

September 19, 2018

## **ONO and Novartis Submit a Supplemental Application for Formulation with New Ingredient of Rivastach<sup>®</sup> Patch and Exelon<sup>®</sup> Patch for 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") announced today that the Companies submitted a supplemental application for the formulation containing a new ingredient of Rivastach<sup>®</sup> Patch ("Rivastach") and Exelon<sup>®</sup> Patch ("Exelon") (rivastigmine), both of which are transdermal patches for the treatment of 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 related to dermal symptoms such as redness and pruritus, etc. at the skin application site have been reported. So, the Companies have developed a formulation containing a new ingredient, replacing the silicon ingredient with a synthetic rubber. The bioequivalence of the respective formulations has now been validated, and the Companies have therefore submitted a supplemental application for a partial change in the manufacturing and marketing approval.

### **About Rivastach<sup>®</sup> Patch and Exelon<sup>®</sup> Patch**

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

As of September 2018, 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, centered on oncology and diabetes. For further information, please refer to the company's website at [www.ono.co.jp/eng](http://www.ono.co.jp/eng).

**About Novartis Pharma K.K.**

Novartis Pharma K.K. is a Japanese subsidiary of the Pharmaceutical Division of Novartis, a world leader in health care headquartered in Basel, Switzerland. In 2017, Novartis Group net sales totaled US\$49.1 billion, with Group R&D investment of approximately US\$9.0 billion. Novartis Group companies employ approximately 125,000 full-time-equivalent associates, and Novartis products are sold in over 150 countries around the world.

[www.novartis.co.jp](http://www.novartis.co.jp)

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