

## Shionogi Enters into a License and Collaboration Agreement for Its Oral β-Secretase Inhibitor Program for the Treatment of Alzheimer's Disease with Janssen Pharmaceuticals, Inc.

**Osaka, Japan, October 31, 2012 -** Shionogi & Co., Ltd. (Head Office: Osaka; President & CEO: Isao Teshirogi, Ph.D.; hereafter "Shionogi") today announced that it has entered into a license agreement with Janssen Pharmaceuticals, Inc., Titusville, NJ, USA, ("Janssen") for a research collaboration and for the development and commercialization of oral  $\beta$ -secretase ("BACE") inhibitors for the treatment of Alzheimer's disease. Janssen Research & Development, LLC, an affiliate of Janssen Pharmaceuticals, Inc., will conduct the clinical development work under the agreement.

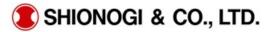
Under the terms of this agreement, the oral BACE inhibitor compounds discovered by Shionogi, including the lead drug candidates, one of which is currently being prepared for clinical studies, will be licensed to Janssen. Inhibition of BACE activity and is expected to reduce the progression of dementia associated with Alzheimer's disease.

Shionogi and Janssen will also jointly conduct a research collaboration for back-up oral small molecules. In the event that one or more of these back-up compounds are selected for clinical studies, Janssen will conduct the development in accordance with mutually agreed plans.

Shionogi will receive an upfront payment from Janssen. Shionogi also is eligible to receive milestone payments from Janssen upon successful completion of key development phases, including marketing approval. After a launch of a product under this agreement, Janssen will have the right to promote it exclusively, and Shionogi shall be entitled to certain royalties. However, Shionogi holds joint promotion rights with Janssen in some territories including Japan and the USA.

Alzheimer's disease is a growing global public health problem and poses enormous challenges for individuals, families and societies. It is anticipated that the number of patients with Alzheimer's disease is increasing around the world for an aging society. Shionogi will strive to supply innovative and effective medicines to patients suffering from Alzheimer's disease and their families in cooperation with Janssen, which has a long history in discovering, developing and marketing medicines to treat disorders of the brain and central nervous system.

Shionogi expects that this collaboration will maximize the potential of its drug candidates and facilitate an appropriate allocation of Shionogi's resources for global research and



development.

Shionogi engages in research, development, manufacturing and marketing activities based on our Company policy: "Shionogi strives constantly to supply the best possible medicine to protect the health and well-being of the patients we serve." To achieve this vision, Shionogi is accelerating our operation globally with other companies and academia and dedicates itself to placing the highest value on patients throughout the world.

The Janssen Pharmaceutical Companies leverage world-class discovery and development expertise and operational excellence to bring to market innovative, effective treatments in five therapeutic areas: cardiovascular and metabolism, immunology, infectious diseases and vaccines, neuroscience, and oncology. For more than 50 years Janssen has been a leader in neuroscience with many innovative products in psychiatry, neurology and pain.

## About Alzheimer's Disease and β-Secretase (BACE) Inhibitors

Alzheimer's disease is characterized by the degeneration and deficiency in nerve cells in the brain which may be caused by the abnormal accumulation of  $\beta$ -amyloid protein. As the disease progresses, brain atrophy occurs and dementia develops. Since Dr. Alois Alzheimer reported the first case in 1906, millions of patients have been diagnosed with Alzheimer's disease. Currently, there are no agents approved to treat the cause of Alzheimer's disease or that can suppress disease progression. BACE inhibitors are a class of compounds that can enter the brain and block the activity of BACE 1, an enzyme needed for the generation of  $\beta$ -amyloid. BACE inhibitors are thought to have potential to prevent the build up of  $\beta$ -amyloid and may thereby help slow or stop Alzheimer's disease.

## **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.

## For further information, contact:

Corporate Communications Department Shionogi & Co., Ltd. Osaka Telephone: +81-6-6209-7885 Fax: +81-6-6229-9596 Tokyo Telephone: +81-3-3406-8164 Fax: +81-3-3406-8099