

XOFLUZA™ (Baloxavir Marboxil) Tablets 10mg/20mg for the Treatment of Influenza Types A and B launched in Japan

Osaka, Japan, March 14, 2018 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) would like to announce that Shionogi launched XOFLUZA™ (generic name: baloxavir marboxil) tablets 10mg/20mg for the treatment of Influenza Types A and B in Japan.

As the cap-dependent endonuclease inhibitor XOFLUZA™ suppresses the replication of influenza viruses by a mechanism different from existing anti-flu drugs. XOFLUZA™ is an oral tablet that will be dosed only once, offering improved compliances and convenience to the patient. XOFLUZA™ was designated for the Sakigake procedure with priority review by the Ministry of Health, Labour, and Welfare of Japan in October 2015. Shionogi was granted approval to manufacture and sell XOFLUZA™ on February 23, 2018.

Shionogi's research and development targets infectious disease as one of its priority areas, and Shionogi have positioned “protecting people from the threat of infectious diseases” as one of its social mission targets. Shionogi strives constantly to bring forth innovative drugs for the treatment of infectious diseases, to protect the health of patients we serve.

‘XOFLUZA™’ Product Description

Product Name	XOFLUZA™ Tablets 10mg/20mg	
Generic Name	Baloxavir Marboxil	
Indications	Influenza Types A and B	
Dosage and Administration:	1. The usual dosage for adults and children over 12 years old is two 20 mg tablets (40 mg as baloxavir marboxil) to be administered once. However, patients with a body weight of 80 kg or more should receive four 20 mg tablets (80 mg as baloxavir marboxil) once.	
	2. For the usual dosage for children younger than 12 years old, the following doses should be administered orally once.	
	Body weight	Dosage
	40kg or more	Two 20mg tablets (40 mg as baloxavir marboxil)
	Less than 40 kg and 20 kg or more	One 20mg tablet (20 mg as baloxavir marboxil)
Less than 20kg and 10kg or more	One 10mg tablet (10 mg as baloxavir marboxil)	

Date of manufacturing and marketing approval in Japan	February 23, 2018
Date if listing in the NHI reimbursement price	March 14,2018
Date of launch	March 14,2018
NHI price	1,507.50 yen per XOFLUZA™Tablet 10mg 2,394.50 yen per XOFLUZA™Tablet 20mg
Manufacturer selling company	Shionogi & Co., Ltd

Supporting information:(past press releases about XOFLUZA™)

Sep/14/2017: [S-033188 Phase 3 CAPSTONE-1 Study Results for Treatment of Influenza Presented at the European Scientific Working Group on Influenza Conference](#)

Oct/6/2017: [SHIONOGI TO PRESENT S-033188 PHASE 3 CAPSTONE-1 STUDY RESULTS FOR TREATMENT OF INFLUENZA AT IDWEEK 2017](#)

Oct/25/2017: [Regarding the Filing for Approval of S-033188 in Japan](#)

Feb/23/2018: [XOFLUZATM \(Baloxavir Marboxil\) Tablets 10mg/20mg Approved for the Treatment of Influenza Types A and B in Japan](#)

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, unavailability 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.

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