



Newron receives Complete Response Letter from US FDA for Xadago® (safinamide)

Milan, Italy – March 29, 2016 – Newron Pharmaceuticals S.p.A. ("Newron") (SIX: NWRN), a research and development company focused on novel CNS and pain therapies, and its partners Zambon S.p.A. and US WorldMeds announced today that a complete response letter from the FDA has been received for safinamide.

The complete response letter requests clinical evaluation of the potential effect of safinamide on behaviors relating to abuse liability and dependence/withdrawal effects as required by the Controlled Substance Staff (CSS) in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

Ravi Anand, MD, CMO, said: "The complete response letter does not require submission of any additional new data/studies/analyses for efficacy or safety in patients with Parkinson's disease. Newron is requesting a meeting with the representatives of the Controlled Substance Staff and Division of Neurological Products to finalize plans for the additional experiments".

Newron and its partners will provide an update on the potential timelines for approval of safinamide in the near future.

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. The US New Drug Application (NDA) has been accepted for review by the FDA. 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.

About US WorldMeds

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. US WorldMeds' portfolio includes Revonto® (dantrolene sodium for injection) for the treatment of malignant hyperthermia, MYOBLOC® (rimabotulinumtoxinB) Injection for the treatment of cervical dystonia in adults and APOKYN® (apomorphine hydrochloride injection) for the acute, intermittent treatment of hypomobility, "off" episodes associated with advancing Parkinson's disease. In addition, US WorldMeds is working on the development of a non-narcotic drug product (Lofexidine) for the treatment of opiate withdrawal symptoms. 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

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