Press Release

Shionogi Got Approval of Additional Indication of INTUNIV® in Japan for Treatment of Adult ADHD

Osaka, Japan, June 18, 2019 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced the approval for INTUNIV ® (guanfacine hydrochloride) for the treatment of attention deficit hyperactivity disorder (ADHD) with additional indication in adult patients.

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 (as of March 2018). In Japan, Shionogi launched INTUNIV® for indication of ADHD in pediatric patients on May 2017.

Shionogi 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. Shionogi filed for partial change approval for adult patients based on the abovementioned data.

Shionogi will make every effort to contribute to ADHD therapy with INTUNIV® as an option for the treatment.

Press Release

Product Summary: INTUNIV ®

- Product Name: INTUNIV ® Tablets 1mg/3mg
- Generic Name: Guanfacine hydrochloride
- Indications: Attention deficit hyperactivity disorder (ADHD)
  (The wording "for pediatric use" is deleted starting from June 18, 2019)
- Dosage & Administration: Patient under 18 years old: (the underlined part is added from June 18,2019)
  In general, start administrating this drug 1mg daily (as guanfacine) to patients under 18 years old with the body weight under 50kg, and 2mg daily to those with body weight 50kg or over; Increase the dose by 1mg each at intervals of one week or longer up to the maintenance dose. The dosage should be adjusted depending on the symptoms. The drug should be administered orally once daily.
  Patients 18 years or older:
  In general, start administering this drug 2mg daily to those who are 18 years or older; Increase the dose by 1mg each at intervals of one week or longer up to the maintenance dose from 4 to 6mg daily. The dosage should be adjusted depending on the symptoms. However, the maxim dose should not exceed 6mg per day. The drug should be administered orally once daily.
- NHI price: 407.20 yen per INTUNIV ® Tablet 1mg
  537.50 yen per INTUNIV ® Tablet 3mg

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)