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ONO files an application for RIVASTACH® PATCH for adding dosage and administration in Japan

ONO PHARMACEUTICAL CO., LTD. (Osaka, Japan; President, Representative Director and CEO: Gyo Sagara, "ONO") today filed an application for the approval of partial changes in the manufacturing and marketing authorization of transdermal patch therapy "RIVASTACH® PATCH" (generic name: rivastigmine) to treat mild-to-moderate Alzheimer's disease in order to add dosage and administration in which the dose is increased to the maintenance dose by one step (apply to skin once-daily with dose of 9 mg as an initial dose and once-daily dose of 18 mg as the maintenance dose after 4 weeks).

RIVASTACH PATCH is a transdermal patch applied to skin once-daily (back, upper arm, or chest) which was approved with an indication of "Inhibition of progress in dementia symptoms of mild-to-moderate Alzheimer's disease" in April 2011. This drug is currently used in a 3 step-up dosing regimen: starting with a once-daily dose of 4.5 mg; adding dose by 4.5 mg every 4 weeks, in principle, and achieving a once-daily dose of 18 mg as the maintenance dose 12 weeks after the start of administration. However, in countries other than Japan, this drug is used in a dosage and administration with one step-up dosing regimen from a once-daily dose of 9 mg to once-daily dose of 18 mg.

In terms of tolerability, cholinesterase inhibitors, including RIVASTACH PATCH, which is used for treatment of Alzheimer's disease, are generally starting at low dose and increased gradually to the maintenance dose. In contrast, for the treatment of progressive neurodegenerative diseases such as Alzheimer's disease, it is important to initiate treatment as early as possible to inhibit the progression. Thus, it is desired to shorten the step-up dosing period to achieve the effective dose of the drug as fast as possible.

Therefore, based on the requests from medical health professionals and patients to achieve the maintenance dose earlier, a clinical study was conducted to compare and evaluate the tolerability, safety and efficacy of one step-up dosing regimen with the currently approved three step-up dosing regimen in order to add dosage and administration that allow to achieve the maintenance dose in one step in Japan.
Furthermore, based on the results of this study, an application for the approval of partial changes to add the one step-up dosing regimen to the current dosage and administration was filed.

Rivastigmine is a drug discovered and developed by Novartis Pharma AG (Basel, Switzerland) in abroad. In Japan, It was co-developed by Novartis Pharma K.K. and ONO since 2007, being approved in April 2011 and launched under the trade name of "EXELON ® PATCH" by Novartis Pharma K.K and "RIVASTACH PATCH" by ONO in July 2011. In overseas countries, 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 90 countries worldwide as one of the standard therapeutic drug for mild-to-moderate Alzheimer's disease (as of September 2014).