PRESSRELEASE

SHIONOGI

# Shionogi Announces Approval of XOFLUZA® (Baloxavir Marboxil) in Taiwan for Pediatrics Aged 5 to <12 years for Treating and Preventing Influenza

OSAKA, Japan, April 15, 2024 – Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that its group company—Taiwan Shionogi & Co., Ltd. (Taiwan Shionogi)—has received approval of a supplemental New Drug Application (sNDA) for Xofluza® (baloxavir marboxil) for the treatment and postexposure prophylaxis for influenza virus infection for pediatrics aged 5 to <12 years.

Xofluza® is available for adults and children of ≥12 years of age for treating influenza A or B virus acute infection and the postexposure prophylaxis of influenza in Taiwan.[1, 2] The newly approved indication extends the option for treating and preventing influenza virus infections to children aged 5 to <12 years, who weigh >20 kg, offering a new choice for managing influenza.

Shionogi is committed to the principle of "protecting people worldwide from the threat of infectious diseases" as our key focus, which is based on the complete care for infectious diseases. Shionogi will continue to work diligently to collect and analyze data on the efficacy and safety of Xofluza and to provide information for appropriate use.

**About Xofluza® (baloxavir marboxil)**

Xofluza is a first-in-class, single-dose oral medicine with an innovative mechanism of action that has demonstrated efficacy among several influenza viruses, including in vitro activity against oseltamivir-resistant and avian strains (H7N9, H5N1) in nonclinical studies.[3, 4, 5] Xofluza is designed to inhibit the cap-dependent endonuclease protein, which is essential for viral replication and approved in >70 countries for treating influenza types A and B. Xofluza was discovered by Shionogi & Co., Ltd. and is being further developed and commercialized globally in collaboration with the Roche Group (including Genentech in the US) and Shionogi & Co., Ltd. Under this agreement, Roche holds worldwide rights of Xofluza, excluding Japan and Taiwan, which will be retained exclusively by Shionogi & Co., Ltd. Moreover, the Roche Group is preparing to apply for an expansion of the indication to include <1-year-old children.

**Forward-looking statements**

*This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties, which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions, such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.*

**References**


1 Press release on November 25, 2019 (PDF)
Shionogi Announces XOFLUZA® Tablets 20mg for the Treatment of Influenza A or B virus Acute Infection Launched in Taiwan.

2 Press release on January 15, 2021
Shionogi Announces Approval of XOFLUZA® (Baloxavir Marboxil) in Taiwan for the Post-Exposure Prophylaxis of Influenza Virus Infection.

3 Hayden FG, et al. N Engl J Med. 2018;379:913–923.

4 Noshi T, et al. Antiviral Res. 2018;160:109–117.

5 Taniguchi K, et al. Sci Rep. 2019;9:3466.

6 Press release on March 14, 2018
XOFLUZA™ (Baloxavir Marboxil) Tablets 10mg/20mg for the Treatment of Influenza Types A and B launched in Japan.

7 Press release on November 27, 2020
Shionogi Announces Supplemental New Drug Application for XOFLUZA® in Japan for the Post-Exposure Prophylaxis of Influenza Virus Infection was Approved.

8 Press release on July 4, 2023
Shionogi Filed for a Supplemental New Drug Application of XOFLUZA® (Baloxavir Marboxil) in Taiwan for Pediatrics Aged 5 to Under 12 for the Treatment and Prevention of Influenza Infection.