ENGLISH TRANSLATION

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Meiji announces Initiation of Phase II/III and Long-term Clinical Trials of ME2125 (safinamide) for the Treatment of Parkinson's Disease

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Meiji Seika Pharma Co., Ltd. (Headquarter: Tokyo, Japan, President: Daikichiro Kobayashi, "Meiji") announces that it has initiated Phase II/III confirmatory and Phase III long-term clinical trials of ME2125 (development code name, INN: safinamide) as add-on therapy to levodopa in Japanese patients with Parkinson's disease with the "wearing-off" phenomenon*1.

ME2125 is a selective monoamine oxidase type B (MAO-B) inhibitor developed by Newron Pharmaceuticals S.p.A. (Head Office: Milan, Italy. CEO: Stefan Weber, "Newron"). ME2125 is associated with inhibition of sodium channels and modulation of release of glutamate as well as inhibition of degradation of dopamine, and it is expected to be a new drug for the treatment of Parkinson's disease acting through both dopaminergic and non-dopaminergic mechanisms of action. The results from clinical trials conducted outside Japan in patients with mid to late stage Parkinson's disease demonstrated an increase in daily "on-time"*2 and improvement in motor symptoms.

ME2125 was approved by the European Commission in February 2015 and launched in Germany. In the US, the new drug application is under review from March 2015. In January 2012, Meiji was granted the exclusive rights by Newron to research, development, manufacturing and marketing of ME2125 in Japan and key Asian territories.

Meiji is continuously contributing to deliver and develop therapies for central nervous system disorders, one of our strategic fields, serving as a "Specialty and Generic Pharmaceuticals Company".

*1: A phenomenon that the effect of levodopa become fade and have the Parkinson's disease symptoms before the next dose of levodopa.
*2: A time when levodopa is working well and symptoms are controlled.

About Newron Pharmaceuticals S.p.A.

Newron (SIX: NWRN) is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central nervous system (CNS) and pain. The Company is headquartered in Bresso near Milan, Italy.

Marketing authorization in the EU for safinamide was granted by the EU Commission in February 2015, followed by the launch in Germany in May 2015. The New Drug Application (NDA) has been accepted for review by the FDA. In March 2014, an MAA has been submitted to Swissmedic.

Newron's additional projects are based on highly promising treatments for rare disease patients and are at various stages of clinical development. They include sarizotan for patients with Rett syndrome, for which Newron received Orphan Drug Designation in both the US and the EU, sNN0031 for patients with Parkinson's disease non-responsive to oral drug treatments, sNN0029 for patients with amyotrophic lateral sclerosis (ALS) and ralfinamide for patients with specific rare pain indications. Newron is also developing NW-3509 as potentially the first add-on therapy for the treatment of patients with positive symptoms of schizophrenia.

For further information, please access to www.newron.com