

November 4, 2009
Shionogi & Co., Ltd.

Shionogi Filed a New Drug Application for Peramivir, a Novel Anti-viral Drug for Influenza

Shionogi & Co., Ltd. (Head office: Osaka; President: Isao Teshirogi) today announced that it filed a New Drug Application (NDA) for peramivir, a novel anti-viral drug for influenza (a neuraminidase inhibitor, S-021812) in October.

Based on the results of several clinical studies, Shionogi aims to receive indications of both single dose administration for adult uncomplicated seasonal influenza infection and multiple dose administration for the patients at high-risk. This NDA filing is the first application for marketing approval of peramivir in any country. The Company has initiated a clinical study for pediatric use and it will make its best effort to get the results as soon as possible.

On October 23, the U.S. Food & Drug Administration (FDA) issued an Emergency Use Authorization (EUA) in the USA for intravenous (i.v.) peramivir for hospitalized adult and pediatric patients for whom therapy with an i.v. drug is clinically appropriate. Additional information regarding the EUA is available at: www.cdc.gov/h1n1flu/eua. BioCryst Pharmaceuticals, Inc. has recently initiated two Phase III clinical studies in hospitalized patients to support its future application for Marketing Approval in the USA.

Under the social situation that the novel anti-influenza drug is needed for the H1N1 influenza pandemic, Shionogi has been making its best effort to prepare for the NDA since the positive results of the Phase 3 clinical studies of peramivir were announced in the middle of July. Consequently Shionogi achieved its objective to rapidly file the NDA within 3 months since it obtained the results of Phase 3 studies.

Shionogi, as a leading company of anti-infective drugs, will continuously direct its resources into research and development and also into educational activities to make contributions to the treatment of infectious diseases, especially for bacterial and viral infections.

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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