Newron announces 2018 financial results and provides outlook for 2019

Milan, Italy, March 5, 2019 – Newron Pharmaceuticals S.p.A. ("Newron"), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central and peripheral nervous system, today announces its financial results and operational highlights for the year ended December 31, 2018 and provides an outlook for 2019.

Highlights:

Sarizotan (Rett syndrome)

- Newron successfully completed enrollment in the STARS Phase III study (results from the study are expected in Q4 2019)
- At its R&D Day in New York City in October, Newron presented baseline data from more than 100 patients treated in the STARS study, suggesting, amongst other findings, that up to 70 percent of patients suffering from Rett syndrome experience on average 22 episodes of clinically significant apneas/hour of waking time
- Newron participated at the international conference "Rett Syndrome Research, Towards the Future" in Rome and provided an update on the first ever International Burden of Illness (BOI) study in Rett syndrome

Evenamide (Schizophrenia)

- Newron has completed discussions with and gained agreement from the regulatory authorities in Europe, the United States and Canada for a Phase III program, consisting of two pivotal studies for efficacy, and is on track to commence these trials in Q2 2019:
  - one study in patients with chronic schizophrenia experiencing inadequate benefit for symptoms of their psychosis on current atypical antipsychotic monotherapy
  - the second study will be performed with patients with treatment-resistant schizophrenia whose psychotic symptoms are not responding adequately to treatment with clozapine

Xadago®/safinamide (Parkinson's disease)

- Zambon and its regional partners have gained approval for Xadago®/safinamide in Australia, Canada, Brazil and Colombia; launches in these territories are expected within the next twelve months
- Dossiers for marketing authorisation of Xadago® are currently under review in Mexico and Israel
- Zambon is engaged in discussions for additional Xadago® distribution agreements in Southern Europe, the Middle East, Africa and South America
- Meiji Seika Pharma announced that the primary endpoint was met in a Phase II/III study of safinamide in patients with Parkinson's disease in Japan, and has subsequently filed for marketing authorisation in this territory
- Zambon has completed discussions with US Food and Drug Administration (FDA) on the design of a potentially pivotal efficacy study to evaluate the effects of Xadago®/safinamide in patients with levodopa induced dyskinesia (PD LID); this study is expected to start in H1 2019

Corporate

- Newron has secured long term funding of up to EUR 40 million from the European Investment Bank to expand its R&D activities and support pivotal and post-approval development programs related to the central nervous system (CNS). As a result, with cash on hand and short term investments as of December 31, 2018, the Company has, at its disposal, total available funds of up to EUR 84 million, which will cover the pursuit of its development programs and operations as currently contemplated beyond 2020

- At the 2018 Annual General Meeting, Newron's shareholders approved all resolutions, including granting the Board of Directors:
  - the ability to issue up to an aggregate of EUR 1,426,987.60 in shares and/or convertible bonds
  - powers to create American Depositary Shares and to list them on Nasdaq or on any other market in the United States

Stefan Weber, Newron's Chief Executive Officer, commented:
"Overall, 2018 was a highly productive year for the Company. We, along with our global partners, have made significant progress in each of our development programs. Our STARS study reached an important milestone and the Evenamide clinical program is on track to start in Q2 2019. We also continued to follow our partners' progress globally with Xadago®/safinamide. We remain grateful to our shareholders who have granted our Board the ability to issue additional securities, as well as the powers to create American Depositary Shares and to potentially list them in public markets in the US, which is an option we are considering. Thus, we anticipate an exciting year in 2019."

Sarizotan: Addressing respiratory disturbances in Rett syndrome patients

In the reporting year, Newron made significant progress with its compound sarizotan for patients with Rett syndrome. The STARS study enrolment has been completed with more than 130 Rett syndrome patients screened and qualified. According to the baseline data from the study, up to 70 percent of patients experience significant apneas with at least 10 percent of their time spent without breathing. As a result, oxygen saturation in these patients may fall below 90 percent for up to 48 minutes cumulatively per hour. To date, treatment with sarizotan has been well tolerated with a very low rate of discontinuation due to adverse events or lack of efficacy. Approximately 90 percent of patients who have completed the 24-week double-blind period have continued into the long-term open-label extension. Results from the study are expected to be reported in Q4 2019.

In addition, during "Rett Awareness Month" in September 2018, Newron provided an update on the world's first International BOI study in Rett syndrome at an international conference in Rome, Italy. The study is designed to collect the missing information on the human and financial cost of Rett syndrome for patients and their families as well as caregivers and health workers. The BOI is being undertaken in parallel with Newron's pivotal Phase III STARS study in patients with Rett syndrome.

Evenamide: Redefining the treatment of poor/non-response in patients with schizophrenia

Newron's Phase III development program for Evenamide progressed well in 2018 and is on track to start in Q2 2019, following discussions with the European Medicines Agency (EMA), the FDA and the Canadian HPB. The Evenamide development program consists of two pivotal efficacy studies in patients with schizophrenia, one study in patients experiencing worsening of psychosis on atypical antipsychotics, and the other study in treatment-resistant schizophrenia patients not responding to clozapine. Positive results in both studies could lead to the approval of Evenamide as a new add-on therapy for patients with schizophrenia, showing inadequate response to their current medication.

Xadago®/safinamide: Continuing to make commercial progress across the globe

In 2018 and early 2019, Newron's partner Zambon, and its regional partners, have gained approval for Xadago®/safinamide for patients with Parkinson's disease in Australia, Canada, Brazil and Colombia; launches in these territories are expected within the next twelve months. In addition, Xadago® was made available to patients in France without social security reimbursement. Newron's partner Meiji Seika Pharma announced that the primary endpoint was met in a Phase II/III study of safinamide in patients with Parkinson's disease in Japan and has subsequently filed for marketing authorisation in this territory.

Currently, dossiers for marketing authorisation of Xadago®/safinamide are under review in Mexico and Israel; furthermore, Zambon is engaged in discussions for additional Xadago® distribution agreements in Southern Europe, the Middle East, Africa and South America. Zambon has also completed discussions with the FDA on

the design of a potentially pivotal efficacy study to evaluate the effects of Xadago®/safinamide in patients with PD LID; this study is expected to start in H1 2019.

In 2015, Safinamide was approved in Europe, in 2017 in the US; it has subsequently been launched in 14 EU countries, Switzerland and the United States; in 2018, Newron's annual royalty stream from the marketed territories increased by 41% to EUR 4.0 million compared to 2017.

Financial Highlights:

- Royalties increased by 41%, from EUR 2.9 million in 2017 to EUR 4.0 million
- Total revenues decreased to EUR 4.0 million from EUR 13.4 million (2017) in the reporting period due to one-time milestone payments received from Zambon in 2017 (no milestones in 2018 vs. EUR 10.4 million in 2017)
- Research and development expenses increased to EUR 9.8 million (2017: EUR 8.6 million), net of Italian R&D tax credits of EUR 5.9 million
- Cash used in operations increased to EUR 16.1 million (2017: EUR 8.4 million)
- In 2018, Newron has secured a long term funding of up to EUR 40 million from the European Investment Bank
- Newron's cash position, including available financial assets and cash and cash equivalents, was EUR 43.9 million at year-end (2017: EUR 60.1 million)

Financial Summary (IFRS):

In thousand EUR (except per share information)

	2018	**2017**
Licence income	-	10,430
Royalties from contracts with customers	4,025	2,855
Other income	0	143
Revenues	**4,025**	**13,428**
Research and development expenses, net	9,835	8,596
Operating loss	**14,978**	**4,346**
Financial result, net	(41)	(955)
Net loss	**15,035**	**5,282**
Loss per share	0.84	0.32
Cash used in operating activities	16,108	8,404
Cash, cash equivalents, other short-term financial assets	43,853	60,081
Total assets	59,731	73,024

Newron's full 2018 Annual Report is available on www.newron.com/financial-report-2018

Outlook for 2019:

"2019 will be an important year for our Company. We look forward to commencing our Phase III program with Evenamide, consisting of two pivotal studies, in Q2 2019, and are expecting the results from our STARS Phase III study with Sarizotan in Q4 2019. We also expect additional approvals and launches of Xadago®/safinamide during 2019 and the launch of a potentially pivotal efficacy study to evaluate the effects of this compound in patients with levodopa induced dyskinesia in H1 2019 by our partner Zambon. We started 2019 with total available funds of up to EUR 84 million, which will cover the pursuit of Newron's development programs and operations as currently contemplated beyond 2020," outlined Stefan Weber, CEO of Newron.

2019 Shareholders' Meeting Agenda:

Newron's Board of Directors has approved the below agenda for the April 2, 2019, Shareholders' meeting, which will take place at the Company's registered office in Bresso (Mi), Italy, starting at 10 am CET. The formal invitation to shareholders will be issued and disclosed in the statutory papers on or around March 5. The full invitation and supporting material will be made available on the Company's website on the same date. The agenda is as follows:

1. Approval of the financial statements as at December 31, 2018
2. Appointment of the statutory auditors for the three-year period 2019-2021 and, therefore, until the approval of the financial statements as at 31 December 2021, and determination of their fees
3. Appointment of the auditing company for the period 2019-2021

Dial-in details to the media/analyst/investor conference on March 5, 2019, 3-4 pm CET:

The Newron management team will present the 2018 full-year results and provide an update and guidance for 2019. The conference call can be accessed via the following dial-in numbers:

- Switzerland/Europe: +41 (0) 58 310 50 00
- United Kingdom: +44 (0) 207 107 0613
- United States: +1 (1) 631 570 5613
- Italy: +39 (0) 2 805 88 20

The slide deck used in the call is available at www.newron.com/downloads/reports-presentations--webcasts/2019

Upcoming events:

- Annual Shareholders' meeting: April 2, 2019
- Half-year report 2019: September 12, 2019

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 authorisation for the treatment of Parkinson's disease in the European Union, Switzerland, the USA, Australia, Canada, Brazil and Colombia 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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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, the timing of commencement of various clinical trials and receipt of data and current and future collaborations for the development and commercialization of its product candidates, (2) the market for drugs to treat CNS diseases and pain conditions, (3) Newron's 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 difficulties in enrolling clinical trials, 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 programs, development activities, commercialization 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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