Thursday, Oct 17, 2019

Genentech Announces FDA Approval of Xofluza (Baloxavir Marboxil) for People at High Risk of Developing Influenza-Related Complications

Single-dose Xofluza is the first and only antiviral medicine indicated specifically for patients at high risk of developing serious complications from influenza (flu)

The Centers for Disease Control and Prevention (CDC) defines people at high risk of serious flu complications as those who have conditions such as asthma, chronic lung disease, diabetes, heart disease, morbid obesity or adults 65 years of age or older

South San Francisco, CA -- October 17, 2019 --

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application (sNDA) for Xofluza™ (baloxavir marboxil) for the treatment of acute, uncomplicated influenza, or flu, in people 12 years of age and older who have been symptomatic for no more than 48 hours and who are at high risk of developing flu-related complications. Xofluza is a first-in-class, one-dose oral medicine with a novel proposed mechanism of action that inhibits polymerase acidic endonuclease, an enzyme essential for viral replication.

“With the flu season rapidly approaching, we can now offer Xofluza as the first and only FDA-approved treatment option indicated specifically for those at high risk of flu complications,” said Levi Garraway, M.D., Ph.D., chief medical officer and head of Global Product Development. “People with chronic conditions such as asthma, heart disease and diabetes are at higher risk of developing serious complications from the flu, so it is critical that these patients speak with their healthcare providers about possible treatment at the first signs and symptoms of the disease.”

The flu has the potential to cause a variety of complications, ranging from sinus or ear infections to more serious complications such as pneumonia. This expanded

indication for Xofluza was approved based on results from the Phase III CAPSTONE-2 study of a single dose of 40 mg or 80 mg of Xofluza compared to oseltamivir (75 mg twice daily for five days), or placebo in people 12 years of age or older who met CDC criteria for being at high risk of complications from the flu. Xofluza significantly reduced the time to improvement of flu symptoms compared to placebo, including in people infected with the flu type B virus. Adverse events reported in at least 1% of adult and adolescent subjects treated with Xofluza included diarrhea (3%), bronchitis (3%), nausea (2%), sinusitis (2%) and headache (1%).

Xofluza is currently approved in several countries for the treatment of flu types A and B. In October 2018, Xofluza was first approved by the FDA for the treatment of acute, uncomplicated flu in otherwise healthy people 12 years of age and older who have been symptomatic for no more than 48 hours, representing the first new antiviral to treat the flu in the U.S. in 20 years.

About CAPSTONE-2

CAPSTONE-2 is a Phase III, multicenter, randomized, double-blind study that evaluated a single dose of Xofluza compared with placebo and oseltamivir in people 12 years of age or older who are at a high risk of complications from the flu. The Centers for Disease Control and Prevention (CDC) defines people at high risk of serious flu complications as those who have conditions such as asthma, chronic lung disease, diabetes, heart disease, morbid obesity or adults 65 years of age or older. The study was conducted globally by Shionogi & Co., Ltd.

Participants enrolled in the study were randomly assigned to receive a single dose of 40 mg or 80 mg of Xofluza, placebo or 75 mg of oseltamivir twice a day for five days. The primary objective of the study was to evaluate the efficacy of a single dose of Xofluza compared with placebo by measuring the time to improvement of flu symptoms. Key findings from the study found that:

- Xofluza significantly reduced the time to improvement of flu symptoms versus placebo in people at high risk of complications from the flu (median time 73 hours versus 102 hours; p<0.001).
- Similar efficacy results were seen between Xofluza and oseltamivir in relation to duration of symptoms (median time 73 hours versus 81hours).
- In subjects infected with type B virus, the median time to improvement of flu symptoms was shorter in the Xofluza group compared to the placebo group (75 hours versus 101 hours respectively).
- Adverse events reported in at least 1% of adult and adolescent subjects treated with Xofluza included diarrhea (3%), bronchitis (3%), nausea (2%), sinusitis (2%) and headache (1%). Xofluza was well-tolerated and no new safety signals were identified.

About Xofluza ™ (baloxavir marboxil)

Xofluza is a first-in-class, one-dose oral medicine with a novel proposed mechanism of action that has demonstrated efficacy in a wide range of influenza viruses, including in vitro activity against oseltamivir-resistant strains and avian strains (H7N9, H5N1) in non-clinical studies. Unlike other currently available antiviral treatments, Xofluza is the first in a new class of antivirals designed to inhibit the cap-dependent endonuclease protein, which is essential for viral replication.

Xofluza is being further studied in a Phase III development program, including children under the age of one (NCT03653364), severely ill, hospitalized people with the flu (NCT03684044), as well as to assess the potential to reduce transmission of the flu from an infected person to healthy people (NCT03969212).

Xofluza was discovered by Shionogi & Co., Ltd. and is being further developed and commercialized globally in collaboration with the Roche Group (which includes Genentech in the U.S.) and Shionogi & Co., Ltd. Under the terms of this agreement, Roche holds worldwide rights to Xofluza excluding Japan and Taiwan, which will be retained exclusively by Shionogi & Co., Ltd.

XOFLUZA U.S. Indication

XOFLUZA is a prescription medicine used to treat the flu (influenza) in people 12 years of age and older who have had flu symptoms for no more than 48 hours and who are otherwise healthy or at high risk of developing flu-related complications.

It is not known if XOFLUZA is safe and effective in children younger than 12 years of age or weighing less than 88 pounds (40 kg).

Important Safety Information

Do not take XOFLUZA if you are allergic to baloxavir marboxil or any of the ingredients in XOFLUZA.

Before you take XOFLUZA, tell your healthcare provider about all of your medical conditions, including if you:

- Are pregnant or plan to become pregnant. It is not known if XOFLUZA can harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if XOFLUZA passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Talk to your healthcare provider before you receive a live flu vaccine after taking XOFLUZA.

Take XOFLUZA with or without food. Do not take XOFLUZA with dairy products, calcium-fortified beverages, laxatives, antacids, or oral supplements containing iron, zinc, selenium, calcium, or magnesium.

If you take too much XOFLUZA, go to the nearest emergency room right away.

XOFLUZA may cause serious side effects, including allergic reactions.

Get emergency medical help right away if you develop any of these signs and symptoms of an allergic reaction:

- trouble breathing
- skin rash, hives or blisters
- swelling of your face, throat or mouth
- dizziness or lightheadedness

The most common side effects are diarrhea, bronchitis, sinusitis, headache, and nausea.

XOFLUZA is not effective in treating infections other than influenza. Other kinds of infections can have symptoms like those of the flu or occur along with flu and may need different kinds of treatment. Tell your healthcare provider if you feel worse or develop new symptoms during or after treatment with XOFLUZA or if your flu symptoms do not start to get better.

Please see the XOFLUZA full Prescribing Information for complete safety information.

You are encouraged to report side effects to Genentech by calling 1-888-835-2555 or to the FDA by visiting http://www.fda.gov/medwatch or calling 1-800-FDA-1088.

About Genentech in Influenza

Influenza, or flu, is one of the most common, yet serious, infectious diseases, representing a significant threat to public health. Since 2010, the Centers for Disease Control and Prevention (CDC) estimates that the flu has resulted annually in 9.3 to 49 million illnesses, 140,000 to 960,000 hospitalizations and 12,000 to 79,000 deaths. Although vaccines are an important first line of defense in preventing the flu, there is a need for new medical options for prophylaxis and treatment. Other antiviral medicines have limitations with respect to efficacy, convenience of dosing and resistance. Genentech is committed to addressing the unmet need in this area through its agreement with Shionogi & Co., Ltd. to develop and commercialize Xofluza.

About Genentech

Founded more than 40 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious and life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit http://www.gene.com.

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