first week of November. Xofluza will be available as 20 mg and 40 mg tablets.