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ONO PHARMACEUTICAL CO., LTD.

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NDA Submission in Japan for rivastigmine patch, the first transdermal patch therapy to treat Alzheimer's disease

Novartis Pharma K.K. and Ono Pharmaceutical Co., Ltd. announced today that an application for manufacturing and marketing approval of rivastigmine transdermal patch (ENA713 / ONO-2540), the first and only transdermal treatment for Alzheimer's disease, has been submitted in Japan on February 26. The companies had jointly developed the compound in Japan.

The neurotransmitter acetylcholine is crucial for memory, thinking and behavior and it is thought that Alzheimer's disease is associated with a reduced production of acetylcholin in the brain. Rivastigmine belongs to a class of drugs known as cholinesterase inhibitors, which increase neurotransmitter activity in the brain. It is in the only treatment which inhibits both enzymes involved in the breakdown of acetylcholine – acetylcholinesterase and butyrylcholinesterase.

At present, since donepezil is the only treatment for Alzheimer's disease in Japan, new treatment options are desired. The rivastigmine transdermal patch is therefore expected to contribute to benefit of patients, their families and medical professionals.

Also, recent years have seen the development of various transdermal absorption-type drugs from the viewpoint of convenience and compliance. The patch formulation of rivastigmine also offers improved convenience, e.g. caregivers can easily confirm the administration of the drug, thus making it possible to improve compliance and reduce the caregiver's burden.

Developed by Novartis Pharma of Switzerland, the rivastigmine patch was first approved in July 2007 in the United States and, since then, has been approved in more than 70 countries including EU members (as of the end of July 2009) with its position being one of the standard therapies for mild-to-moderate Alzheimer's disease.