FDA APPROVES XADAGO® (SAFINAMIDE)

FOR PARKINSON'S DISEASE (PD) PATIENTS

First New Chemical Entity (NCE) approved for PD patients with motor fluctuations in the U.S.A. in over a decade

Milan, Italy and Morristown, NJ, U.S.A., – March 21, 2017 – 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, and its partners Zambon S.p.A. and US WorldMeds, LLC, announced today that the Food and Drug Administration (FDA) has approved the use of Xadago® (safinamide) for the treatment of Parkinson's disease as add-on therapy to levodopa/carbidopa. Parkinson's disease affects an estimated 7 to 10 million patients worldwide, of whom 1 million are in the U.S.A.

C. Warren Olanow, M.D. FRCPC, FRCP(HON), stated: "The approval of Xadago® as a treatment for patients with Parkinson's disease by the FDA represents an important milestone as it is the first New Chemical Entity approved for the treatment of Parkinson's disease in the USA in over a decade." Dr. Olanow, Professor and Chairman Emeritus of the Department of Neurology and Professor Emeritus of the Department of Neuroscience at the Mount Sinai School of Medicine in New York City continued, "Xadago® as an add-on to levodopa/carbidopa provided a significant reduction in OFF time and a significant increase in ON time without troublesome dyskinesia in PD patients experiencing motor fluctuations."

Ravi Anand, Newron's CMO, commented: "International, randomized, clinical trials have demonstrated that Xadago® significantly improves ON time, OFF time, and Parkinsonism compared to standard of care without increasing time spent with troublesome dyskinesia in patients experiencing motor fluctuations while on optimized levodopa/carbidopa therapy. Additionally, the onset of improvement of motor fluctuations occurred early in treatment."

P. Breckinridge ("Breck") Jones, CEO of US WorldMeds said: "We are thrilled by the FDA's approval of Xadago® and are excited to have a key role in the introduction of a new medicine for Parkinson's disease. We will now accelerate our US launch preparations to get Xadago® to Parkinson's patients in need of new treatment options."

Dr Charlotte Keywood, Global Head R&D, Zambon, said: "We are delighted with the approval of Xadago® in the USA. This first new treatment for a decade represents an important addition to the treatment choices for patients with PD and their doctors. In order to more fully characterize the clinical benefits of Xadago®, Zambon will continue to work with our partners on new clinical trials".

Marketing authorization in the EU for Xadago® was granted by the EU Commission in February 2015, and by Swissmedic in November 2015. Following the 2015 European approval and the launch in Germany, Xadago® has been launched by Zambon in 10 further European markets in 2016 including Italy, Spain, UK, Belgium, Denmark, Sweden, Luxembourg, the Netherlands, Norway, and Switzerland.

About Xadago® (safinamide)

Safinamide is a New Chemical Entity with a mode of action characterized by selective MAO-B-inhibition. Results from two double-blind, placebo-controlled, multinational, 6-month studies with over 1,100 patients revealed that safinamide provides statistically significant increases in on time without troublesome dyskinesia, as well as a decrease in off time. Safinamide is a once-daily dose and has no diet restrictions due to its high MAO-B versus MAO-A selectivity. Zambon has the rights to develop and commercialize XADAGO globally, excluding Japan and other key territories where Meiji Seika has the rights to develop and commercialize the compound. The rights to develop and commercialize Xadago® in the U.S.A. have been granted to US WorldMeds, by Zambon.

References:
Borgohain R, et al.(2014) Randomized trial of safinamide add-on to levodopa in Parkinson's disease with motor fluctuations. Mov Disord, 29: 229–237.

Schapira A, Fox S, Hauser R, et al. (2016) Assessment of safety and efficacy of safinamide as a levodopa adjunct in patients with Parkinson disease and motor fluctuations. A randomized clinical trial. JAMA Neurology 2017 Feb 1;74(2):216-224. doi: 10.1001/jamaneurol.2016.4467

About Parkinson's disease

Parkinson's disease (PD) is the second most common chronic progressive neurodegenerative disorder in the elderly after Alzheimer's disease, affecting 1-2% of individuals aged ≥ 65 years worldwide. The prevalence of the PD market is expected to grow in the next years due to the increase in the global population and advancements in healthcare that contribute to an aging population at increased risk for PD. The diagnosis of PD is mainly based on observational criteria of muscular rigidity, resting tremor, or postural instability in combination with bradykinesia. As the disease progresses, symptoms become more severe. L-dopa remains as the most effective treatment for PD, and over 75% of the patients with PD receive L-dopa. However, long-term treatment with L-dopa leads to seriously debilitating motor fluctuations, i.e. phases of normal functioning (ON-time) and decreased functioning (OFF-time). Therefore, as the disease progresses, additional medications are added on to L-dopa to help with management of these motor fluctuations.

References:
https://www.michaeljfox.org/page.html?what-is-parkinsons-infographic
BMC Oertel. European Handbook of Neurological Management, Vol1, Chapter 14 & 15, 2011.

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, with a subsidiary in Morristown, NJ, U.S.A. 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 U.S.A. Meiji Seika has the rights to develop and commercialize the compound in Japan and other key Asian territories. In addition to Xadago® for Parkinson's disease, Newron has a strong pipeline of promising treatments for rare disease patients at various stages of clinical development, including sarizotan for patients with Rett syndrome and ralfinamide for patients with specific rare pain indications. Newron is also developing Evenamide as the potential first add-on therapy for the treatment of patients with positive symptoms of schizophrenia. www.newron.com.

About US WorldMeds, LLC

US WorldMeds is a specialty pharmaceutical company dedicated to developing, licensing and commercializing unique and significant specialty pharmaceuticals that address unmet medical needs or overcome limitations of existing products. Through sound science and targeted commercialization, the Kentucky-based company continually strives to identify specialty and orphan products for diseases with limited patient populations. For more information about US WorldMeds, visit www.usworldmeds.com.

About Zambon

Zambon is a leading Italian pharmaceutical and fine-chemical multinational company that has earned a strong reputation over the years for high quality products and services. Zambon is well-established in 3 therapeutic areas: respiratory, pain and women's care, and is very strongly committed to its entry into the CNS space. Zambon S.p.A produces high quality products thanks to the management of the whole production chain which involves Zach (Zambon chemical), a privileged partner for API, custom synthesis and generic products. Zambon is headquartered in Milan and was established in 1906 in Vicenza. Zambon is present in 15 countries with subsidiaries and more than 2,600 employees with manufacturing units in Italy, Switzerland, France, China and Brazil. Zambon products are commercialized in 73 countries.
For details on Zambon please see: www.zambongroup.com.

Important Safety Information

Do not take Xadago® if you are taking opioid medications including meperidine, tramadol, methadone, or prorpoxyphene as it could result in serious sometimes fatal reactions. Also, do not take Xadago® with amphetamine, cyclobenzaprine, dextromethorphan, methylphenidate, or St. John's wort. You also should not take AZILECT with other monoamine oxidase inhibitors (MAOIs), as it could result in an unsafe rise in blood pressure. During treatment with Xadago®, you may experience increases in blood pressure. Inform your physician if you have a history of high blood pressure. Possible symptoms of an unsafe rise in blood pressure include severe headache, blurred vision, confusion, seizures, shortness of breath, severe anxiety, and nausea/vomiting. Contact your doctor or seek immediate medical attention if you experience any of these symptoms. Restriction of foods and beverages containing tyramine is usually not required when treated with the recommended doses of Xadago®. However, it is recommended that you avoid foods containing high amounts of tyramine such as aged cheeses as some patients may have an increased sensitivity that could lead to an unsafe rise in blood pressure. Inform your physician if you are taking, or planning to take, any prescription or over-the-counter drugs, especially antidepressants. The combination of MAO-B inhibitors such as Xadago® and antidepressants has resulted in a serious and sometimes fatal condition called serotonin syndrome. Do not drive, operate heavy machinery, work in high places or do other dangerous activities until you know how Xadago® affects you. You should not take Xadago® if you have severe liver disease. Do not exceed a dose of 50 mg per day of Xadago® if you have moderate liver disease. The most common side effects seen with Xadago® are uncontrolled movements (dyskinesia), falls, nausea, and insomnia.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-888-492-3246.
You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

For more information

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Important Notices

This document contains forward-looking statements, including (without limitation) about (1) Newron's ability to develop and expand its business, successfully complete development of its current product candidates and current and future collaborations for the development and commercialisation of its product candidates and reduce costs (including staff costs), (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's anticipated future revenues, capital expenditures and financial resources, and (4) assumptions underlying any such statements. In some cases these statements and assumptions can be identified by the fact that they use words such as "will", "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "target", and other words and terms of similar meaning. All statements, other than historical facts, contained herein regarding Newron's strategy, goals, plans, future financial position, projected revenues and costs and prospects are forward-looking statements. By their very nature, such statements and assumptions involve inherent risks and uncertainties, both general and specific, and risks exist that predictions, forecasts, projections and other outcomes described, assumed or implied therein will not be achieved. Future events and actual results could

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