Newron reports half-year 2017 results

Milan, Italy – September 14, 2017 – Newron Pharmaceuticals S.p.A. ("Newron") (SIX: NWRN), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system, today announced its results for the half year ended June 30, 2017.

Half Year 2017 Highlights

- US FDA approval received for Xadago® (safinamide) for Parkinson's disease patients. Consequently, Newron received EUR 11.3 million milestone payments from Zambon. Post-period, Newron, Zambon and US WorldMeds announced that Xadago® is available in the US for Parkinson's disease patients
- Zambon launched Xadago® in Portugal for patients with mid- to late-stage Parkinson's disease. Seqirus and Zambon entered into a partnership for Xadago® in Australia and New Zealand; Meiji Seika and Eisai entered into a collaboration for the development and commercialization of Xadago® in Japan and Asia; Valeo Pharma and Zambon formed a partnership for Xadago® in Canada
- Encouraging results of phase IIa study with Evenamide in patients with schizophrenia were presented at the International Congress on Schizophrenia Research
- Newron amended the ongoing STARS study to include Rett syndrome patients under 13 years of age; a poster was presented in the US on the current Burden of Disease Study in Rett syndrome

Stefan Weber, CEO of Newron, commented: "The past six months have been a milestone period for Newron: Xadago® received approval by the FDA and was launched in the US, following the introduction into twelve European markets, offering an important new treatment option for the Parkinson's community. Our pipeline products Evenamide and sarizotan have also made good progress during the period and we are excited about their potential as we move into 2018 and beyond."

Xadago® now available in the US

Xadago® for Parkinson's disease received formal approval in the US in March. Post-period, Newron announced that Xadago® is now available in the US as an add-on therapy for patients with Parkinson's disease currently taking levodopa/carbidopa and experiencing so-called "OFF" episodes. As a result of the US approval, the Company received EUR 11.3 million milestone payments from its partner Zambon.

Newron and its partner Zambon, together with academic and regulatory experts, are in the process of designing a potentially pivotal efficacy study to evaluate the effects of safinamide in patients with levodopa induced dyskinesia (PD LID). The study design, based upon previously reported clinical and pre-clinical data for PD LID, will be discussed with regulators in the European Union and the USA. The study is expected to start in 2018.

Further to the US launch, in April, Zambon launched Xadago® in Portugal. During this period, Zambon also entered into partnerships with Seqirus in Australia and New Zealand and with Valeo Pharma in Canada. Seqirus will undertake registration and commercialisation of Xadago® in Australia and New Zealand, and in Canada, Valeo Pharma will be responsible for all regulatory,

sales and marketing, quality, and distribution activities. Newron's partner in Asia, Meiji Seika, entered into a collaboration with Eisai for the development and commercialization of Xadago® in Japan and Asia

Encouraging progress with Evenamide
The period has also seen great progress for the other products in Newron's portfolio, including Evenamide. Encouraging preliminary results of a phase 2a study were released in January, which was followed by more detailed results in March, presented at the 16th International Congress on Schizophrenia Research, in San Diego. The results of the study indicate that Evenamide improved symptoms of psychosis compared with placebo when added to two of the most commonly prescribed atypical antipsychotics in patients with chronic schizophrenia.

Ravi Anand, Newron's CMO, said, "We anticipate conducting an adequate and well-controlled study to demonstrate efficacy and safety/tolerability of fixed doses of Evenamide as add-on to second generation antipsychotics in patients experiencing worsening of symptoms of psychosis. We intend to initiate a global, six-week double-blind, placebo controlled study in the future. Furthermore, an international panel of schizophrenia experts has advised on the development of this compound for a potential orphan indication in Clozapine-treatment-resistant schizophrenia, which imparts a number of relevant advantages, including a potentially faster entry to the market. Feedback on this proposal will be requested during forthcoming meetings with the authorities."

Study with Sarizotan Amended
Another significant achievement was announced in May when the FDA approved the amendment of the ongoing Sarizotan Treatment of Apneas in Rett Syndrome (STARS) study to include Rett syndrome patients as young as six years of age. The potential benefits of Sarizotan will now be evaluated in these younger patients prior to the significant worsening that occurs in these patients' disease with age. Experts believe that earlier onset of treatment in Rett's patients may be associated with less deterioration of respiratory and neurological symptoms. Newron is working towards completion of recruitment by the end of 2017 and intends to report top-line results from the study in 2018.

Newron continues to advance its leadership within the Rett community, notably through the first qualitative study to examine the burden of Rett syndrome on individuals and their caregivers. A poster entitled "Burden of Disease in Rett Syndrome: A Qualitative Analysis" was presented at the ISPOR 22nd Annual International Meeting in May (International Society for Pharmaeconomics and Outcome Research) in the US. This poster presented the results of a targeted literature search and preliminary findings from a qualitative interview study aimed at describing the burden of Rett syndrome on individuals and their families.

Financial Highlights
For the first six months of 2017, Newron shows a net profit of EUR 1.5 million, compared to a loss of EUR 8.8 million in the same period in 2016. Cash used in operating activities has been reduced from EUR 8.9 million in HY1 2016 to EUR 1.5 million this year. These positive developments are mostly due to the substantial increase of revenues (EUR 11.7 million versus EUR 3.9 million in HY1 2016), including one-time milestone payments from Zambon for the US approval of Xadago® and an increase of more than 50% in royalty payments received from Zambon (EUR 1.3 million versus EUR 0.85 million in HY1 2016) due to new countries entered and increased sales. At the same time, Newron's R&D expenses have been reduced from EUR 8.2 million in 2016 to EUR 4.6 million, largely due to the completion of the Evenamide phase IIa study and Italian R&D tax credits of EUR 2.1 million that can be offset with future tax and social contribution payments by Newron. G&A expenses

reached EUR 4.4 million in the first six months of 2017, unchanged from HY1 2016. Cash and short term investments at June 30, 2017 were at EUR 45.1 million, compared to EUR 46.5 million at the beginning of the year 2017.

Financial Summary (IFRS)

In EUR thousand (except per share information)

	HY1 2017	HY1 2016
Licence income/Royalties	11,682	3,891
Research and development expenses	(4,608)	(8,240)
General and administrative expenses	(4,448)	(4,402)
Net profit/loss	1,542	(8,754)
Profit/loss per share - Basic	0.10	(0.64)
Cash used in operating activities	(1,487)	(8,945)
	As of June 30, 2017	**As of Dec. 31, 2016**
Cash and cash equivalents	40,431	42,948
Total assets	57,329	56,591

Further details and the full financial details are available in Newron's Half-Year 2017 Report, which is available for download at **http://www.newron.com/financial-report-2017**

About Newron Pharmaceuticals

Newron (SIX: NWRN) is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system. 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, Switzerland and the USA, and is commercialized by Newron's Partner Zambon. US WorldMeds holds the commercialization rights in the USA. 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 Evenamide 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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