Phase III CAPSTONE-2 Study Showed That Baloxavir Marboxil Reduced Symptoms in People at High Risk of Complications From the Flu

South San Francisco, CA – July 16, 2018 – Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that the Phase III CAPSTONE-2 study assessing the safety and efficacy of baloxavir marboxil in people at high risk of complications from the flu met the study's primary objective, and showed superior efficacy in the primary endpoint of time to improvement of influenza symptoms versus placebo . The Centers for Disease Control and Prevention (CDC) defines people at high risk for serious flu complications to include adults 65 years of age or older, or those who have conditions such as asthma, chronic lung disease, diabetes or heart disease – for these people, the flu can lead to hospitalization or even death.

Baloxavir marboxil also demonstrated superior efficacy compared to placebo and oseltamivir for important secondary endpoints, including reducing the time that the virus continued to be released (viral shedding) and reducing viral levels in the body. Furthermore, baloxavir marboxil significantly reduced the incidence of influenza-related complications compared to placebo. Baloxavir marboxil was well tolerated and no safety signals were identified. Full results from the CAPSTONE-2 study will be presented at upcoming medical meetings. Baloxavir marboxil was discovered and developed by Shionogi & Co., Ltd., and is sold in Japan under the trade name Xofluza®.

"Baloxavir marboxil is the first antiviral to show a clinically meaningful benefit in people who are most susceptible to complications from the flu, including older people and those living with certain medical conditions," said Sandra Horning, M.D., chief medical officer and head of Global Product Development. "We plan to submit the results of this second positive Phase III study for baloxavir marboxil to healthcare authorities, and look forward to discussing next steps since there are no current antiviral medicines approved to specifically treat this high-risk population."

Baloxavir marboxil has already demonstrated a clinically significant benefit over placebo in otherwise healthy people in the Phase III CAPSTONE-1 study. The U.S. Food and Drug Administration (FDA) recently accepted a New Drug Application (NDA) and granted Priority Review to baloxavir marboxil as a single-dose, oral treatment for acute, uncomplicated influenza in people 12 years and older based on the CAPSTONE-1 study and the Phase II study, and is expected to make a decision on approval by December 24, 2018. If approved, baloxavir marboxil would be the first single-dose oral antiviral, and the first medicine with a novel proposed mechanism of action to treat the flu in nearly 20 years.

About CAPSTONE-2

CAPSTONE-2 is a Phase III, multicenter, randomized, double-blind study that evaluated a single dose of baloxavir marboxil compared with placebo and oseltamivir in people 12 years 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 for serious flu complications to include adults 65 years of age or older, or those who have conditions such as asthma, chronic lung disease, diabetes or heart disease. 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 baloxavir marboxil (according to body weight), placebo or 75 mg of oseltamivir twice a day for five days. The primary objective of the study evaluated the efficacy of a single dose of baloxavir marboxil compared with placebo by measuring the time to improvement of influenza symptoms. Important secondary endpoints were time to resolution of fever, time to cessation of viral shedding and the proportion of participants positive for influenza virus titer, or virus levels in the body, by time point, and incidences of influenza-related complications.

About Baloxavir Marboxil

Baloxavir marboxil is a first-in-class, single-dose investigational oral medicine with a novel proposed mechanism of action designed to target the influenza (“flu”) A and B viruses, including oseltamivir-resistant strains and avian strains (e.g. H7N9, H5N1). Unlike other currently available antiviral treatments, baloxavir marboxil is the first in a new class of antivirals designed to inhibit the cap-dependent endonuclease protein within the flu virus, which is essential for viral replication.

Baloxavir marboxil will also be studied in a Phase III development program including pediatric and severely ill hospitalized populations with influenza.

Baloxavir marboxil was discovered by Shionogi & Co., Ltd. and is being developed globally by 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 baloxavir marboxil excluding Japan and Taiwan, which will be retained exclusively by Shionogi & Co., Ltd. Baloxavir marboxil was approved in February 2018 by the Japanese Ministry of Health, Labour and Welfare for the treatment of influenza types A and B in adult and pediatric patients, and is being commercialized in Japan and marketed under the brand name Xofluza®.

About Genentech in Influenza

Influenza, or flu, is one of the most common, yet serious, infectious diseases. Globally, annual epidemics result in 3 to 5 million cases of severe disease, millions of hospitalizations and up to 650,000 deaths worldwide. For people at higher risk of flu complications, like pneumonia and bronchitis, the flu can lead to hospitalization or death, or can make long-term health

problems worse. 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. Current treatments – including vaccines and antiviral medicines – have limitations as flu viruses are constantly changing and new antiviral medicines are necessary. Genentech is committed to addressing the unmet need in this area through its agreement with Shionogi & Co., Ltd. to develop and commercialize baloxavir marboxil.

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.

Source: Genentech

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