Xadago® (safinamide) New Drug Application
Late-Cycle Review Meeting Completed with U.S. FDA

Milan, Italy, Sept. 30, 2015 – Newron Pharmaceuticals S.p.A. ("Newron"), a research and development company focused on novel central nervous system (CNS) and pain therapies, and its commercial and development partner, Zambon S.p.A., an international pharmaceutical company, announced today that the late-cycle review meeting for the New Drug Application (NDA) for Xadago® (safinamide) has been completed with the U.S. Food and Drug Administration (FDA).

The FDA extended the review time for the Xadago® NDA by the standard period of three months to review the late submission of additional financial disclosure forms for the MOTION and SETTLE clinical studies. This extends the PDUFA date to March 29, 2016.

About Xadago®

Xadago® (safinamide), an alpha-aminoamide, is currently being developed by Newron as an add-on therapy to dopamine agonists or to levodopa in patients with early or mid- to late-stage Parkinson's disease (PD). It has both dopaminergic and non-dopaminergic activities, including selective and reversible inhibition of monoamine oxidase B (MAO-B), activity-dependent sodium channel antagonism and inhibition of glutamate release in vitro.

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. Marketing authorization in the EU for Xadago® (safinamide) was granted by the EU Commission in February 2015, followed by the launch by Zambon in the first key EU country - Germany - in May 2015. The New Drug Application (NDA) has been accepted for review by the FDA, as reported in March 2015. In March 2014, Zambon, Newron's partner, submitted an MAA to Swissmedic. Zambon has the rights to develop and commercialize safinamide globally, excluding Japan and other key Asian territories, where Meiji Seika has the rights to develop and commercialize the compound. 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, sNN0031 for patients with Parkinson's disease non-responsive to oral drug treatments, sNN0029 for patients with amyotrophic lateral sclerosis (ALS) and ralfinamide for patients with specific rare pain indications. Newron is also developing NW-3509 as potentially the first add-on therapy for the treatment of patients with positive symptoms of schizophrenia. www.newron.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. It is well-established in 2 therapeutic areas: respiratory, with a special focus on Rare Diseases and on chronic diseases as asthma and BPCO; and CNS with Xadago® (safinamide) for the Parkinson treatment. Zambon Spa is very strongly committed also to pain and woman care areas. The Group produces high quality products thanks to the management of the whole production chain which involves Zambon chemical (Zach), a privileged partner for API, custom synthesis and generic products. Headquartered in Milan and established in 1906 in Vicenza, Zambon is based in 19 countries with subsidiaries and more than 2,600 employees with manufacturing units in Italy, Switzerland, France, China and Brazil. Company products are commercialized in 84 countries.

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Important Notices

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into future collaborations and licensing agreements, (7) litigation, (8) loss of key executive or other employees, (9) adverse publicity and news coverage, and (10) competition, regulatory, legislative and judicial developments or changes in market and/or overall economic conditions. Newron may not actually achieve the plans, intentions or expectations disclosed in forward-looking statements and assumptions underlying any such statements may prove wrong. Investors should therefore not place undue reliance on them. There can be no assurance that actual results of Newron's research programmes, development activities, commercialisation plans, collaborations and operations will not differ materially from the expectations set out in such forward-looking statements or underlying assumptions.

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