## Shionogi Receives Approval of Additional Dosage and Administration of Carbapenem Antibiotic Products: "Finibax<sup>®</sup> 0.25g IV Solution" and "Finibax<sup>®</sup> 0.25g IV Solution Kit"

**Osaka, Japan, April 22, 2011** - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that it had received approval in Japan for the additional dosage and administration of "Finibax<sup>®</sup> 0.25g IV Solution" and "Finibax<sup>®</sup> 0.25g IV Solution Kit" (generic name: doripenem hydrate), carbapenem antibiotic products, which allows the products to be administered 3g as a maximum daily dose.

"Finibax<sup>®</sup> 0.25g IV Solution", launched in September, 2005 in Japan, is a parenteral injection of carbapenem antibiotic discovered and developed by Shionogi and exhibits a strong and broad antibacterial spectrum, covering gram-positive to gram-negative bacteria as well as aerobic to anaerobic bacteria. Since this antibiotic has a strong antibacterial activity against *Pseudomonas aeruginosa*, which causes a remedial problem as one of offending bacteria of serious and intractable infections, it has been prescribed with high usability in treating various types of moderate to serious infections. "Finibax<sup>®</sup> 0.25g IV Solution Kit", comprising the injectable antibiotic and its diluting agent, was also launched in June, 2006, as a product enhanced convenience, aseptic condition and assuredness in preparation.

Finibax<sup>®</sup>/Doribax<sup>®</sup> have already been approved in 78 countries of the world and the approval of the maximum daily dose of 3g in Japan is the first achievement in the world. Recently, some strains with low sensibilities against the carbapenem antibiotics are increasing in offending bacteria of serious and intractable infections including *Pseudomonas aeruginosa* and *Acinetobacter*, thereby the cases of difficult-to-treat have often been reported. From such a background, Shionogi decided that higher dosage was necessary for Finibax<sup>®</sup> to utilize its stronger antibacterial activity for the patients, and in March, 2010, the Company had submitted the application for the additional dosage and administrations, 1g three times a day (3g daily) as a maximum for the patients with serious and intractable infections. With this approval, Finibax<sup>®</sup> is expected to offer an additional treatment option for the patients suffering from serious and intractable infections.

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.

## **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.

## For further information, contact:

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