

FOR IMMEDIATE RELEASE



SHIONOGI ANNOUNCES FDA APPROVAL OF KAPVAY™ – THE FIRST AND ONLY THERAPY APPROVED FOR USE WITH STIMULANT MEDICATION FOR THE TREATMENT OF ADHD

FLORHAM PARK, NJ (October 4, 2010) – Shionogi Inc., the U.S.-based group company of Shionogi & Co., Ltd., today announced the U.S. Food and Drug Administration approval of the non-stimulant medication KAPVAY™ (clonidine hydrochloride) extended-release tablets, an extended-release oral formulation for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children and adolescents ages 6-17 years. KAPVAY™ is the only formulation of clonidine hydrochloride approved by the FDA for the treatment of ADHD, and is the first and only FDA-approved ADHD treatment indicated for use as add-on therapy to stimulant medication. KAPVAY™ can also be used as monotherapy when treating ADHD.

An oral, non-stimulant, twice-daily therapy, KAPVAY™ is a centrally acting alpha₂-adrenergic receptor agonist. While the mechanism of action of alpha₂ agonists in ADHD is not known, it is believed to involve the pre-frontal cortex (PFC) of the brain. Studies suggest that the PFC regulates attention and plays a critical role in impulse control, working memory and executive function.

“The FDA approval of KAPVAY™ represents an exciting milestone in the field of ADHD,” said Donald C. Manning, MD, PhD, Chief Medical Officer of Shionogi Inc. “The extended-release formulation of KAPVAY™ minimizes the peaks and troughs in blood levels, thereby decreasing overactivation of the alpha receptors in the brain and periphery. We look forward to providing this important, beneficial treatment for ADHD to patients, both as monotherapy and add-on therapy to stimulants.”

“ADHD is a complex disorder that requires individualized treatment. While there are prescription treatment options available, many ADHD patients on stimulants do not achieve adequate control of symptoms,” explained Rakesh Jain, MD, MPH, Director of Psychiatric Drug Research for R/D Clinical Research at Lake Jackson, Texas, and an investigator in the clinical trials. “KAPVAY™, when added to a stimulant, addresses an unmet need, and improves ADHD symptoms beyond what is achieved by stimulants alone. This is a significant step forward for the treatment of ADHD to have an approved product for add-on therapy in our treatment armamentarium.”

ADHD is a neurobehavioral disorder that occurs in childhood and may continue into adolescence and adulthood, which affects more than 4.5 million children ages 3-17 in the U.S. alone. Approximately 3-7 percent of U.S. school-aged children are believed to suffer from this disorder. Symptoms include difficulty staying focused and paying attention, difficulty controlling behavior, and hyperactivity/over-activity.

This approval is based on two Phase III studies, which demonstrated efficacy at 5-weeks that children and adolescents (6-17 years) with ADHD treated with KAPVAY™ experienced statistically significant improvements in core symptoms of ADHD – inattention, hyperactivity and impulsivity. The most common and drug related adverse reactions (incident at least 5% and twice the rate of placebo) included

somnolence, fatigue, upper respiratory tract infection (cough, rhinitis, sneezing), irritability throat pain (sore throat), insomnia, nightmares, emotional disorder, constipation, nasal congestion, increased body temperature, drug mouth and ear pain. Maintenance efficacy has not been systemically evaluated and patients who are continued on longer-term treatment require periodic reassessment.

About KAPVAY™

Administered orally, clonidine hydrochloride exerts its pharmacological effects as a centrally acting alpha₂-adrenoceptor agonist. The formulation in KAPVAY™ is designed to delay the absorption of active drug in order to decrease peak to trough plasma concentration differences.

Important Safety Information

KAPVAY™ should not be used in patients with known hypersensitivity to clonidine.

KAPVAY™ has not been studied in children with ADHD less than 6-years old.

Use KAPVAY™ with caution in patients at risk for hypotension, bradycardia and heart block. Measure heart rate and blood pressure prior to initiation of therapy, following dose increases, and periodically while on therapy. Advise patients to avoid becoming dehydrated or overheated.

Somnolence and sedation have been observed with KAPVAY™. Consider the potential for additive sedative effects with CNS depressant drugs. Caution patients against operating heavy equipment or driving until they know how they respond to KAPVAY™.

Patients should be instructed not to discontinue KAPVAY™ therapy without consulting their physician due to the potential risk of withdrawal effects. KAPVAY™ should be discontinued slowly in decrements of no more than 0.1 mg every 3 to 7 days.

In patients who have developed localized contact sensitization or other allergic reaction to clonidine in a transdermal system, substitution of oral clonidine hydrochloride therapy may be associated with the development of a generalized skin rash, urticaria or angioedema.

Use in patients with vascular disease, cardiac conduction disease, or chronic renal failure: Monitor carefully and uptitrate slowly.

Clonidine may potentiate the CNS-depressive effects of alcohol, barbiturates or other sedating drugs.

Caution is warranted in patients receiving clonidine concomitantly with agents known to affect sinus node function or AV nodal conduction (e.g., digitalis, calcium channel blockers and beta-blockers) due to a potential for additive effects such as bradycardia and AV block.

Do not use KAPVAY™ concomitantly with other products containing clonidine.

To report SUSPECTED ADVERSE REACTIONS, contact Shionogi Pharma, Inc. at 1-800-849-9707 ext. 1454 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For full prescribing information, please visit www.KAPVAY.com.

About Alpha₂ Agonists

The prefrontal cortex (PFC) which regulates attention appears to be an important area of the brain affected in patients with ADHD. Specifically, studies suggest that the PFC plays a critical role in impulse control, working memory and executive function. Postsynaptic alpha₂-adrenoceptors are one of several biological receptors important for PFC function.

About ADHD

ADHD is a neurobehavioral disorder that most often occurs in childhood and may continue into adolescence and adulthood. There are three subtypes of ADHD: predominantly hyperactive-impulsive, predominately inattentive, and combined hyperactive-compulsive and inattentive, with the latter being the most common. ADHD symptoms fall under three main categories: inattention, hyperactivity and impulsivity, which can include behaviors such as trouble focusing, frequent daydreaming, excessive talking, fidgeting/squirming, chronic impatience and difficulty waiting their turn, depending on the category.

The cause of ADHD is not yet known. However, research has shown potential links to genetic and environmental factors. While there is no cure for ADHD, the disorder can be managed with a variety of treatments including parental education and training, behavioral therapy and prescription medication.

ADHD is one of the most common childhood psychiatric disorders. In the United States alone, more than 4.5 million children ages 3-17 have been diagnosed, as of 2006. Approximately 3-7 percent of U.S. school-aged children are believed to suffer from this disorder. Boys are also more than twice as likely to be diagnosed (11 percent) as girls (4 percent).

About Shionogi & Co., Ltd.

Headquartered in Osaka, Japan, Shionogi & Co., Ltd. is a major research-driven pharmaceutical company dedicated to placing the highest value on patients. Shionogi's Research and Development currently targets three therapeutic areas: Infectious Diseases, Pain, and Metabolic Syndrome. The Company has provided such innovative medicines as Crestor and Doripenem, which have been successfully delivered to millions of patients. In addition, Shionogi is engaged in new research areas such as allergy and cancer. Contributing to the health 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. For more information on Shionogi Inc., headquartered in Florham Park, NJ, please visit www.shionogi-inc.com.

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.

Contact:

Shionogi Inc.

Yoshimasa Kyokawa

Telephone: +1-678-459-1558

ykyokawa@shionogi-inc.com

HealthStar Public Relations

Dave Schemelia

Telephone: +1-609-468-9325

dschemelia@healthstarpr.com

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