Newron initiates Phase II study of sNN0031 in patients with Parkinson's disease

Milan, Italy, January 14, 2015 – Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel CNS and pain therapies, announced today the initiation of a Phase II study of its novel molecule sNN0031 in patients with Parkinson's disease (PD). The sNN0031 Phase II safety and preliminary evidence of efficacy trial is supported by funding from the European Commission (FP7 Framework Program).

sNN0031 is a recombinant human platelet-derived growth factor-BB (rhPDGF-BB) that is administered intracerebroventricularly (ICV). Administration of sNN0031 in animal models of PD has resulted in a dose-dependent proliferation of subventricular and striatal cells and also counteracted the behavioral and/or tissue effects of prior exposure to neurotoxins for dopaminergic neurons. In animal models a 14 day treatment resulted in a long-lasting improvement in Parkinsonian symptoms and dopamine transporter (DAT) - binding, a marker of dopamine system integrity and function. Based on its mechanism of stimulating existing progenitor cells to enhance dopaminergic activity, rhPDGF-BB may offer a new therapeutic option for patients with PD who do not benefit from treatment with optimized standard of care using oral therapies.

Previous studies of sNN0031 in PD patients showed that the ICV administration of sNN0031 was well tolerated. DAT, assessed using brain imaging, indicated a dose-dependent positive effect in brain regions damaged in PD.

The study will include patients with advanced PD on standard of care oral medication who will receive 6 µg/day in two cycles of 14 days each, separated by three months, in a randomized, placebo-controlled double blind design using an implantable pump and brain catheter. The trial has received approvals from Health authorities in the UK, Germany and Sweden, as well as from the ethic committees of the centres involved in the trial. The study will enroll 20 patients who will be assessed for safety and efficacy for nine months as part of this study. Multiple clinical safety and efficacy rating scales will be used in combination with biochemical analyses and brain imaging.

About sNN0031
sNN0031 is a novel drug candidate for the treatment of Parkinson's disease that is designed to act on neural stem and progenitor cells in the brain. In animal models of Parkinson's disease, treatment with sNN0031 restores motor function and improves neurochemical deficits. In a Phase I/II trial in patients with PD, it was well tolerated and demonstrated preliminary beneficial effects on biochemical markers of the degenerating dopamine system in PD patients. The product is comprised of the naturally occurring protein PDGF-BB (platelet-derived growth factor BB) formulated for intracerebroventricular (ICV) delivery. The intended therapy involves short-term continuous infusion of sNN0031 into the ventricular lumen, in order to optimize PDGF-BB access to the lateral ventricular walls of the brain where the targeted stem and progenitor cells reside. sNN0031 holds the potential to halt and even reverse disease progression, a much-needed improvement over currently available treatments, which only address the symptoms of Parkinson's disease.

About Newron Pharmaceuticals
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. Following the submission of the Marketing Authorization Application (MAA) for safinamide for the treatment of Parkinson's disease to the European Medicines Agency (EMA) in December 2013, CHMP has recommended to approve safinamide in the EU on Dec. 19, 2014. An MAA has been submitted to Swissmedic in March, 2014, by Zambon. The New Drug Application NDA to the US FDA has been re-submitted by Newron on Dec. 26, 2014. Newron is working towards global approval of the compound, together with its partners. Zambon Group has the rights to commercialize safinamide globally, excluding Japan and other key Asian territories where Meiji Seika has the rights to develop and commercialize the compound. Newron's additional projects are based on highly promising treatments for rare disease patients and are at various stages of clinical development, including sarizotan for patients with Rett syndrome, sNN0031 for patients with Parkinson's disease, non-responsive to oral drug treatments, sNN0029 for patients with ALS and ralfinamide for patients with specific rare pain indications. Newron is also developing NW-3509 as the potential first add-on therapy for the treatment of patients with positive symptoms of schizophrenia. www.newron.com

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