

February 15, 2010  
Shionogi & Co., Ltd.

## **Shionogi Files an Additional Application for Pediatric Use of “RAPIACTA<sup>®</sup>” a Novel Anti-viral Drug for Influenza**

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Shionogi & Co., Ltd. (Head Office: Osaka, Japan; President: Isao Teshirogi; hereafter “Shionogi”) announced that it has filed an additional application for pediatric use of “RAPIACTA<sup>®</sup>” (generic name: peramivir), a novel anti-viral drug for the treatment of infection with influenza A or B virus strain, on February 15, 2010.

RAPIACTA<sup>®</sup> is the world’s first intravenous injection for treatment of influenza infection, which was launched for adult use in Japan on January 27, 2010. Many patients and medical practitioners hope for an additional option to treat pediatric influenza infections as children with influenza can be at risk of severe symptoms and complications. Therefore, Shionogi filed a NDA for adult use of RAPIACTA<sup>®</sup> as soon as it confirmed the safety and efficacy of the drug in clinical trials, and at the same time, the Company started a clinical study in children last fall. The submission of additional indications of both single and multiple dose administration in pediatric patients is based on the results of about 100 pediatric cases treated in the study.

RAPIACTA<sup>®</sup> is a novel anti-viral drug for influenza (neuraminidase inhibitor) for both single dose administration for adult uncomplicated seasonal influenza infection as well as single or multiple dose administration for adult patients at high-risk. This drug is sufficiently effective and expected to improve compliance against seasonal influenza virus infection with a single-dose administration as an outpatient treatment. It is also widely available for treatment of patients with severe and life-threatening influenza and when oral treatments are not a viable alternative. Shionogi believes that RAPIACTA<sup>®</sup> represents an important therapeutic advance for patients with influenza.

Shionogi continues to make its best effort to get the approval for pediatric use as soon as possible. As a leading company of anti-infective drugs, Shionogi is committed to directing its resources into research and development and educational activities to contribute to the treatment of infectious diseases, especially of bacterial and viral origin.

### **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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