

March 14, 2019

## ONO and Novartis Pharma Receive a Supplemental Approval for Formulation with New Ingredient of Rivastach<sup>®</sup> Patch and Exelon<sub>®</sub> Patch for the Treatment of Alzheimer's Disease Dementia

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") and Novartis Pharma K.K. (Tokyo, Japan; Kazunari Tsunaba, President; "Novartis Pharma") announced that the Companies received a supplemental approval for the formulation containing a new ingredient of Rivastach<sup>®</sup> Patch and Exelon<sub>®</sub> Patch (generic name: rivastigmine) on March 13, both of which are transdermal patches for suppression of the progression of symptoms associated with mild to moderate Alzheimer's disease dementia, as a partial change in the approved items of the manufacturing and marketing approval.

\*Both Rivastach and Exelon are available in the patch formulation of 4.5 mg, 9 mg, 13.5 mg and 18 mg.

With the current formulation containing a silicon ingredient, adverse drug reactions have been reported related to dermal symptoms at the patch application site such as redness and pruritus, etc. As a result, the companies developed a formulation that replaces the silicon ingredient with a synthetic rubber, and submitted a supplemental application in September 2018 for a partial change in the approved items of the manufacturing and marketing approval.

The Companies expect that the approval will further contribute to patients' treatment adherence.

ONO and Novartis Pharma will continuously promote proper use of the products to further improve the quality of life (QOL) of patients.

## About Rivastach® Patch and Exelon® Patch

Rivastigmine is an acetylcholinesterase inhibitor discovered by Novartis (Headquarters: located in Basel, Switzerland). In Japan, ONO and Novartis Pharma initiated the co-development of the product in April 2004. In April 2011, the Companies received the manufacturing and marketing approval for the products for suppression of the progression of symptoms associated with mild to moderate Alzheimer's disease dementia. ONO and Novartis Pharma launched the products under the product names of Rivastach<sup>®</sup> Patch and Exelon<sub>®</sub> Patch, respectively, in July 2011.

Rivastigmine has been approved in more than 90 countries around the world as one of the standard therapies for mild to moderate Alzheimer's disease dementia, starting with the US in July 2007 and the EU in September 2007.

## About Ono Pharmaceutical Co., Ltd.

Ono Pharmaceutical Co., Ltd., headquartered in Osaka, is an R&D-oriented pharmaceutical company committed to creating innovative medicines in specific fields. ONO focuses primarily on oncology and diabetes as major field. For further information, please refer to the company's website at www.ono.co.jp/eng.

## About Novartis

Novartis is reimagining medicine to improve and extend people's lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world's top companies investing in research and development. Novartis products reach more than 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 130,000 people of nearly 150 nationalities work at Novartis around the world. Find out more at www.novartis.com.

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