Newron reports half-year 2015 results

Milan, Italy – September 15, 2015 – Newron Pharmaceuticals S.p.A. ("Newron", SIX: NWRN), a research and development company focused on novel central nervous system (CNS) and pain therapies, today announces its financial results for the half year ended June 30, 2015.

Half-Year 2015 Highlights

- EU Commission approves Xadago® (safinamide) for mid- to late-stage Parkinson's patients
- Launch of Xadago® by partner Zambon in Germany
- Xadago® New Drug Application accepted for filing by the U.S. Food and Drug Administration (FDA); PDUFA date 29 December 2015
- Positive opinion received from the European Medicines Agency for Orphan Medicinal Product Designation for sarizotan to treat patients with Rett Syndrome; after end of reporting period, Orphan Drug Designation received from European Commission and U.S. FDA
- Phase II study of sNN0031 in patients with Parkinson's disease and Phase II study of sNN0029 in patients with Amyotrophic Lateral Sclerosis initiated
- Completion of first-in-man U.S. Phase I study of novel sodium channel blocker NW-3509
- Closing of EUR 23.4m private placement from leading EU and U.S. investors
- Strong cash position of EUR 44.0m at 30 June 2015

Stefan Weber, CEO of Newron, commented: "We enter the second half of 2015 in a strong position, with EUR 44 million of cash and equivalents. We are pleased that Xadago® is now commercially available to patients in Germany and are excited by its future roll-out across Europe by our partner Zambon. We are now also awaiting the decisions by the FDA, following the successful refiling in the U.S., and by Swissmedic, which, if positive, will trigger further milestones. Our key pipeline projects sarizotan and NW-3509 are progressing well, with the commencement of new studies during the remainder of 2015. We remain focused on building and strengthening our position as a leading player in the CNS space."

The European Commission approved the use of Xadago® for mid- to late-stage Parkinson's disease patients following the recommendation of the Committee for Medicinal Products for Human Use (CHMP). This is the first new chemical entity in 10 years to receive approval in Europe for the treatment of Parkinson's disease. In May, our partner Zambon launched Xadago® in Germany, to be followed by the roll-out into other EU territories. In addition, Newron received news from the U.S. Food and Drug Administration (FDA) that the New Drug Application (NDA) for Xadago® has been accepted for review. The completion of the NDA review is currently expected on 29 December 2015 (the PDUFA date).

In the first half of 2015, Newron made good progress with sarizotan, a new chemical entity for the treatment of Rett Syndrome. The Committee for Orphan Medicinal Products (COMP) issued a positive opinion recommending sarizotan as an orphan medicinal product to the European Commission for the treatment of Rett Syndrome. After closing of the reporting period, the European Commission and the U.S. FDA granted Orphan Drug Designation to sarizotan for this indication. Newron has conducted extensive discussions with regulatory authorities in Europe, the U.S. and Canada and has consulted with the group of international investigators who will be performing the study to finalize the protocol for a potentially pivotal placebo-controlled study. If approved, sarizotan is likely to be the first product that Newron commercializes on its own.

Newron also announced the completion of the first-in-man U.S. Phase I study of its novel, voltage-gated sodium channel blocker NW-3509, for which an Investigational New Drug (IND) application was accepted by the U.S. FDA as add-on to antipsychotics for patients with schizophrenia. The Phase I study in 54 healthy subjects demonstrated that NW-3509 was well tolerated at all doses. Based on these results, in 2015 we plan to initiate a Phase II trial of NW-3509 as add-on treatment in schizophrenic patients on stable and adequate doses of atypical antipsychotics whose symptoms are not effectively controlled by their medication.

In January, Newron initiated a Phase II study of sNN0031 as a recombinant human platelet-derived growth factor-BB for the treatment of severe, treatment-resistant Parkinson's disease, an orphan indication. This study of safety, tolerability and preliminary evidence of efficacy is supported by a grant from the European Union. Based on preclinical data and results from previous studies of sNN0031 in Parkinson's disease patients, the compound was well tolerated, and a dose-dependent, positive effect was observed in dopamine uptake in brain regions damaged in Parkinson's disease. sNN0031 may offer a new therapeutic option for those patients who do not benefit from treatment with current standard of care using oral therapies.

In parallel, Newron initiated a Phase II study, supported by the Wellcome Trust, of sNN0029, a novel recombinant human vascular endothelial growth factor (rhVEGF-165) in patients with Amyotrophic Lateral Sclerosis (ALS). Significant benefit was demonstrated in an earlier study in ALS patients at the highest dose. sNN0029 has both direct and indirect effects in preventing death of motor neurons, suggesting it may represent a unique treatment opportunity for patients with this life-threatening rare disease.

Both sNN0029 and sNN0031 are delivered into the brain with a medical device from a third-party supplier. During the second quarter, the device supplier entered into a consent decree with U.S. health authorities that prevents it from commercializing the device until certain quality issues are resolved. Although the FDA exempted the performance of clinical studies from the ban, requests for additional information from health authorities and ethics committees have impacted the progress of the studies.

Shareholders demonstrated their support in March by approving a capital increase of up to 1.3 million additional shares. In April, current and new institutional investors from Europe and the U.S., including Aviva, J.P. Morgan Asset Management, Investor AB, Sphera Global HealthCare Fund and Nyenburgh, subscribed to 843,072 newly issued shares, raising gross proceeds of EUR 23.4 million. These funds are being used to accelerate the development of the innovative product pipeline, particularly the lead clinical programs for sarizotan and NW-3509.

Interim financial statements

In the first six months of 2015, Newron invested EUR 7.6 million into drug development and preparations for regulatory submission of Xadago®, up from EUR 6.5 million in 2014. Of these, EUR 2.8 million have been covered by our Xadago® partner Zambon as well as by grants. Therefore, for the first six months of the year, net R&D expenses were EUR 4.7 million, up from 2014 expenses of EUR 2.6 million. G&A expenses reached EUR 4.1 million, up from EUR 3.5 million in 2014. Revenues for the first half of 2015 were EUR 2.0 million, stemming from milestone payments under the collaboration with partner Zambon, as well as first royalties from Xadago® sales in Germany. The net loss for the first six months of 2015 is EUR 6.9 million, compared to EUR 4.6 million in the first half of 2014. With EUR 44.0 million cash and short-term investments, Newron has a solid cash position, which should take the Company well beyond expected key value inflexion points and related revenues.

Financial Summary (IFRS)

In EUR thousand (except per share information)

	HY1 2015	HY1 2014
Licence income/Royalties	1,893	1,300
Other income	86	100
Research and development expenses*	4,723	2,620
General and administration expenses	4,058	3,498
Net loss	6,923	4,596
Loss per share	0.52	0.37
	30/6/2015	**30/6/2014**
Cash, cash equivalents, other short term fin. assets	44,000	31,390
Total assets	55,670	44,626
Net cash used in operating activities	5,257	4,443

* Net of safinamide development cost reimbursed by Zambon and net of R&D grants/tax credits

For further details see the Half-Year 2015 Report, which is available for download at:
http://www.newron.com/financial-report

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 in the first key EU country - Germany - in May 2015. The New Drug Application (NDA) has been accepted for filing by 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, including 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, and sNN0029 for patients with ALS and ralfinamide for patients with specific rare pain indications. Newron is also developing NW-3509 as the potential first add-on therapy for the treatment of patients with positive symptoms of schizophrenia.

For more information

Media	Investors and analysts
Stefan Weber - CEO Phone: +39 02 6103 46 26 E-mail: pr@newron.com **UK/Europe** Julia Phillips FTI Consulting Phone: +44 (0)20 3727 1000 **Switzerland** Martin Meier-Pfister IRF Communications Phone: +41 43 244 81 40 **Germany** Anne Hennecke MC Services AG Phone: +49 211 52925222 anne.hennecke@mc-services.eu	Stefan Weber - CEO Phone: +39 02 6103 46 30 E-mail: ir@newron.com **Germany** Anne Hennecke MC Services AG Phone: +49 211 52925222 anne.hennecke@mc-services.eu

U.S. David Connolly LaVoieHealthScience Phone: +1 617 374 8800, Ext. 108 dconnolly@lavoiehealthscience.com	**U.S.** Kristina Coppola LaVoieHealthScience Phone: +1 617 374 8800, Ext. 105 kcoppola@lavoiehealthscience.com

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 differ materially from those set out in, contemplated by or underlying the forward-looking statements due to a number of important factors. These factors include (without limitation) (1) uncertainties in the discovery, development or marketing of products, including without limitation negative results of clinical trials or research projects or unexpected side effects, (2) delay or inability in obtaining regulatory approvals or bringing products to market, (3) future market acceptance of products, (4) loss of or inability to obtain adequate protection for intellectual property rights, (5) inability to raise additional funds, (6) success of existing and entry 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.

Newron does not undertake any obligation to publicly update or revise forward-looking statements except as may be required by applicable regulations of the SIX Swiss Exchange, where the shares of Newron are listed.

This document does not contain or constitute an offer or invitation to purchase or subscribe for any securities of Newron, and no part of it shall form the basis of or be relied upon in connection with any contract or commitment whatsoever.