Press Release

Shionogi Submits New Drug Application of INTUNIV® in Japan for Treatment of Adult ADHD

Osaka, Japan (August 10, 2018) - Shionogi & Co., Ltd. (hereafter "Shionogi") today announced that Shionogi applied for approval to manufacture and sell the therapeutic agent for adult indication of attention deficit hyperactivity disorder (ADHD), INTUNIV® Tablets 1mg/3mg (generic name: guanfacine hydrochloride).

Shionogi & Shire conducted the clinical studies of INTUNIV® in adult ADHD patients (18 years old and over) in Japan first in the world. INTUNIV® demonstrated a statistically significant improvement compared with placebo in the primary endpoint of ADHD evaluation scale*. INTUNIV® also demonstrated statistically significant superior efficacy compared with placebo in the clinically important secondary endpoint of the clinical global impression improvement scale (CGI-I). Additionally, INTUNIV® demonstrated favorable safety and efficacy profile in long-term treatment for 1 year at longest.

INTUNIV® is a 'selective α_{2A} adrenergic receptor agonist', firstly approved as a drug for ADHD with this mechanism of action, and INTUNIV® is a non-central nervous system stimulant that is to be administered once daily and has been approved as a drug for ADHD in pediatric patients (6 to 17 years old) in 36 countries including Japan. In Japan, Shionogi launched INTUNIV® for indication of ADHD in pediatric patients on May 2017.

Shionogi will further contribute to treatment of ADHD through providing INTUNIV® as a new treatment option for adult ADHD patients. For more details on ADHD, please refer to http://www.adhd-info.jp.

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About Shionogi

Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to bringing benefits to patients based on its corporate philosophy of “supplying the best possible medicine to protect the health and wellbeing of the patients we serve.” Shionogi’s research and development currently target two therapeutic areas: infectious diseases, and pain/CNS disorders. For over 50 years, Shionogi has developed and commercialized innovative oral and parenteral anti-infectives. In addition, Shionogi is engaged in new research areas, such as obesity/geriatric metabolic disease and oncology/immunology. Contributing to the health and quality of life of patients around the world through development in these therapeutic areas is Shionogi's primary goal. For more details, please visit www.shionogi.co.jp/en/.

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.

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Reference

* ADHD-RS-IV with adult prompts total score (Japanese version)