PRESSRELEASE

SHIONOGI

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

OSAKA, Japan, July 4, 2023 - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that Shionogi has filed for a supplemental new drug application (sNDA) of Xofluza® (baloxavir marboxil) in Taiwan for treatment and post-exposure prophylaxis for influenza virus infection for pediatrics aged 5 to under 12 years.

Xofluza® has been available for adults and children 12 years of age and older for the treatment of influenza A or B virus acute infection and the post-exposure prophylaxis of influenza in Taiwan.[1, 2] After approving the sNDA, it is expected that Xofluza will contribute as a new option for single oral dose for treatment and prevention of influenza, even for pediatrics aged 5 to under 12 years in Taiwan.

Shionogi is committed to the principle "Protecting people worldwide from the threat of infectious diseases" as our key focus, and is working on the realization of total care for infectious diseases. Shionogi will continue to work diligently to collect and analyze data on the efficacy and safety of Xofluza and 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 in a wide range of influenza viruses, including in vitro activity against oseltamivir-resistant strains and avian strains (H7N9, H5N1) in non-clinical studies.[3, 4, 5] Xofluza is designed to inhibit the cap-dependent endonuclease protein, which is essential for viral replication, and approved in more than 70 countries for the treatment of influenza types A and B. 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.Xofluza is being further studied in a global phase III development program, including in children under the age of one as well as to assess its potential to reduce transmission of influenza from an infected person to healthy people by Roche Group.

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.

For Further Information, Contact:

SHIONOGI Website Inquiry Form : https://www.shionogi.com/global/en/contact.html

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.