Shionogi & Co., Ltd.

Shionogi Receives an Approval for an Additional Indication for Pediatric Use of RAPIACTA®, a Novel Anti-viral Drug for Influenza

Osaka, Japan, October 27, 2010 – Shionogi & Co., Ltd. (Head Office: Osaka; President and Representative Director: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that it received approval for the additional indication for pediatric use of "RAPIACTA®" (generic name: peramivir), a novel anti-viral drug for the treatment of infection with influenza A or B virus strain.

RAPIACTA® is the world's first approved intravenous injection for treatment of influenza infection, which was launched for adult use in Japan on January 27, 2010. Parents and medical practitioners desire an additional option to treat pediatric influenza infections, as children with influenza can be at risk of severe symptoms and complications. Therefore, Shionogi conducted a clinical study of 117 pediatric patients, and in February 2010 submitted the application for an additional indication to treat pediatric patients with influenza infection. Usage of existing products for infants has been restricted because of insufficient safety evaluation. With this approval for the additional indication for pediatric patients, RAPIACTA® offers a new treatment option for children and infants suffering from influenza infections. For children and adults, this drug has been shown to be effective and is expected to improve compliance against seasonal influenza virus infection with a single-dose administration. It is also indicated for patients with severe and life-threatening influenza and where oral administration is difficult or not possible. Shionogi believes that RAPIACTA® represents an important therapeutic advance for all patients with influenza.

Shionogi has collected data on all patients who received RAPIACTA® during a specific period of time after launch to delineate its clinical utilization and safety. To keep health care professionals informed of the proper use of the product, Shionogi submitted a summary of this experience to the Ministry of Health, Labour and Welfare. It was reported that in 1,174 cases evaluated, 0.9% of adverse events reported were considered related to RAPIACTA® therapy, and the most frequent adverse events reported were diarrhea and emesis. In 60 pediatric cases treated by dose/weight (10mg/kg), no adverse events were noted. As it was judged that additional efforts for tracking safety events at this time were not needed, Shionogi has ended the monitoring of all patients who received RAPIACTA®. However, Shionogi will continue to evaluate safety information reported and conduct appropriate post marketing surveillance studies based on the utilization. Utilizing surveillance studies for pediatric patients will be included in those studies.

Shionogi is expected to secure an adequate supply for about 970,000 people for this fiscal year (through March 2011) as a result of its maximum efforts. In addition, the Company is ensuring the manufacturing capability of a stable supply for urgent demands.

Shionogi, as a leading company of anti-infective drugs, is committed to directing its resources into research and development and also into educational activities in order to contribute globally to the treatment of infectious diseases, especially of bacterial and viral origin.

RAPIACTA® for Intravenous Drip Infusion Product Overview

Product Name:	RAPIACTA® 300mg bag for intravenous drip infusion RAPIACTA® 150mg vial for intravenous drip infusion
Generic Name:	Peramivir Hydrate
Indication:	Infection with influenza A or B virus strain
Form and Content:	300mg of peramivir in one bag (60mL) for intravenous drip infusion 150mg of peramivir in one vial (15mL) for intravenous drip infusion
Dosage and Administration:	Adults: In general, a single dose of 300mg of peramivir is to be administrated to adult patients as intravenous drip infusion over longer than 15 minutes. For patients at high-risk, a single dose of 600mg of peramivir is to be administrated as intravenous drip infusion over longer than 15 minutes one time daily, but multiple daily doses are also a treatment option depending on the condition of the patient. The dosage should be adjusted according to the age or medical condition of the patient. Children: In general, a single dose of 10mg/kg per day of peramivir is to be administrated to pediatric patients as intravenous drip infusion over longer than 15 minutes, but multiple daily doses are also a treatment option depending on the condition of the patient. The single dosage can increase up to 600mg.
Approval Date:	January 13, 2010 (Additional pediatric indication: October 27, 2010)
Price:	5,634 yen per bag (300mg) 3,032 yen per vial (150mg)

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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