

Shionogi Enters into a License and Collaboration Agreement with Roche for its Anti-Flu Drug, S-033188

Osaka, Japan, February 29, 2016 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced that it has entered into a license and collaboration agreement with F. Hoffmann-La Roche Ltd. (Head Office: Basel, Switzerland; CEO: Severin Schwan, L.L.D.; hereafter “Roche”) for the development and commercialization of its oral anti-influenza drug S-033188, discovered by Shionogi.

S-033188 is a cap-dependent endonuclease inhibitor^{*1}, with a novel mechanism of action. It is expected to be a one-time, single-dose therapy for influenza, having the potential to be both more convenient and, with its novel mechanism of action, more effective than existing marketed anti-influenza products, which are neuraminidase inhibitors^{*2}. In October, 2015, S-033188 has been designated for priority review by the Ministry of Health, Labour, and Welfare of Japan, as a “Sakigake fast-track review candidate.” A Phase II study is currently ongoing in Japan, and S-033188 is projected to be launched in Japan in Shionogi’s fiscal year 2017, which ends March 31, 2018.

Under the terms of this agreement, Shionogi will conduct development of S-033188 in collaboration with Roche worldwide, with the exception of Japan and Taiwan which will be retained exclusively by Shionogi. Shionogi received an undisclosed upfront payment from Roche and is also eligible to receive milestone payments upon successful completion of key development and registration milestones, including marketing approval. Roche will have the right to commercialize S-033188 worldwide (excluding Japan and Taiwan), with Shionogi retaining certain co-promotion rights in the US. Shionogi shall be entitled to receive royalties from Roche on S-033188 sales.

Influenza virus causes an acute and severe respiratory tract infection and is prevalent primarily during the winter season. In the elderly and other high risk populations, influenza infection is associated with significant morbidity and mortality. Roche has previous successful experience in the development of treatments for influenza. Through this cooperation, Shionogi’s goal, consistent with its overall mission, is to supply an innovative and effective medicine to patients worldwide suffering from influenza virus infection.

Note:

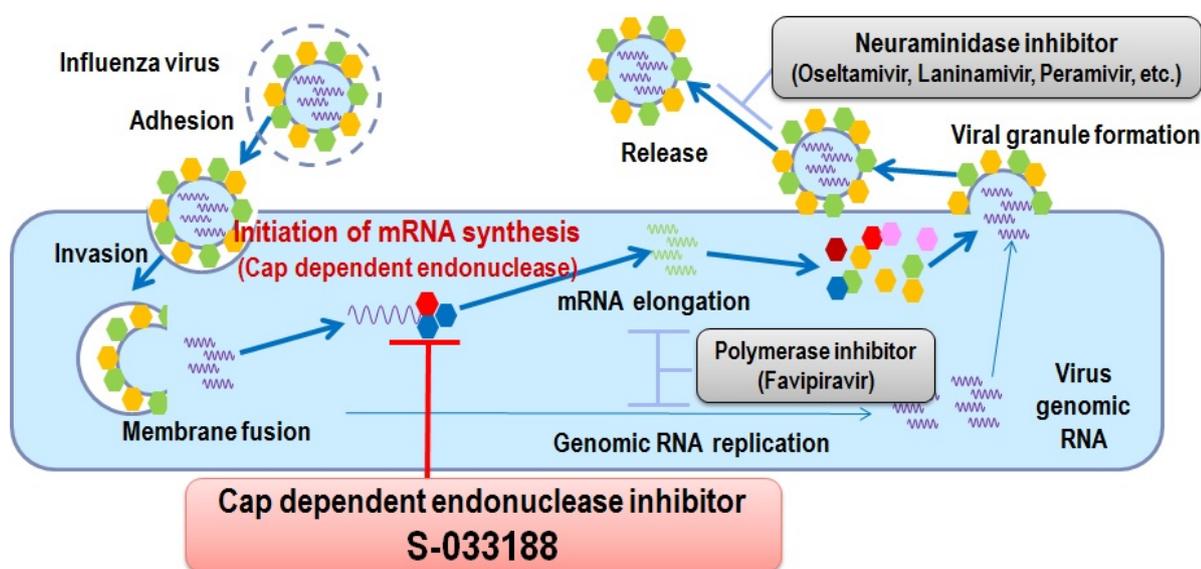
*1: Cap-dependent endonuclease inhibitor

- Inhibits the initiation of mRNA synthesis, which is the first proliferation step after the entry of the influenza virus into the cell.

- Results in the inability to produce the proteins needed for virus proliferation, thereby inhibiting viral granule formation.
- It is expected that a cap-dependent endonuclease inhibitor will strongly inhibit virus proliferation in the host cell, thus sharply reducing viral load.

*2: Neuraminidase inhibitor

- Neuraminidase inhibitors block the neuraminidase enzyme of the influenza virus. This blockade prevents the virus from budding from the host cell, thereby preventing its reproduction.



* Q2 FY2015 Financial announcement (Slide 34)

http://www.shionogi.co.jp/en/ir/pdf/e_p151030.pdf

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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