

# Shionogi and Shire to Collaborate on the Development and Commercialization of the Therapeutic Agents for Attention-Deficit/Hyperactivity Disorder

Osaka, Japan, November 18, 2011 - Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced a collaboration with Shire plc (Head Office: Dublin, Republic of Ireland; CEO: Angus Russell; hereafter "Shire") focused on the development and commercialization of the products, Vyvanse<sup>®</sup> and Intuniv<sup>®</sup>, product names in the US, for the treatment of Attention-Deficit/Hyperactivity Disorder (hereafter "ADHD").

Shionogi will pay an upfront payment to Shire. Under the terms of the agreement, Shionogi and Shire will jointly pursue development of the compounds. After the launch of products, the parties will co-promote and Shionogi will also pay a sales royalty payment on net sales of the products.

ADHD is a behavior disorder which is characterized by poor attention skills, impulsivity and hyperactivity disportionate to age or physical development and the symptoms affect daily life and school work. These characteristics arise in childhood, typically before age 7, and can continue to exhibit through adolescence and adulthood. ADHD also seems to be a dysfunction in central nervous system.

Non-drug treatment for ADHD including the environment modification, which adjusts factors related to inappropriate behaviors, is standard method, but drug treatment is also used when non-drug treatment is insufficient. Mechanisms of Vyvanse<sup>®</sup> and Intuniv<sup>®</sup> are different from those of the existing drugs. Vyvanse<sup>®</sup> is a stimulant which increases the release of dopamine and norepinephrine into extraneuronal space and blocks the reuptake of these monoamines into the presynaptic neuron to stimulate the both neurons. Intuniv<sup>®</sup> is a non-stimulant which enhances the activity of norepinephrinergic neuron via their receptors in the synapse.

Shionogi has been committed to directing its resources into the development, marketing and educational activity for the proper usage on the antidepressant, Cymbalta<sup>®</sup> in the therapeutic areas of central nervous system in Japan. Collaboration between Shionogi and Shire on the development and commercialization of Vyvanse<sup>®</sup> and Intuniv<sup>®</sup>, which have been prescribed for many ADHD patients including those in the US, will bring new treatment options to ADHD patients in Japan. Shionogi is striving to make contributions to the treatment of central nervous system diseases.

# About Vyvanse<sup>®</sup> and Intuniv<sup>®</sup>

Vyvanse<sup>®</sup> and Intuniv<sup>®</sup> are the therapeutic agents for ADHD owned by Shire. Vyvanse<sup>®</sup> has been approved in Canada and Brazil since the launch in the US in July, 2007 and its sales was 634 million dollars in 2010. Intuniv<sup>®</sup> was also launched in the US in November, 2009 and its sales was 166 million dollars in 2010.



#### **About Shire**

Shire's strategic goal is to become the leading specialty biopharmaceutical company that focuses on meeting the needs of the specialist physician. Shire focuses its business on Attention-Deficit /Hyperactivity Disorder (ADHD), human genetic therapies, gastrointestinal diseases and regenerative medicine as well as opportunities in other therapeutic areas to the extent they arise through acquisitions. Shire's in-licensing, merger and acquisition efforts are focused on products in specialist markets with strong intellectual property protection and global rights. Shire believes that a carefully selected and balanced portfolio of products with strategically aligned and relatively small-scale sales forces will deliver strong results.

For further information on Shire, please visit the Company's website: www.shire.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.

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