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ONO obtained approval for additional "dosage and administration" of RIVASTACH® PATCH for the treatment of Alzheimer-Type Dementia
– Introduction of a one-step titration that enables more rapid administration of effective dosage–

ONO PHARMACEUTICAL CO.,LTD. (Osaka, Japan; President, Representative Director and CEO, Gyo Sagara; "ONO") announced today that ONO obtained the approval for partial changes in the manufacturing and marketing authorization of transdermal patch therapy "RIVASTACH® PATCH" (generic name: rivastigmine, hereinafter RIVASTACH PATCH) to treat mild-to-moderate Alzheimer-type dementia (hereinafter AD) to add "dosage and administration", in which the dose is increased to the maintenance dose by one step (applied to the skin at a starting dose of 9 mg once daily, then the dose is increased to a maintenance dose of 18 mg once daily at Week 4).

Previously, RIVASTACH PATCH was used only in a "dosage and administration" with the three-step titration dosing regimen, where RIVASTACH PATCH is administered at a starting dose of 4.5 mg once daily, then the dose is increased by 4.5 mg every 4 weeks, as a general rule, and to a maintenance dose of 18 mg once daily at Week 12. However, for the treatment of progressive neurodegenerative diseases such as AD, it is important to initiate treatment at an effective dose as early as possible for controlling the symptoms of the disease. Thus to obtain a better efficacy within a shorter time point, it is required to reach an effective dose as fast as possible. The additional approval of one-step titration dosing regimen makes it possible to increase RIVASTACH PATCH to the effective dose of 18mg/day within 4weeks after start of treatment.

A double-blind comparative clinical study was conducted in Japanese AD patients to evaluate whether the tolerability of RIVASTACH PATCH is comparable between the one-step titration dosing regimen and the approved three-step titration dosing regimen. The primary endpoint was the percentage of subjects who discontinued treatment because of an adverse event (hereinafter referred to as the "treatment withdrawal rate due to an adverse event"). The treatment withdrawal rate due to an adverse event was 15.0% for the one-step titration dosing regimen and 18.5% for the three-step titration dosing regimen, demonstrating that there was no marked difference in tolerability and safety between the dosing regimens. In addition, efficacy was comparable between both dosing regimens.

In addition to three-step titration dosing regimen, the newly approved one-step titration dosing regimen for RIVASTACH PATCH enables physicians to choose an appropriate step titration dosing regimen depending on their patient's symptoms and tolerability. We are happy to serve the needs of AD patients and their families by providing this new treatment dosing option.

Rivastigmine is a drug discovered and developed by Novartis Pharma AG (Head office: Basel, Switzerland). In Japan, it had been co-developed by Novartis Pharma K.K (President: Dirk Kosche).and ONO since 2007, was approved for marketing in April 2011, and then launched under the trade name of "RIVASTACH PATCH" and "EXELON PATCH" from ONO and Novartis Pharma K.K., respectively, in July 2011. Outside Japan, since the drug was approved in the United States in July 2007 and in the EU in September 2007, it has been approved in more than 92 countries worldwide as one of the standard therapeutic drugs for mild-to-moderate Alzheimer-type dementia (as of May 2015).