XADAGO® (SAFINAMIDE) NOW AVAILABLE IN THE U.S. FOR PARKINSON'S DISEASE PATIENTS

- XADAGO (safinamide) is a once-daily tablet for Parkinson's disease patients as an add-on to levodopa/carbidopa who are experiencing "off" episodes, providing "on" time without troublesome dyskinesia [involuntary movements].
- XADAGO is the first New Chemical Entity (NCE) approved in the U.S. for motor fluctuations in Parkinson's disease in more than a decade.
- US WorldMeds has licensed XADAGO for U.S. distribution from Zambon, a pharmaceutical company based in Milan. XADAGO has been available since 2015 in the EU and is now sold in 12 countries.

MILAN, Italy and LOUISVILLE, Ky. – July 11, 2017 — Alliance partners Newron Pharmaceuticals S.p.A. and Zambon S.p.A. based in Milan, and Louisville-based US WorldMeds announced today that XADAGO (safinamide) is now available as an add-on therapy for U.S. patients with Parkinson's disease (PD) currently taking levodopa/carbidopa and experiencing "off" episodes. It is not known if XADAGO is effective to treat PD when taken as a single medicine (monotherapy). XADAGO, a once-daily tablet, is the first New Chemical Entity approved in the U.S. for PD-related motor fluctuations in more than a decade for the estimated 1 million patients currently affected by PD.

According to the U.S. Food and Drug Administration (FDA), an "off" episode is a time when a patient's medications are not working well, causing an increase in Parkinson's symptoms, such as tremor and difficulty walking. XADAGO is an inhibitor of monoamine oxidase B (MAO-B). Inhibition of MAO-B activity, by blocking the breakdown of dopamine, is thought to result in an increase in dopamine levels and a subsequent increase in dopaminergic activity in the brain.

Dr. Stuart Isaacson, MD, Director Boca Raton Institute for Neurodegenerative Disorders commented: *"The approval of XADAGO offers an important new treatment option for the Parkinson's community. XADAGO is the first New Chemical Entity approved for the treatment of PD-related motor fluctuations in the U.S. in over a decade. In clinical trials, patients on once-daily XADAGO demonstrated significant improvement in 'on' time without troublesome dyskinesia."*

The efficacy of XADAGO was shown in clinical trials with over 1100 PD patients who were taking levodopa/carbidopa and experiencing "off" time. Those receiving XADAGO experienced more beneficial "on" time, a time when Parkinson's symptoms are reduced, without troublesome dyskinesia, compared to those receiving a placebo. The increase in "on" time was accompanied by a reduction in "off" time and better scores on a physician-assessed measure of motor function performed during "on" time than before treatment.

"We are very excited to be launching XADAGO," said P. Breckinridge ("Breck") Jones, CEO of US WorldMeds. *"Part of US WorldMeds' mission is to develop and market meaningful and accessible healthcare products that improve lives and result in a thriving community of patients. We are confident that XADAGO will progress that mission by providing a new treatment option to Parkinson's patients."*

The U.S. Food and Drug Administration (FDA) approved XADAGO, which is under license from Zambon S.p.A, a multinational specialty pharmaceutical company based in Milan. XADAGO has been available since 2015 in the EU and is now sold in 12 countries.

"*Zambon is proud to announce the U.S. market launch of XADAGO by our partner US WorldMeds, whose experience and commitment to Parkinson's disease will bring value to patients in need of new treatment options*," said Roberto Tascione, CEO of Zambon.

US WorldMeds has licensed XADAGO from partner Zambon for distribution in the U.S. and partnered with Newron Pharmaceuticals S.p.A ("Newron", SIX: NWRN), a biopharmaceutical company focused on development of novel therapies for patients with diseases of the central nervous system and pain.

Stefan Weber, CEO of Newron Pharmaceuticals said: "*We are proud to see XADAGO become the first FDA approved new chemical entity for Parkinson's disease in more than 10 years. We believe XADAGO has the potential to significantly improve the quality of life of PD patients in the U.S., as it already has in many other countries around the world.*"

About XADAGO (safinamide)
Safinamide is a New Chemical Entity with a mechanism 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 a statistically significant increase in on time without troublesome dyskinesia, as well as a decrease in off time. Safinamide is a once-daily dose and has high MAO-B versus MAO-A selectivity. Safinamide is an add-on therapy to levodopa/carbidopa, and has not been shown to be effective when used alone. 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. 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 (PD)
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. Early-stage patients are more easily managed on L-dopa. 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). Furthermore, as a result of the use of high doses of L-dopa with increasing severity of the disease, many patients experience involuntary movements known as L-dopa-Induced Dyskinesia (LID). As the disease progresses, more drugs are used as an add-on to what the patient already takes, and the focus is to treat symptoms while managing LID and the "off-time" effects of L-dopa. Most current therapies target the dopaminergic system that is implicated in the pathogenesis of PD, and most current treatments act by increasing dopaminergic transmission that leads to amelioration of motor symptoms.

References:
BMC Oertel. European Handbook of Neurological Management, Vol1, Chapter 14 & 15, 2011. NICE PD guideline, 2006.

About US WorldMeds, LLC
US WorldMeds is a specialty pharmaceutical company that is inspired by the patients and communities where their treatment options are making a difference. US WorldMeds takes an entrepreneurial, agile and personal approach to pharmaceuticals – pioneering research and product development in therapeutic areas that desperately need new solutions. Headquartered in Louisville, Kentucky, US, WorldMeds has more than 15 years of experience in the development, licensure and commercialization of unique products designed to improve the lives of patients with challenging conditions and unmet medical needs, including Parkinson's disease, cervical dystonia, malignant hyperthermia and more. For more information about US WorldMeds, visit www.usworldmeds.com.

About Zambon S.p.A
Zambon is a leading Italian pharmaceutical and fine-chemical multinational group that has earned a strong reputation over the years for high quality products and services. Zambon S.p.A., the pharma company with €600 million sales in 2016, is well-established in 3 therapeutic areas: respiratory, pain and women's health, and is very strongly committed to its entry into the CNS space with Xadago® (safinamide) for the treatment of Parkinson's disease, and rare diseases with Promixin® in cystic fibrosis. Zambon is headquartered in Milan and was established in 1906 in Vicenza. Zambon is present in 19 countries with subsidiaries and almost 2,800 employees with manufacturing units in Italy, Switzerland, France, China and Brazil. Zambon products are commercialized in 84 countries. For details on Zambon please see: www.zambongroup.com.

About Newron Pharmaceuticals S.p.A
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, USA. Xadago® (safinamide) has received marketing authorization for the treatment of Parkinson's disease in the European Union, Switzerland and the USA, and is commercialized by Newron's partner Zambon. US WorldMeds holds the commercialization rights in the USA. 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.

Further Information

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