Newron initiates Phase II study of sNN0029 in patients with Amyotrophic Lateral Sclerosis

Milan, Italy, January 15, 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 sNN0029 in patients with Amyotrophic Lateral Sclerosis (ALS). This safety and preliminary evidence of efficacy Phase II trial of sNN0029 is supported by funding from the Wellcome Trust.

sNN0029 is a recombinant human vascular endothelial growth factor (rhVEGF-165) that is administered intracerebroventricularly (ICV). Administration of sNN0029 in animal models of ALS increased survival of motor neurons that degenerate and are a leading cause of the disability and symptoms in patients with ALS. Animals with the G93A-SOD1 mutation, known to be associated with ALS in humans, who receive rhVEGF-165 survive longer and show improved muscular strength compared to controls. Based on its mechanism of action, i.e. direct and indirect effects preventing death of motor neurons, sNN0029 may represent a unique treatment opportunity for patients with ALS.

An earlier study of sNN0029 in ALS patients at doses up to and including 2 µg/day indicated in preliminary analyses evidence of significant benefit especially in patients at the highest dose on multiple efficacy measures, compared to placebo. Treatment with sNN0029 was well tolerated and many patients have received treatment for up to two years and more.

The new study will include patients with ALS who will receive 4 µg/day as a continuous treatment in a randomized, placebo-controlled double blind fashion using an implantable pump and brain catheter. The trial has been approved by Health authorities and is currently recruiting patients to clinical sites in Belgium and the Netherlands. It will enroll 18 patients who will be assessed for safety and efficacy for three months as part of this study. Multiple clinical safety and efficacy rating scales will be used in combination with biochemical analyses and neurophysiological examination. Patients will be able to receive long term treatment after the study is completed, provided they meet protocol criteria.

About sNN0029

sNN0029 is a novel drug candidate for the treatment of Amyotrophic Lateral Sclerosis (ALS). A recombinant human Vascular Endothelial Growth Factor 165 (rhVEGF165), it is the first treatment to target motor neurons by blocking the activity of genes causing cell death. In preclinical in vivo studies, animals with a defective VEGF-gene displayed motor neuron death in parallel with muscle weakness and atrophy, pointing to the role of VEGF for motor neuron survival. In ALS model animals, VEGF treatment slowed disease progression and increased life span. sNN0029 has also been successfully tested in a three month Phase I/II safety and tolerability study in ALS patients. As ALS is fatal for most patients within a few years of diagnosis, this compound has the potential to address a great unmet medical need. In February 2013, the Wellcome Trust granted an award of up to EUR 2.5 million to support a Phase I/II clinical trial to evaluate the safety and efficacy of higher doses of sNN0029 in patients with ALS.

About The Wellcome Trust
The Wellcome Trust is a global charitable foundation dedicated to improving health. The Trust provides more than £700 million a year to support bright minds in science, the humanities and the social sciences, as well as education, public engagement and the application of research to medicine. The Wellcome Trust's £18 billion investment portfolio gives it the independence to support such transformative work as the sequencing and understanding of the human genome, research that established front-line drugs for malaria, and Wellcome Collection, the Trust's free venue for the incurably curious that explores medicine, life and art.

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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Newron does not undertake any obligation to publicly up-date or revise forward looking statements except as may be required by applicable regulations of the SIX Swiss Exchange where the shares of Newron are listed.

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