

Shionogi Presents New Clinical and Non-clinical Data on S-033188, an Investigational Cap-Dependent Endonuclease Inhibitor for Treatment of Influenza, at the 27th European Congress of Clinical Microbiology and Infectious Diseases

Osaka, Japan, April 24, 2017 - Shionogi & Co., Ltd. reports clinical and non-clinical data on S-033188, a novel cap-dependent endonuclease inhibitor targeting influenza at the 27th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), held in Vienna, Austria, April 22 - 25, 2017.

Key findings for S-033188 reported at ECCMID include the following results:

[Clinical data]

- In a Phase 2 proof-of-concept, randomized, placebo-controlled study, a single oral administration of S-033188 at 10 mg, 20 mg and 40 mg was effective in reducing time to alleviation of symptoms, and led to rapid and profound decline in influenza viral titer. Plasma active drug concentration increased in a dose-proportional manner and was correlated with reduction in viral titer (abstract #1033).

[Non-clinical data]

- Based on pharmacokinetic and pharmacodynamic (PK/PD) analyses in a mouse model, a target plasma active drug concentration of 6.85 ng/ml is expected to achieve more than 10-fold improvement in viral titer reduction compared with a clinically equivalent dose of oseltamivir (Poster #1973).
- S-033188 and its active form S-033447 have more potent in vitro and in vivo activity against highly pathogenic H5N1 avian influenza virus than oseltamivir (Poster #1974).
- One day oral dosing of S-033188 (5 or 50 mg/kg BID) exhibited significantly better efficacy in mice infected with influenza B virus compared to a clinically equivalent dose of oseltamivir (Poster #1971).

Shionogi is currently conducting two global Phase 3 studies in otherwise healthy individuals and those at high risk for influenza-associated complications. Patient enrollment in one Phase 3 study in otherwise healthy individuals was recently completed

About Influenza

Epidemic and pandemic influenza remain a major public health concern, and novel influenza drugs that will offer significant improvement over current therapy are urgently needed. Worldwide, annual influenza epidemics are estimated to result in 3 to 5 million cases of severe illness, and about 250,000 to 500,000 deaths¹. In general, those at highest risk of influenza-associated complications include children under 2 years of age, adults over 65 years of age, pregnant women, and people of any age with certain medical conditions, including chronic heart, lung, metabolic diseases (such as diabetes) and weakened immune systems.

About S-033188

S-033188 is a cap-dependent endonuclease inhibitor with a novel mechanism of action being studied for the treatment of influenza. S-033188 is an investigational product being developed for one-time dosing, and has the potential to be more effective than existing marketed anti-influenza products. Development and commercialization are in collaboration with F. Hoffmann-La Roche Ltd.

About Shionogi

Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of “supplying the best possible medicine to protect the health and wellbeing of the patients we serve.” Shionogi’s research and development currently target two therapeutic areas: infectious diseases, and pain/CNS disorders. For over 50 years, Shionogi has developed and commercialized innovative oral and parenteral anti-infectives. In addition, Shionogi is engaged in new research areas, such as obesity/geriatric metabolic disease and oncology/immunology. Contributing to the health and quality of life of patients around the world through development in these therapeutic areas is Shionogi's primary goal. For more details, please visit www.shionogi.co.jp/en/. For more information on Shionogi Inc., the U.S. –based subsidiary of Shionogi & Co., Ltd., headquartered in Florham Park, NJ, USA, please visit www.shionogi.com. For more information on Shionogi Ltd., the UK-based subsidiary of Shionogi & Co. Ltd., headquartered in London, England, please visit www.shionogi.eu.

Forward Looking Statement

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.

Contacts:

Corporate Communications, Shionogi & Co., Ltd.

Telephone: +81-6-6209-7885

Fax: +81-6-6229-9596

###

References

1. <http://www.who.int/mediacentre/factsheets/fs211/en/> WHO website, Influenza (Seasonal), Fact sheet N°211, March 2014