

April 22, 2011

## **ONO PHARMACEUTICAL CO., LTD.**

President and Representative Director: Gyo Sagara

Code No: 4528 at the first section of the Tokyo and Osaka Stock Exchange

INQUIRIES: Kinya Morimoto, Managing Director, Corporate Communications

### **Approval Received for Rivastach<sup>®</sup> Patch, for the treatment of Alzheimer's disease - Japan's first transdermal patch therapy for dementia -**

Ono Pharmaceutical Co., Ltd. (Osaka, Japan) announced today that it has received regulatory approval in Japan for Rivastach<sup>®</sup> Patch (rivastigmine transdermal patch), for suppression of the progress of symptoms associated with mild to moderate dementia of Alzheimer's type, which is the first transdermal treatment for Alzheimer's disease in Japan.

Rivastach<sup>®</sup> Patch is a class of drugs known as cholinesterase inhibitor and the only treatment which inhibits both acetylcholinesterase and butyrylcholinesterase.

In the clinical study performed in Japan, Rivastach<sup>®</sup> Patch has shown efficacy in control of worsening of cognitive function\* over placebo. The drug has also shown efficacy over placebo in ADL\*\*, the secondary endpoint of the study. The efficacy in cognitive function and ADL has been shown in clinical studies overseas. <sup>(1)(2)</sup>

Rivastach<sup>®</sup> Patch is a drug in transdermal system with once-daily dosing by applying to the skin either on the back, upper arm or chest. The drug is therefore expected to reduce the burden on caregivers in dosing control and assistance because it provides easier dosing and enables a visual confirmation of dosing. In addition, sustained release of the drug absorbed through the skin controls a sharp increase in blood concentration of the drug and reduces gastrointestinal side-effect such as nausea and vomiting.

"Rivastach<sup>®</sup> Patch offers an additional new treatment option for patients with Alzheimer's disease, their families, caregivers and healthcare professionals," said Professor Yu Nakamura of Kagawa University Medical School, Department of Psychiatry and Neurology. "In patients suffering Alzheimer's disease, a decline in ADL in addition to cognitive functions also increases the burden on caregivers. Rivastach<sup>®</sup> Patch however demonstrated the improvement of ADL in the clinical study performed in Japan. As a drug in transdermal system reduces dosing control burden, the drug is expected to help maintain or improve QOL of patients with Alzheimer's disease, their families and caregivers."

Rivastach<sup>®</sup> Patch is a drug discovered by Novartis Pharma of Switzerland. In Japan, Ono and Novartis Pharma K.K. jointly developed it from the clinical study started in 2007. The drug was first approved in the United States in July 2007 and in the EU in September 2007. Since then, it has been approved as one of the standard therapies for mild-to-moderate Alzheimer's disease in more than 82 countries around the world (as of January 2011).

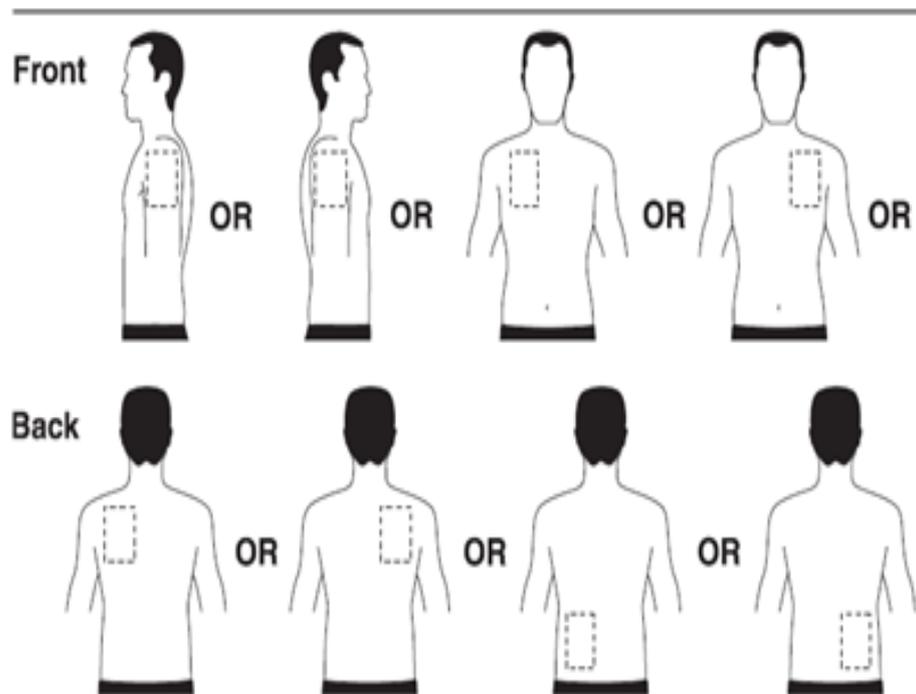
- \* Clinical endpoints evaluating cognitive functions in the clinical study mainly included word regeneration, verbal ability, auditory understanding ability of language, designation of manual fingers and articles, and orientation.
- \*\* ADL (Activities of Daily Living) is a term used in healthcare to refer to daily self-care activities including eating, excretion, bathing, and dressing.

**Reference:**

- (1) Winblad, B. Et al.: Int. J. Geriatr. Psychiatry 22(5): 456, 2007
- (2) Winblad, B. Et al.: Int. J. Geriatr. Psychiatry 22(5): 485, 2007

**PRODUCT SUMMARY:**

Product Name	Rivastach <sup>®</sup> Patch 4.5mg, 9mg, 13.5mg, or 18mg
Generic Name	Rivastigmine transdermal system
Indication	Suppression of the progress of symptoms associated with mild to moderate dementia of Alzheimer’s type
Dosage and Administration	Usually, for adults, starting with a single dose of 4.5mg as rivastigmine, once daily, the dose can be increased by 4.5mg each time every 4 weeks in principle and up to the maintenance dose of 18mg once daily. Rivastach <sup>®</sup> Patch should be applied to intact healthy skin either on the back, upper arm or chest, and replaced with a new one every 24 hours.



Date of Approval      April 22, 2011

Manufactured and  
Distributed by      Ono Pharmaceutical Co., Ltd.