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Genentech Announces FDA Approval of Xofluza to Treat Influenza in Children Aged Five and Older

Xofluza is the first and only single-dose oral medicine for the treatment of influenza to be approved for children as young as five years of age The FDA also approved Xofluza to prevent influenza in children aged five and older following contact with an infected person

South San Francisco, CA -- August 11, 2022 --
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 in otherwise healthy children aged five to less than 12 years of age who have been symptomatic for no more than 48 hours. This marks the first single-dose oral influenza medicine approved for children in this age group. Additionally, the FDA approved Xofluza for the prevention (post-exposure prophylaxis) of influenza in children aged five to less than 12 years of age following contact with someone with influenza. ®

“Despite the ongoing COVID-19 pandemic, influenza continues to be a threat to public health, and effective influenza antivirals remain critical to alleviating the burden on healthcare systems,” said Levi Garraway, M.D., Ph.D., chief medical officer and head of Global Product Development. “Xofluza has proven to be an important tool in fighting and preventing influenza in adults as well as adolescents, and we are pleased to now offer households and younger children our single-dose oral treatment.”

According to the Centers for Disease Control and Prevention, influenza can be a serious illness for young children. During the ongoing COVID-19 pandemic, there have been significantly fewer influenza cases likely due in large part to social distancing and mask wearing. However, in the U.S. 2018-2019 influenza season, there were more than 6 million illnesses, thousands of hospitalizations and more than 100 deaths for children aged five to 17 caused by influenza.

“Historically, school-aged children have played a significant role in the community transmission of influenza. The annual influenza vaccine continues to be the most important first step to prevent illness in children, though there can still be breakthrough cases where antiviral treatment is needed,” said Dr. Pedro Piedra, miniSTONE-2 study investigator and professor of molecular virology and microbiology, pediatrics at Baylor College of Medicine. “Today’s FDA approval provides children with a single-dose antiviral option, Xofluza, to treat influenza."

The FDA approval is based on results from two Phase III studies, miniSTONE-2 and BLOCKSTONE. miniSTONE-2 evaluated Xofluza compared with oseltamivir in otherwise healthy children and included patients aged five to less than 12 years with an influenza infection and displaying influenza symptoms for no more than 48 hours. BLOCKSTONE evaluated Xofluza compared with placebo as a preventive treatment for household members (adults and children) who were living with someone with influenza. The results from these studies were published in *The Pediatric Infectious Disease Journal* and *The New England Journal of Medicine* respectively.

Adverse events reported in at least 5% of pediatric patients (ages five to 11 years) treated with Xofluza included vomiting (5%) and diarrhea (5%).

Xofluza is already FDA-approved to treat influenza in people 12 years of age and older who have had influenza symptoms for no more than 48 hours and who are otherwise healthy or at high risk of developing influenza-related complications. Xofluza is also approved to prevent influenza in people 12 years of age and older following contact with someone with influenza (known as post-exposure prophylaxis). Xofluza is available as a one-dose, single tablet.

About Xofluza (baloxavir marboxil)®

Xofluza is a first-in-class, single-dose oral medicine with an innovative 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. Xofluza is the first in a class of antivirals designed to inhibit the cap-dependent endonuclease protein, which is essential for viral replication.

In October 2018, Xofluza was first approved by the FDA for the treatment of acute, uncomplicated influenza 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 influenza in the U.S. in over 20 years.

Xofluza is being further studied in a Phase III development program, including children under the age of one (NCT03653364) as well as to assess the potential to reduce direct transmission of influenza from otherwise healthy patients to household contacts (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 who have flu symptoms for no more than 48 hours and who are:
    - otherwise healthy adults and children 5 years of age and older, or
    - adults and children 12 years of age and older who are at high risk of developing problems from the flu.
- prevent the flu in people 5 years of age and older following contact with a person who has the flu (post-exposure prophylaxis).

XOFLUZA does not treat or prevent illness that is caused by infections other than the influenza virus.

XOFLUZA does not prevent bacterial infections that may happen with the flu.

It is not known if XOFLUZA is safe and effective for the treatment and prevention of the flu in children less than 5 years of age. XOFLUZA is not for use in children less than 5 years of age.

Important Safety Information

Who should not take XOFLUZA?

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

in XOFLUZA.

What should I tell my healthcare provider before using 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.
  - **Breastfeeding or plan to breastfeed.** It is not known if XOFLUZA passes into your breast milk.
- **Talk to your healthcare provider before you receive a live flu vaccine after taking XOFLUZA.**
- **Tell your healthcare provider about all of the medicines you take,** including prescription and over-the-counter medicines, antacids, laxatives, vitamins, and herbal supplements.

What are the possible side effects of XOFLUZA?
Serious side effects may include

- **Allergic reaction.** Get emergency medical help right away if you develop any of the following signs or 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 of XOFLUZA for treatment of the flu in adults and adolescents (12 years of age and older) were diarrhea, bronchitis, nausea, sinusitis, and headache.

The most common side effects of XOFLUZA for treatment of the flu in children (5 years of age to less than 12 years of age) were diarrhea and vomiting.

These are not all the possible side effects of XOFLUZA. Call your healthcare provider for medical advice about side effects.
XOFLUZA is not effective in treating or preventing 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.

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.

Please see full Prescribing Information, including Patient Product Information.

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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