## Roche announces FDA approval of Xofluza for the prevention of influenza following contact with an infected person

- **Xofluza is the first single-dose influenza medicine approved to prevent influenza for those who have had contact with an infected person (post-exposure prophylaxis)**
- **Roche also provides an update on the sNDA filing for Xofluza in the paediatric setting**

Basel, 24 November 2020 - Roche (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) as a treatment to prevent influenza in people 12 years of age and older following contact with someone with influenza (known as post-exposure prophylaxis). Xofluza is the first single-dose influenza medicine approved for post-exposure prophylaxis.

"With today's approval, Xofluza is now available as the first single-dose, post-exposure preventive treatment for influenza," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We're hopeful that reducing the burden of influenza may help to mitigate the strain on our healthcare system amid the COVID-19 pandemic."

Post-exposure prophylaxis with single-dose Xofluza was evaluated in the phase III BLOCKSTONE study, which was recently published in The New England Journal of Medicine.[1] BLOCKSTONE evaluated Xofluza compared with placebo as a preventive treatment for household members (adults and children) who were living with someone with influenza. Xofluza showed a statistically significant prophylactic effect on influenza after a single oral dose in people exposed to an infected household contact. The proportion of household members 12 years of age and older who developed influenza was 1% in participants treated with Xofluza and 13% in the placebo-treated group. Xofluza was well tolerated in this study and no new safety signals were identified.

"The flu is a serious illness that burdens households and sickens millions across the US every year," said Serese Marotta, Chief Operating Officer at Families Fighting Flu. "As we are about to enter a flu season within a global COVID-19 pandemic, we welcome Xofluza as a single-dose flu medicine to be used preventively after exposure to flu."

The most frequently reported adverse events (occurring in at least 1% of adult and adolescent influenza patients treated with Xofluza) included diarrhoea (3%), bronchitis (3%), nausea (2%), sinusitis (2%), and headache (1%).

Additionally, Roche is determining a path forward with the FDA for a potential indication for Xofluza as a treatment for acute uncomplicated influenza in otherwise healthy children (one to 12 years of age) and for the prevention of influenza in the same age group who have been exposed to influenza. Xofluza is currently not approved for use in this population.

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Xofluza is already FDA-approved to treat acute uncomplicated 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.[2] Although some of the symptoms of COVID-19 and influenza can look similar, the two illnesses are caused by completely different viruses. Xofluza is specifically designed to treat influenza viruses only and is not effective against SARS-CoV-2, the coronavirus causing COVID-19.[3]

**About BLOCKSTONE** [1, 3]
BLOCKSTONE is a phase III, double-blind, multicentre, randomised, placebo-controlled, post-exposure prophylaxis study that evaluated a single dose of Xofluza® (baloxavir marboxil) compared with placebo in household members (adults and children) who were living with someone with influenza confirmed by a rapid influenza diagnostic test (the 'index patient'). The study was conducted by Shionogi & Co., Ltd. in Japan during the 2018-2019 influenza season.

Those diagnosed with influenza were required to have onset of symptoms for less than 48 hours and participants were required to have lived with those diagnosed for more than 48 hours. The participants were randomised to receive a single dose of Xofluza (dose according to body weight) or placebo as a preventive measure against developing influenza.

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**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.[4] Xofluza is the first in a class of antivirals designed to inhibit the cap-dependent endonuclease protein, which is essential for viral replication.[4, 5]

Xofluza is available in the US and in several other countries for the treatment of influenza types A and B. In the US, Xofluza is approved for the treatment of acute, uncomplicated influenza in people 12 years of age and older who are otherwise healthy or at high risk of developing serious complications from influenza, and who have been symptomatic for no more than 48 hours. Xofluza is also approved for post-exposure prophylaxis of influenza in people 12 years of age and older following contact with an individual who has influenza. Xofluza was the first new antiviral to be approved by the FDA in 20 years.

Robust clinical evidence has demonstrated the benefit of Xofluza in several populations (otherwise-healthy, high-risk and post-exposure prophylaxis). 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 transmission of influenza from an infected person to healthy people (NCT03969212). [6, 7]

Xofluza was discovered by Shionogi & Co., Ltd. and is being further developed and commercialised globally in collaboration with the Roche Group (which includes Genentech in the US) 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.

**About Roche in Influenza**
Influenza is one of the most common, yet serious, infectious diseases, representing a significant threat to public health. Globally, seasonal epidemics result in three to five million cases of severe disease, millions of hospitalisations and up to 650,000 deaths every year.[8, 9, 10, 11] Roche has a long heritage in developing medicines that contribute to public health. We are committed to bringing innovation in the field of infectious diseases, including influenza. Tamiflu® (oseltamivir) has made a significant difference both to the treatment of seasonal influenza as well as in the management of recent pandemics, and we are proud to have brought this innovative medicine to patients. Although vaccines are an important first line of defence in preventing influenza, there is a need for new medical options for prevention (prophylaxis) and treatment. Other antiviral drugs have limitations with respect to efficacy, convenience of dosing, and resistance. Roche is committed to addressing the unmet need in this area through its agreement with Shionogi & Co., Ltd. to develop and commercialise Xofluza.

**About Roche**
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones

Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.



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