Newron reports half-year 2016 results

Milan, Italy – September 15, 2016 – 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, 2016.

Half Year 2016 Highlights

- Xadago® (safinamide) launched by Zambon for patients with Parkinson's disease in ten additional European countries (Switzerland, Spain, Italy, Belgium, Denmark, Sweden, the U.K., Luxembourg, the Netherlands and Norway)
- Re-submission of the New Drug Application (NDA) for Xadago® expected in 2016, following US FDA clearance
- Phase II study of Evenamide (NW-3509) presented at the 5th Biennial Schizophrenia International Research Society Conference
- Investigational New Drug application for sarizotan for the treatment of Rett syndrome approved by the US FDA
- "Sarizotan Treatment of Apneas in Rett Syndrome" (STARS) potentially pivotal trial design presented at US Rett Syndrome Symposium – study initiated in July
- Burden of Disease study initiated with International Advisory Board meeting at 2016 Rett Syndrome Foundation Meeting

Stefan Weber, CEO of Newron, commented: "It is exciting to see Xadago® available to patients with Parkinson's disease in eleven European countries, being well received by patients and doctors and generating revenues with impressive growth rates. Since it was first launched in Germany roughly 12 months ago, we have received cumulated royalty revenues of EUR 1.3 million on product sales by Zambon, revenues growing at a rate of 50% over each prior quarter. We expect to be re-submitting the NDA for Xadago® to the US FDA in 2016, still, and look forward to hearing from the authority with regards to the US approval in due course. Our innovative pipeline of Central Nervous System (CNS) drugs is progressing well and with a solid cash position and strong pipeline, we are well placed to build and strengthen our position as a leading player in the CNS disease area."

"We confirm our outlook for the full-year 2016 provided in March. On the basis of higher expected royalties on net sales of Xadago® in various European territories over the full year 2016 period, plus additional milestone payments and potential income from safinamide due from Zambon, 2016 revenue is expected to notably increase over 2015. R&D expenses will be higher compared to 2015, due to clinical development costs for the efficacy studies for sarizotan and NW-3509. Available liquidity will take Newron well through most of 2017, beyond expected key value inflection points," Stefan Weber, CEO of Newron, added.

Xadago® available in four of the five key European pharmaceutical territories

During the first half of 2016, Xadago® was launched by Newron's partner Zambon in Switzerland, Spain, Italy, Belgium, Denmark, Sweden, the UK, Luxembourg and, post period, The Netherlands and Norway. A substantially increased number of patients across Europe, including four of the five key European pharmaceutical territories, can now be treated using Xadago®, the first New Chemical Entity in ten years to receive Marketing Authorization from the European Union Commission for the treatment of Parkinson's disease.

In March, Newron received a complete response letter (CRL) from the US Food and Drug Administration (FDA) for Xadago®. However, at the end of July, the company and its partners Zambon and US WorldMeds were informed that the FDA no longer required Newron to perform any studies to clinically evaluate the potential abuse liability or dependence/withdrawal effects of Xadago®, that were the key subject of the CRL. As no additional data, studies or analyses for efficacy or safety in patients with Parkinson's disease had been required under the CRL, as already communicated, Newron expects to be re-submitting the New Drug Application (NDA) to the US FDA in 2016, still.

Newron is committed to finding innovative therapies for patients suffering from Parkinson's disease and other CNS diseases. In order to further strengthen this commitment, Newron in 2016 supported the Rare Disease Day, the Rett Symposium as well as World Parkinson's Disease Awareness Day. These global initiatives are helping to raise awareness of rare diseases and Parkinson's disease respectively and the company fully supports their mission to improve the lives of all patients affected.

Encouraging progress with sarizotan and Evenamide

In May, Newron received the U.S. FDA's approval of its Investigational New Drug (IND) application for the evaluation of sarizotan for the treatment of patients with Rett syndrome. In July, Newron initiated the "Sarizotan Treatment of Apneas in Rett Syndrome" (STARS) study, which is a potentially pivotal clinical study to evaluate the efficacy, safety and tolerability of sarizotan in patients with Rett syndrome suffering from respiratory symptoms. The initiation of the STARS study is an exciting milestone in the company's development program for sarizotan; Newron expects to be able to report the results of this trial in due course.

In April, Newron presented a poster at the 5th Biennial Schizophrenia International Research Society Conference on Evenamide (NW-3509), its new generation antipsychotic that acts through pathways that are not targeted by current treatments or other putative antipsychotics. The abstract was entitled: "Evenamide (NW-3509), a Putative Antipsychotic, Targets Abnormal Electrical Activity and Glutamatergic Abnormalities in Improving Psychotic Symptoms in Patients with Schizophrenia in a Phase II, Placebo-controlled Trial". The research presented at this conference is another positive step in the development of Evenamide, whose Phase II clinical study results are anticipated to read out in Q4 2016.

Financial Highlights

In the first six months of 2016, Newron has invested EUR 9.2 million into drug development and preparations for regulatory submission of safinamide, up from EUR 7.6 million in 2015. The increase is predominantly due to the Phase II study of Evenamide in patients with schizophrenia and the preparations of the potentially pivotal study with sarizotan in Rett syndrome. Of these R&D expenses, EUR 1.0 million has been reimbursed by its safinamide partner Zambon. Therefore, for the first six months of this year, net R&D expenses were EUR 8.2 million, up from 2015 expenses of EUR 4.7 million. General and administrative expenses were EUR 4.4 million in the first six months of 2016, up from EUR 4.1 million in 2015. The company's revenues for the first half of 2016 were EUR 3.9 million, up from EUR 2.0 million in 2015, including milestone payments under the collaboration with partner Zambon (EUR 3.0 million, up from EUR 1.8 million in 2015) and royalty payments on Xadago® sales, which were up to EUR 852 thousand in the first six months, from EUR 93 thousand in 2015. Newron's net loss for the first six months of 2016 is EUR 8.8 million, compared to EUR 6.9 million in the first half of 2015.

Cash and short term investments at June 30, 2016 were at EUR 34.9 million, compared to EUR 40.9 million at the beginning of the year, also reflecting the exercise in March 2016 of a purchase option

for 209,364 shares by a shareholder under a 2015 subscription and option agreement, generating proceeds of EUR 3.0 million.

Financial Summary (IFRS)

In EUR thousand (except per share information)

	HY1 2016	HY1 2015
Licence income/Royalties	3,891	1,893
Other income	17	86
Research and development expenses	(8,240)	(4,723)
General and administration expenses	(4,402)	(4,058)
Net loss	8,754	6,923
Loss per share	0.64	0.52
Cash used in operating activities	(8,945)	(5,257)
	As of June 30, 2016	**As of Dec. 31, 2015**
Cash, cash equivalents, other short term financial assets	34,879	40,931
Total assets	38,714	44,380

Further details and the full financial details are available in Newron's Half-Year 2016 Report, which is available for download at **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. 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 US. 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 NW-3509 as the potential first add-on therapy for the treatment of patients with positive symptoms of schizophrenia.
For more information, please visit: **www.newron.com**

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