



PRESS RELEASE

Newron Pharmaceuticals Successfully Completes Pilot Study of Safinamide in Restless Legs Syndrome

Milan, Italy – January 11, 2005 – Newron Pharmaceuticals SpA, a research and development company focused on novel CNS therapies, announced today that treatment with its investigational new drug, safinamide, resulted in a significant improvement in all efficacy parameters studied when administered to patients with Restless Legs Syndrome (RLS). Safinamide was also found to be well tolerated and did not exhibit any clinically relevant side-effects. RLS is a neurological disorder, characterized by jerky movements of the lower extremities which appear mostly in the evening and during sleep.

“We found that treatment with safinamide improved RLS symptoms. Sleep architecture was not modified; conversely sleep fragmentation was positively influenced, as this is often the most distressing aspect of the disorder. The treatment was very well tolerated and did not result in any clinically relevant side effects,” said Prof. Luigi Ferini Strambi, MD, Head of the Sleep Disorders Center, San Raffaele Hospital, Milan and study director. “In spite of the short duration and open nature of the study, these positive results, in particular the outcome of the polysomnographic studies, appear important in reference to the currently used dopaminergic drugs. On this basis safinamide deserves further exploration as a novel approach in the treatment of RLS.”

A total of ten patients with RLS were enrolled into a single-center, Phase II, open pilot study of safinamide which was conducted at the Sleep Disorders Center, San Raffaele Hospital in Milan. Each patient was administered safinamide (100 mg/day orally) at bedtime for two weeks.

“RLS is a common condition that is frequently misdiagnosed. Only two drugs are approved specifically for RLS, and only available in specific countries, so treatment often involves the off-label use of existing CNS therapy. Therefore, there is a great demand for better and more effective medicines for this disturbing disorder,” said Dr. Luca Benatti, CEO of Newron. “Initial evidence suggests that safinamide may prove effective in the treatment of RLS. We will continue our evaluation and we are planning larger clinical trials.”

About RLS

RLS is a growing neurological condition affecting approximately 5% of the adult population in the US and EU. It is characterized by jerky movements or an uncomfortable, often painful, sensation in the lower extremities that mostly appear in the evening, at rest and during sleep. RLS is commonly associated with frequent awakenings at night and somnolence during the day, thus negatively affecting a patient’s quality of life. In many cases, RLS can lead to bouts of depression and in some, suicide.

About Safinamide

Safinamide is being investigated in confirmatory Phase III trials worldwide following success in treating the symptoms of Parkinson’s disease in Phase II studies. In addition, safinamide has also shown preliminary efficacy in reducing seizures in patients with fits refractory to currently available antiepileptic medications. Safinamide is a unique molecule with multiple mechanisms of action, including sodium channel blocking activity, calcium channel modulation, glutamate release inhibition and a potent, selective and reversible inhibition of monoamine oxidase (MAO)-B, without a MAO-A effect.

About Newron Pharmaceuticals

Newron Pharmaceuticals S.p.A (www.newron.com) is a research and development company focused on novel ion channel based therapies for diseases of the Central Nervous System (CNS), particularly Parkinson's disease, epilepsy and pain. In addition to safinamide, Phase II trials with ralfinamide, a potent sodium channel blocker for the treatment of neuropathic pain are ongoing. Newron's clinical pipeline is supported by a broad portfolio of early stage proprietary compounds generated by our ion channel drug discovery platform. Newron is headquartered in Bresso, near Milan, Italy.

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