Newron reports half-year 2018 results

Milan, Italy – September 13, 2018 – 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 financial results for the half year ended June 30, 2018.

Half Year 2018 Highlights

- Significant progress with patient enrolment into STARS Phase III study for the treatment of Rett syndrome with sarizotan – 117 patients qualified for inclusion, 109 of 129 patients randomized to treatment (August 27, 2018)
- First Burden of Disease (BOD) study in Rett syndrome aligned with STARS study
- Discussions completed with regulatory authorities in Europe, the US and Canada to design two potentially pivotal efficacy studies with Evenamide in patients with schizophrenia
- Primary endpoint met in Phase II/III clinical study of safinamide as add-on therapy to levodopa in patients with Parkinson's disease, conducted by Newron's partner Meiji Seika Pharma together with Eisai Co. in Japan, expected to lead to filing for marketing approval in Japan
- Dossiers for marketing authorization of Xadago® currently under review in Australia, Brazil, Canada, Colombia and Israel
- Newron's partner Zambon leading discussions on additional Xadago® distribution agreements in Europe and Middle East
- Zambon in advanced discussions with US Food and Drug Administration (FDA) on the design of a potentially pivotal efficacy study to evaluate the effects of Xadago® in patients with levodopa-induced dyskinesia

Stefan Weber, Chief Executive Officer of Newron, commented: "The first half of 2018 has been another productive period for Newron. We are delighted with the progress we have made with our ongoing study in sarizotan and towards the upcoming Evenamide trials and are encouraged by our partners' progress globally with Xadago®/safinamide. With available cash and cash equivalents of EUR 50 million as per June 30, 2018, we anticipate our funding will take us to 2020, beyond expected key value inflection points. Newron also continues to evaluate non-dilutive funding opportunities. We look forward to updating you on the progress of our innovative pipeline and commercial activities throughout the rest of the year and take this opportunity to invite you to mark your calendar for our October 31, 2018, R&D day."

Sarizotan: Patient enrolment on track

In June 2018, Newron announced that more than 100 patients, aged six and above, had qualified for inclusion into its STARS (Sarizotan Treatment of Apneas in Rett Syndrome) Phase III study. By the end of August, that number had increased to 117, of which 109 patients had been randomized to treatment. Newron is therefore on track to reach its target of enrolling 129 patients during the remaining months of 2018 and expects to report results from the study by the end of H1 2019. The study is focused on patients suffering from Rett syndrome who present with clinically significant daytime apneas during the course of the disease, which present in approximately 70% of patients. Treatment with sarizotan has been well tolerated with a very low rate of discontinuation due to adverse events or lack of efficacy. To date, nearly 90% of patients who have completed the 24-week double-blind period have continued in the long-term open-label extension.

Evenamide: Two potentially pivotal efficacy studies upcoming
Newron made considerable progress towards initiating a Phase III development program with Evenamide, by completing discussions with the regulatory authorities in the EU, the US and Canada. Newron plans to initiate two potentially pivotal efficacy studies – one in patients with schizophrenia experiencing worsening of psychosis on atypical antipsychotics and another in treatment-resistant schizophrenia patients not responding to the antipsychotic drug clozapine. Newron expects to initiate both studies in H1 2019 and will provide further details during the Company's upcoming R&D day on October 31, 2018 in New York (a webcast of which will be available).

Xadago®/safinamide: dossiers for marketing authorization currently under review
Newron's partner Zambon is in advanced discussions with the US FDA on the design of a study to demonstrate the anti-dyskinetic effect of Xadago® in Parkinson's disease patients with levodopa-induced dyskinesia (LID). In Japan, Newron's partner Meji Seika together with Eisai announced that the primary endpoint was met in a Phase II/III study with safinamide as add-on to levodopa. Meiji Seika now plans to continue the clinical trials it is conducting and submit a file for marketing approval with the Japanese Pharmaceutical and Medical Device Agency in H2 2018.

With respect to commercial activities, Newron is pleased to hear from its partners that dossiers for marketing authorization are currently under review in Australia, Brazil, Canada, Colombia and Israel, potentially leading to additional launches in the next quarters. Also, Newron understands that Zambon is entertaining discussions supporting the distribution of Xadago® in additional territories in Europe and the Middle East. Furthermore, Newron understands that partner US WorldMeds is currently in negotiations with Medicare in the US and would expect that sales revenues in the US will reflect an agreement, from 2019 on.

Financial Highlights
For the first six months of 2018, Newron reports a net loss of EUR 7.6 million, compared to a profit of EUR 1.6 million in the same period in 2017 (prior year revenues included one-time milestone payment of EUR 10.4 million). Cash used in operating activities has increased to EUR 9.4 from EUR 1.5 million in 2017. Xadago® royalty payments received from Zambon increased by 54% (EUR 2.0 million versus EUR 1.3 million in 2017). At the same time, Newron's R&D expenses have increased moderately to EUR 5.0 from EUR 4.6 million in 2017, largely due to the ongoing STARS study in Rett syndrome. Newron has again profited from Italian R&D tax credits of EUR 2.6 million (that can be offset with future tax and social contribution payments by the Company), versus EUR 2.1 million in 2017. G&A expenses reached EUR 4.4 million in the first six months of 2018, unchanged from 2017 and 2016. Cash and Other current financial assets at June 30, 2018 were at EUR 50.6 million, compared to EUR 60.1 million at the beginning of the year.

Financial Summary (IFRS)
In EUR thousand (except per share information)

	HY1 2018	HY1 2017
Licence income/Royalties	2,008	11,687
Research and development expenses	(5,029)	(4,608)
General and administrative expenses	(4,407)	(4,448)
Net profit/loss	(7,555)	1,584
Profit/loss per share - Basic	(0.42)	0.10
Cash used in operating activities	(9,431)	(1,487)

	As of June 30, 2018	As of Dec. 31, 2017
Cash and Other current financial assets	50,636	60,081
Total assets	65,076	73,024

Further details and the full financial details are available in Newron's Half-Year 2018 Report, which is available for download at **http://www.newron.com/financial-report-2018**

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®/safinamide 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**

For more information, please contact

Newron
Stefan Weber – CEO
+39 02 6103 46 26
pr@newron.com

UK/Europe
Julia Phillips / Natalie Garland-Collins, FTI Consulting
+44 20 3727 1000
SCnewron@fticonsulting.com

Switzerland
Martin Meier-Pfister, IRF Communications
+41 43 244 81 40
martin.meier-pfister@irfcom.ch

Germany/Europe
Anne Hennecke, MC Services
+49 211 52925222
anne.hennecke@mc-services.eu

USA
Paul Sagan, LaVoieHealthScience
+1 617 374 8800, Ext. 112
psagan@lavoiehealthscience.com

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