Newron announces results of Phase I study of NW-3509
Phase II study in schizophrenia patients
planned for Q2 2015

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 completion of the first in man US Phase I study of its novel sodium channel blocker NW-3509. This new chemical entity (NCE) is a product of Newron's in-house ion-channel discovery program that also identified safinamide, a unique dual mechanism treatment that was recommended for approval by the CHMP in December 2014 as an add-on treatment for Parkinson's disease (PD), and has been submitted for the same indication in the US.

NW-3509 is an orally available NCE that specifically targets voltage-gated sodium channels. It modulates sustained repetitive firing, without inducing impairment of normal neuronal excitability. NW-3509 normalizes glutamate release induced by aberrant sodium channel activity.

The Phase I study performed in 54 healthy subjects in six independent cohorts (nine subjects each) who received single doses of NW-3509 ranging from 1-30 mg, or placebo (2:1), was overseen by an Independent Safety Monitoring Board who reviewed all safety, tolerability and plasma level data at each dose level prior to recommending administration of higher doses.

NW-3509 was well-tolerated at all doses. At the maximum feasible dose of 30 mg, adverse events reported in the NW-3509 group (three subjects) included somnolence, headache, and orthostatic tachycardia, while one placebo subject complained of somnolence. In general, most events were transient, and were rated as mild in severity. No pattern of abnormal results was detected in vital signs, laboratory tests, or ECG results in NW-3509-treated subjects compared to placebo. Plasma concentrations of NW-3509 increased with higher doses; the mean Cmax at 20 mg and higher doses matched or exceeded the efficacious plasma concentrations in animal models of schizophrenia when NW-3509 was given as add-on therapy.

Newron plans to perform a double-blind, placebo-controlled randomized Phase II trial of NW-3509 as add-on treatment in schizophrenic patients on stable and adequate doses of atypical antipsychotics, whose symptoms are not effectively controlled by their medication. This 4-week study of the safety and preliminary evidence of efficacy of NW-3509 will be performed internationally and is expected to start in Q2 2015.

The potential benefits of NW-3509 have been demonstrated in extensive animal models predictive of efficacy in psychiatric diseases, including models of psychosis and schizophrenia, such as amphetamine-induced hyperactivity, sensorimotor gating and information processing deficits (pre-pulse inhibition impairment induced by different stimuli), mania and depression. Efficacy of NW-3509 has also been demonstrated in models of aggression and compulsive behavior, as well as in short- and long-term memory tests. Sub-threshold doses of NW-3509 increased the activity of inactive doses of both typical

and atypical antipsychotics in models of schizophrenia, psychosis and mania. Preclinical data indicate that NW-3509 may add to or synergize with antipsychotic drugs to produce a combined therapeutic effect by modulating glutamate and dopamine systems that have been associated with schizophrenia symptoms.

Ravi Anand, Newron's CMO, stated: "NW-3509 may improve efficacy of current antipsychotics, allowing a reduction of their dosage, and of associated side effects e.g., metabolic syndrome, tardive dyskinesia, extra-pyramidal side effects (EPS). Moreover, given its neuronal stabilization properties, NW-3509 may reduce relapses and prevent or treat episodes of psychosis due to established super-sensitivity psychosis (SSP) induced by antipsychotics. It may also benefit domains of symptoms such as cognition, mood disorders and suicidality that are currently not managed effectively by available treatments."

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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