SHIONOGI & CO., LTD.

Shionogi Launches "Endoxan® Powder 100mg for Oral" for Nephrotic Syndrome

Osaka, Japan, July 30, 2012 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that it has launched "Endoxan® powder 100mg for oral" (generic name: cyclophosphamide hydrate) for nephrotic syndrome (limited to be used only on the condition that enough effects are not seen in the appropriate treatment by corticosteroid) in Japan.

The First Committee on New Drugs of the Pharmaceutical Affairs and Food Sanitation Council, held on April, 2011, was evaluated preliminary and allowed to submit an additional indication of former "Endoxan® tablets 50mg for oral" which Shionogi has been providing. Shionogi submitted an additional indication of nephrotic syndrome on May, 2011 and received a marketing and manufacturing approval on September, 2011. However, administered dosage for nephrotic syndrome is "Normally for a child, Endoxan® should orally be administered 2～3mg/kg a day for 8～12 weeks." So, it is difficult to adjust administered dosage by the former Endoxan® tablets. Regarding this additional indication of Endoxan®, the Investigational Committee for the Unapproved Drugs and Off-label Drug Use with High Medical Needs, established by the Ministry of Health, Labour and Welfare, requested development of a product for children to Shionogi.

Due to reasons like above, Shionogi has developed and launched "Endoxan® powder 100mg for oral" which is controllable for administered dosage. Shionogi anticipates the product will bring an appropriate treatment to patients and medical experts and is striving to make contributions to the resolution of the Unapproved Drugs and Off-label Drug Use.

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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