Press Release

Acquisition of Marketing Approval for VYVANSE® Capsule 20mg/30mg for Treatment of Attention Deficit Hyperactivity Disorder

Osaka, Japan, April 12, 2019 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that that Shionogi received marketing approval for VYVANSE® (lisdexamfetamine dimesylate) from the Ministry of Health, Labour and Welfare on March 26, 2019. The product is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children.

VYVANSE® is a once-daily drug that stimulates the release and blocks the reuptake of dopamine-noradrenaline. VYVANSE® is a prodrug-typed product intending to maintain the blood level of a pharmacologically active drug. The prodrug technology contribute its slow conversion in the body into an active drug and inhibit rapid elevation of the blood level.

Because the substance contained in this product is designated as a stimulant drug substance, the product is approved for marketing on the condition that necessary measures are taken, such as prescription by medical experts well-versed in diagnosis/treatment of ADHD which should be given only to appropriate patients, and handling only by medical institutions and pharmacies, where the risks of this drug including dependence can be fully controlled.

Shionogi will establish a strict distribution management system based on the approval conditions and make a positive contribution to therapy for patients who need VYVANSE®.

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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.