



**Newron Reports Positive Pre-IND Meeting with FDA and MHRA  
for its NCE NW-3509  
as an add-on to antipsychotics in patients with schizophrenia**

**Milan, Italy – 11 January 2010** – Newron Pharmaceuticals S.p.A. (“Newron”, SIX: NWRN), a research and development company focused on novel CNS and pain therapies, reports a positive outcome from its Pre-IND and CTA meetings with the US FDA and the UK MHRA for its novel New Chemical Entity, NW-3509. The compound is intended to be developed as an adjunctive treatment for patients with schizophrenia experiencing inadequate benefit from their current antipsychotic treatment. The meetings with the Regulatory Authorities indicated their acceptance of the pharmacological, toxicological and pharmaceutical information collected in IND enabling studies to date, as well as the proposed clinical development plan for Phases I and II. Newron intends to file an IND application in the second half of 2010. NW-3509 would be the first selective sodium channel blocker being specifically developed for schizophrenia therapy.

Pre-clinical studies in an animal model (PPI) that closely mimics the impairment of information processing present in patients have demonstrated that NW-3509 significantly improves this deficit, induced by pharmacological agents and stress. Notably, PPI deficits in schizophrenic patients correlate with core symptoms of psychoses, such as: thought disorder, distractibility, cognition. So far, only clozapine, the most clinically effective anti-psychotic, shows complete reversal of PPI in patients. Moreover, the combination of sub-threshold doses of NW-3509 and risperidone achieves a complete normalization of PPI deficit, like clozapine, but with potentially less side effects than the usual/standard doses of existing antipsychotics.

Efficacy of NW-3509 *per se* has been demonstrated in other animal models of psychosis, aggression, mania and in experiments where cognition was impaired by drugs, or by natural means.

Ravi Anand, M.D., Newron’s Chief Medical Officer, said, “NW-3509 is completely unlike any other compound in development for the treatment of schizophrenia. Its mechanisms of action are distinct from the conventional dopaminergic and serotonergic blockade targeted by most second generation anti-psychotics which still produce only a limited benefit. The addition of NW-3509 to these agents would enhance their efficacy, provide additional benefits such as cognitive improvement, and potentially reduce serious side effects such as weight gain, sexual dysfunction, cognitive and emotional blunting, extrapyramidal symptoms, etc.”



**About NW-3509**

NW-3509 is an innovative compound from a new chemical class whose mechanism of action involves selective modulation of voltage-gated sodium channels (VGSC) that have been implicated in the pathogenesis of psychiatric and neurological disorders. It has been hypothesized that the occurrence of psychotic symptoms is associated with firing abnormalities in specific brain areas. VGSCs modulators might stabilize such membrane hyperexcitability and normalize neuronal functions.

**About Newron Pharmaceuticals**

Newron Pharmaceuticals S.p.A. ([www.newron.com](http://www.newron.com)) is a biopharmaceutical company focused on novel therapies for diseases of the Central Nervous System and pain. Newron is undertaking phase III trials with safinamide for the treatment of Parkinson’s disease (PD) in conjunction with its partner, Merck Serono, which has exclusive worldwide rights to develop, manufacture and commercialize the compound in PD, Alzheimer’s disease, and other therapeutic applications. Newron is in the process of completing a potentially pivotal study (SERENA) with ralfinamide in patients with Neuropathic Low Back Pain (NLBP). There are no approved drugs for the treatment of NLBP, an indication experienced by about 55 million patients in the USA, Europe and Japan. Newron’s additional projects are in development at various stages of preclinical and clinical development, including HF0220 for neuroprotection and NW-3509 for the treatment of schizophrenia. Newron is headquartered in Bresso, near Milan, Italy. The company is listed at SIX Swiss Exchange, trading symbol NWRN.

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