Shionogi Announces Positive Top-Line Results for INTUNIV® Evaluated in Phase 3 Clinical Trial in Adults with ADHD

Osaka, Japan, September 20, 2017 - Shionogi & Co., Ltd (hereinafter "Shionogi") has announced that we have achieved significant improvements in the primary endpoint based on topline results of a Phase III clinical trial conducted in Japan to adult patients with attention deficit/hyperactivity disorder (ADHD) using INTUNIV® (generic name: guanfacine hydrochloride)

INTUNIV® is a 'selective α_{2A} adrenergic receptor agonist', the first medication for ADHD with this mechanism of action, and is a non-central nervous system stimulant that is to be administered once daily and has been approved as a treatment for pediatric patients with ADHD (6 to 17 years old) in 36 countries around the world including Japan. This is the first clinical trial evaluating INTUNIV® in adult patients (18 years old and over) with ADHD and the results are positive.

In this randomized, double-blind multi-center parallel-group, placebo-controlled study, adult patients with ADHD were randomly assigned to INTUNIV® treatment or the placebo treatment group at a ratio of 1:1, where the efficacy and safety after 10 weeks of administration were assessed. Results of the study demonstrated a statistically significant improvement in the amount of change in the baseline of the primary endpoint (ADHD evaluation scale*) in the INTUNIV® group, comparing to the placebo group. INTUNIV® was also significantly better than placebo on the clinically important secondary endpoint of the clinical global impression improvement scale (CGI-I).
No particular issues on safety as well as tolerability in INTUNIV® treatment group were observed. Treatment emergent adverse events ≥ 10% for were somulence, dry mouth, blood pressure decrease, nasophryngitis, dizziness postural and constipation.

Shionogi will evaluate the full data and will investigate plans for disclosure of detailed data.Shionogi will continue to strive to provide INTUNIV® as a new treatment option for adult patients with ADHD.

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)