SHIONOGI & CO., LTD.

Attention deficit/hyperactivity disorder (AD/HD) therapeutic agent 'INTUNIV® Tablets 1 mg/3 mg' launched in Japan

Osaka, Japan (May 26, 2017) - Shionogi & Co., Ltd. (hereafter "Shionogi") would like to announce that Shionogi launched on the indications of the pediatric attention deficit/hyperactivity disorder (AD/HD) therapeutic agent 'INTUNIV® Tablets 1 mg/3 mg' (generic name: guanfacine hydrochloride, code name: S-877503) in Japan.

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]

INTUNIV® is 'selective α2A adrenergic receptor agonist' which is the first medicine with this action mechanism for ADHD and is a non-central nervous system stimulant that is to be administered once daily. Although the mechanism of action of INTUNIV® against ADHD is not fully understood, non-clinical trials show that INTUNIV® strengthens the signal transmission that is reduced in prefrontal cortex by selectively stimulating post-synaptic α2A receptor. As the mechanism of action of this drug is different from that of other ADHD therapeutic drugs marketed in Japan thus far. INTUNIV® is expected to be a new treatment option for ADHD patients.

Shionogi will continue to contribute to the treatment of patients through the provision of INTUNIV® as a new treatment option for ADHD.

[1] American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). American Psychiatric Publishing 2013

'INTUNIV®' Product Description

Product Name	INTUNIV® Tablets 1 mg/3 mg
Generic Name	Guanfacine hydrochloride
Indications	Pediatric attention deficit/hyperactivity disorder (AD/HD)
Pharmacological Effects	Selective α2A adrenergic receptor agonist
Date of manufacturing and marketing approval	March 30, 2017
Date if listing in the NHI reimbursement price	May 24, 2017
Date of launch	May 26, 2017
NHI price	412.20 yen per INTUNIV® Tablet 1mg 544.30 yen per INTUNIV® Tablet 3mg
Marketing Authorization Holder and Manufacturer	Shionogi & Co., Ltd
Promotion Partner	Shire Japan KK

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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