



Ongoing Phase II Study of Evenamide (NW-3509) May Suggest an Alternative Approach to the Treatment of Schizophrenia

Evidence of anti-psychotic efficacy as an add-on to antipsychotics

Milan, Italy – 5 April 2016 – Newron Pharmaceuticals S.p.A. (“Newron”) (SIX: NWRN), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central nervous system (CNS) and pain, announced today that it presented at the 5th Biennial Schizophrenia International Research Society Conference the abstract “Evenamide (NW-3509), a Putative Antipsychotic, Targets Abnormal Electrical Activity and Glutamatergic Abnormalities in Improving Psychotic Symptoms in Patients with Schizophrenia in a Phase II, Placebo-controlled Trial”.

Evenamide (NW-3509) is a new generation antipsychotic that acts through pathways that are not targeted by current treatments or other putative antipsychotics. It is associated with a functional blockade of voltage-gated sodium channels that inhibits glutamate release by reducing the firing rate of hyper-excited neurons and may normalize aberrant cortical and hippocampal activity. A Phase II, placebo-controlled study in patients with schizophrenia experiencing breakthrough symptoms while on adequate doses of risperidone or aripiprazole is ongoing, in which Evenamide is being evaluated at doses of 15-25 mg bid as add-on therapy for reducing positive symptoms and psychotic worsening.

Ravi Anand, MD, Newron’s Chief Medical Officer, stated: “Evenamide (NW-3509) has demonstrated in preclinical models that it provides inhibition of voltage-gated sodium channels without any effect on receptors, enzymes and transporters targeted by most antipsychotics and yet is active in most animal models of psychosis. Intriguingly, in animal models of psychosis, the addition of ineffective doses of both NW-3509 and typical or atypical antipsychotics, showed significant benefit. This finding, if confirmed in poorly responding patients, would suggest that the current practice of switching non-responding patients to another antipsychotic be replaced by the addition of NW-3509 to their regimen. This would avoid such issues as discontinuation effects, need to hospitalize patients, anti-dopaminergic, metabolic, and sexual side effects.”

About Newron Pharmaceuticals

Newron (SIX: NWRN), Bresso / Italy, is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central nervous system (CNS) and pain. Xadago® (Safinamide) has received marketing authorization for the treatment of Parkinson’s Disease in the European Union and Switzerland and is commercialized by Newron’s Partner Zambon. US WorldMeds holds the commercialization rights in the US. Meiji Seika has the rights to develop and commercialize the compound in Japan and other key Asian territories. 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, ralfinamide for patients with specific rare pain indications, and NW-3509 as potentially the first add-on therapy for the treatment of patients with positive symptoms of schizophrenia.



For more information

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