

Regarding the Filing for Approval of S-033188 in Japan

Shionogi filed for approval to manufacture and sell S-033188 for the treatment of Influenza Types A and B under the priority review system of the Ministry of Health, Labor, and Welfare of Japan (“Sakigake fast-track review”)

Osaka, Japan, October 25, 2017 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter “Shionogi”) today announced that Shionogi filed for approval to manufacture and sell the cap-dependent endonuclease inhibitor S-033188, with a novel mechanism of action, for the treatment of Influenza types A and B in adults and children. Since S-033188 suppresses the replication of influenza viruses by a mechanism different from existing anti-flu drugs, S-033188 was designated for priority review by the Ministry of Health, Labor, and Welfare of Japan in October, 2015.

Since treatment with S-033188 requires only a single oral dose regardless of age, it is very convenient, and is expected to improve adherence. In a global Phase 3 study in otherwise healthy patients (CAPSTONE-1), S-033188 demonstrated a greater antiviral effect than Tamiflu®. One day from the start of treatment, virus titer was reduced to undetectable levels in 50% or more of the treated patients, including children. Therefore, S-033188 is expected to be effective in suppressing virus transmission in households, schools, workplaces, and general aerosol-mediated infection. In addition, the S-033188-treated group had statistically significantly fewer treatment-related adverse events than the Tamiflu® group (REFERENCES: [Press release on 6th Oct. 2017](#)). Furthermore, S-033188 demonstrated a strong antiviral effect against various influenza subtypes A, including avian influenza (H5N1 or H7N9), and viruses resistant to existing anti-flu drugs, which points to its potentially important role in addressing future flu pandemics that may arise.

Shionogi is currently conducting a global Phase3 study (CAPSTONE-2) in individuals at high risk for influenza-related complications, in collaboration with F. Hoffmann-La Roche Ltd. (Head Office: Basel, Switzerland; CEO: Severin Schwan, L.L.D.).

Shionogi's research and development targets infectious disease as one of its priority areas, and Shionogi strives constantly to bring forth innovative drugs for the treatment of infectious diseases, to protect the health of patients we serve.

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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