

July 17, 2009
Shionogi & Co., Ltd.

Shionogi announces positive results from Phase3 studies of peramivir, a novel anti-viral drug for influenza

Shionogi & Co., Ltd. (Head office: Osaka; President: Isao Teshirogi) today announced that it has achieved the primary objectives of two Phase3 clinical studies of peramivir (a neuraminidase inhibitor, S-021812) for seasonal influenza virus infection that were conducted during the 2008-2009 influenza season.

In patients with uncomplicated seasonal influenza, Shionogi conducted a three-armed, multi-center, randomized, double-blind, multi-national Asian study that compared the efficacy and safety of a single dose treatment of i.v. peramivir (either 300 mg or 600 mg) and oral treatment with oseltamivir phosphate (Tamiflu®) twice a day for 5 days. A total of 1,099 uncomplicated patients infected with seasonal influenza virus were enrolled at 146 centers (Japan:100; Korea*:25; Taiwan:21). Both the 300 mg and 600 mg single dose peramivir groups demonstrated non-inferiority for the primary endpoint, time to alleviation of symptoms (TTAS), compared to that of the oseltamivir group. The medians for the TTAS for the peramivir 300 mg, peramivir 600 mg and oseltamivir groups were 78.0 hrs, 81.0 hrs and 81.8 hrs, respectively. Occurrence rate of adverse drug reaction was significantly reduced in the 300 mg of peramivir group compared to that of Tamiflu group.

* : Shionogi and Green Cross Corporation, the license holder of peramivir in Korean, co-conducted the portion of the studies in Korea

Additionally, Shionogi conducted a double-blind, multi-center Phase3 study of i.v. peramivir with dosing over multiple days. The study enrolled 42 influenza patients at high-risk of serious complications due to one or more qualifying conditions: diagnosis with poorly controlled diabetes mellitus, a chronic respiratory disease requiring pharmacotherapy, or current treatment with any immunosuppressive drug. Peramivir was administered at 300 mg i.v. or 600 mg i.v. per day, and the duration was adjusted (up to 5 days) on a case-by-case basis, depending on the patient's temperature and clinical condition. In this study, the median time to alleviation of symptoms in all 37 evaluable patients treated with either 300 mg or 600 mg peramivir daily was 68.6 hrs. The median time of each group (300mg and 600mg) were 114.4hrs and 42.3hrs, respectively. The results indicated that the symptoms of influenza of patients with high risk, which is believed to be prolonged were also improved in shorter period.

Peramivir 300 mg or 600 mg i.v. single and multiple doses were generally safe and well tolerated in these trials. Further analyses of the study data, including secondary efficacy endpoints and detailed safety is underway. Additional data will be submitted for presentation at an upcoming medical meeting.

A new anti-influenza virus drug is desirable for suppressing the prevalence of swine-origin influenza

(A/H1N1) and human-to-human infection of highly pathogenic avian influenza (A/H5N1). Shionogi recognizes that to limit the prevalence of pandemic influenza is a social mission for Shionogi. To accomplish the mission, Shionogi has been making its best effort to file the New Drug Application and to get a manufacturing approval as soon as possible.

About peramivir

Peramivir, licensed from US-based BioCryst Pharmaceuticals, Inc. (Head Office: Birmingham, Alabama; CEO: Jon P. Stonehouse) is neuraminidase inhibitor for intravenous infusion being developed by Shionogi in Japan. Highly potent activity of peramivir against influenza A and B viruses has been shown. It has also shown that peramivir has active against highly pathogenic H5N1 (avian flu) viruses. Because of strong binding to neuraminidase and the fact it is not easily dissociated, peramivir is expected to work sufficiently against seasonal influenza virus infection.

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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