Regarding the Application for Manufacture and Sales Approval of “Lisdexamfetamine Dimesylate”, a Therapeutic Agent for Attention Deficit Hyperactivity Disorder

Osaka, Japan, April 13, 2017 - Shionogi & Co., Ltd. (hereafter “Shionogi”) would like to inform you that Shionogi applied for approval to manufacture and sell the therapeutic agent for childhood attention deficit hyperactivity disorder, “Lisdexamfetamine Dimesylate” (development code: S-877489, hereafter “the drug”), today.

ADHD is one of the neurodevelopmental disorders characterized by three main symptoms: inattentiveness, hyperactivity, impulsivity and is the impaired brain function which is treatable by psychosocial treatment/support and medication. Based on DSM-5, the prevalence of ADHD in children and adults is reported to be 5% and 2.5% respectively.1

The drug is a central nervous system stimulant that is thought to act to alleviate the symptoms of ADHD by augmenting the action of the neurotransmitters dopamine and noradrenaline, by promoting their release and inhibiting their re-uptake, via receptors in the synapses.

In addition to Intuniv®, which obtained approval for manufacture and sale on the 30 March, the development of the drug provides new treatment options for ADHD.

Forward Looking Statement

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.

Contacts:

Corporate Communications, Shionogi & Co., Ltd.
Telephone: +81-6-6209-7885
Fax: +81-6-6229-9596

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