Newron announces 2019 financial results and provides outlook for 2020

Milan, Italy, March 5, 2020 – Newron Pharmaceuticals S.p.A. ("Newron") (SIX: NWRN, XETRA: NP5), 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 and operational highlights for the year ended December 31, 2019, and provided an outlook for 2020.

Highlights:

Sarizotan (Rett syndrome)

- Newron successfully completed enrolment of 129 patients in the STARS Phase III study and advanced the study towards the end of the 24-week, double-blind treatment period, with the clinical database locked and blinded
- Newron participated in a meeting with the U.S. Food and Drug Administration (FDA) to discuss the STARS study statistical analysis plan, ahead of STARS clinical trial data unblinding, and now expects top-line results in H1 2020
- The FDA granted Rare Pediatric Disease Designation for sarizotan, following an earlier decision to grant sarizotan Orphan Drug Designation

Evenamide (Schizophrenia)

- Newron and the FDA have agreed on the design and conduct of explanatory studies with Evenamide required to address previously announced potential safety issues raised by the FDA, including a four-week explanatory study in patients with schizophrenia; initial results in rats and humans are expected in Q3 2020
- Subject to the successful completion of these additional studies, Newron intends to commence its proposed Phase III clinical trial program with Evenamide comprising of two efficacy studies

Xadago®/safinamide (Parkinson's disease)

- Zambon and its regional partners have launched safinamide in Australia, Canada and Colombia and received marketing authorization in Brazil and the UAE; Meiji Seika and partner Eisai have launched safinamide in Japan
- Successful negotiations with the Italian authorities have resulted in the reimbursement cap being removed, allowing for further potential revenue growth
- Progress made in plans to perform the levodopa-induced dyskinesia (PD LID) study with Xadago
  - Zambon previously held 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
  - Intention is to perform the study in the US, Europe and Asia/Australia
  - Zambon acknowledges Newron's experience in the development of Xadago in patients with Parkinson's disease; discussions to have Newron as the party responsible for conducting the study; Zambon will remain associated with the study
  - Financial terms to stay unchanged

Corporate

- Newron received two tranches of funding from the European Investment Bank of EUR 10 million and EUR 7.5 million respectively, out of a total of up to EUR 40 million; this funding is used to boost the Company's R&D activities and support its pivotal and post-approval CNS development programs

- In addition to its primary listing on the Swiss Stock Exchange, Newron began trading in Germany on the Düsseldorf Stock Exchange and XETRA to facilitate access to Newron's shares for investors based in the EU via EU brokers
- Cash (incl. Other current financial assets) as of December 31, 2019 is EUR 39.2 million

Stefan Weber, Newron's Chief Executive Officer, commented:

"2019 has been a successful year of strategy execution for Newron. We are pleased to have continued to develop and mature our pipeline of innovative therapies for central and peripheral nervous system diseases. We have made significant progress with our STARS clinical study, advancing the study to the end of the 24-week, double-blind treatment period, with the clinical database locked and blinded. We now expect to announce top-line results from the study later in H1 2020."

Stefan Weber continued: "We are pleased that our partners worldwide were successful in launching safinamide in Australia, Canada, Colombia and Japan and we hope that more patients worldwide will gain access to safinamide through further launches in the coming months. Prior to the start of our Phase III development program with Evenamide in schizophrenia, we have initiated additional short-term explanatory studies which we expect to report initial results in Q3 2020. We would like to thank all our shareholders for their continued support and confidence in Newron, and we look forward to updating markets on our progress throughout 2020."

Sarizotan

In 2019, Newron made significant progress with its STARS clinical study, completing patient recruitment, with 129 Rett syndrome patients qualified and enrolled, and more than 85% of enrolled patients completing the 24-week, double-blind period, have continued into the long-term open-label extension. This is an indicator of the critical need within the Rett syndrome community and demonstrates the potential of a new treatment option such as sarizotan.

In addition, the U.S. Food and Drug Administration (FDA) decided to grant a Rare Pediatric Disease Designation to sarizotan, which followed earlier decisions by the U.S. and EU authorities to grant Orphan Drug Designations to this compound for the U.S. and the EU. Newron believes that this highlights the large unmet medical need in Rett syndrome, as well as represents progress towards potential marketing authorization with U.S., Canadian and EU regulatory agencies in the future. This designation also represents progress towards qualifying sarizotan for a rare pediatric disease priority review voucher upon potential future U.S. marketing approval.

A communication from the FDA in December suggested that Newron discuss the Company's statistical analysis plan in a meeting prior to unblinding the STARS clinical trial results. The clinical database has been locked and remains blinded. We currently expect unblinding of the STARS clinical trial data and disclosure of the top-line results in H1 2020. Subject to a positive study outcome, our goal is to initiate discussions with the regulatory agencies towards filing of the dossiers for marketing authorization. Upon regulatory approval, Newron intends to commercialize sarizotan for Rett syndrome in the U.S. and – if viable – in key EU territories.

As part of its commitment to the rare disease patient community, Newron is conducting a landmark International Burden of Illness study, partnered with the global Rett syndrome community. The survey outreach launched in the beginning of November 2019 in the U.S. and aims to deliver data and analytics to quantify the physical, emotional and financial challenges of Rett syndrome for patients, their families and caregivers. In February 2020, this survey outreach was expanded to reach families and caregivers in the U.K., Germany, Italy and Australia.

Evenamide

In May, the FDA requested that Newron complete additional short-term explanatory studies in rats and human subjects to address questions on findings from a recently completed pre-clinical study of Evenamide. The Company engaged with the FDA in order to address the agency's concerns prior to the initiation of the Phase III development program. In early January 2020, Newron announced that it had reached agreement with the FDA on the design and conduct of these explanatory studies with Evenamide, as well as the protocol for a

first, four-week explanatory study in patients with schizophrenia. Newron expects to see initial results from these additional studies in rats and humans in Q3 2020.

Subject to the successful completion of these studies, Newron intends to commence its proposed Phase III clinical trial program with Evenamide in two pivotal efficacy studies in patients with schizophrenia. One for patients experiencing worsening of psychosis on atypical antipsychotics, and the other study in ultra-treatment-resistant schizophrenia patients not responding to clozapine, with the latter representing an orphan-like indication affecting approximately 20,000 to 25,000 patients in the U.S. (with similar numbers in the EU). Positive results in both studies could lead to Evenamide being the first add-on therapy for the treatment of patients with positive symptoms of schizophrenia who show an inadequate response to their current atypical medication. In key territories, Newron expects to commercialize Evenamide itself in the treatment-resistant schizophrenia indication.

Xadago®/safinamide

In 2019, Meiji Seika together with Eisai announced the approval and launch of safinamide in Japan, under the brand name Equfina®. Seqirus launched Xadago® (safinamide) in Australia, Zambon in Colombia, and Valeo Pharma in Canada under the brand name Onstryv®. Xadago® has received marketing approval in Brazil and the United Arab Emirates and dossiers for marketing authorization are currently under review in Mexico and Israel. Newron is pleased with this progress and remains optimistic for additional launches in 2020.

Newron's total income from the marketed territories increased by 75% over the prior year, to EUR 7.0 million, of which EUR 2.3 million is due to one-time non-refundable milestone payments. The Company expects further growth in Europe, aided by the cap on reimbursement being removed in Italy effective March 1, 2019.

Newron progresses in the plans to perform the LID study with Xadago: Zambon had previously held 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. The intention is to perform the study in the U.S., Europe and Asia/Australia.

Zambon acknowledges Newron's experience in the development of Xadago in patients with Parkinson's disease and there have been discussions to have Newron as the party responsible for conducting the study. Zambon will remain associated to the study. Financial terms will stay unchanged: Newron will make a fixed financial contribution to the study, in return for a one-time milestone payment and a greater share of royalties should the study lead to a label extension.

Financial Highlights:

- In 2019, Xadago®-related payments received increased by 75% (EUR 7.0 million versus EUR 4.0 million in 2018), including a one-time milestone payment for approval in Japan of net EUR 2.0 million.
- At the same time, Newron's net R&D expenses increased to EUR 17.4 million from EUR 9.8 million in 2018, largely due to the ongoing STARS study in Rett syndrome and work relating to the preparation for the two pivotal efficacy studies in patients with schizophrenia.
- Newron received Italian R&D tax credits of EUR 5.0 million that can be offset with future tax and social contribution payments by the Company, versus EUR 5.9 million in 2018.
- In 2019, G&A expenses reached EUR 9.9 million compared to EUR 8.8 million in 2018 (increase refers to evaluation of and preparation for additional listings of Newron's shares).
- In 2019, Newron reported a net loss of EUR 20.2 million, compared to EUR 15.0 million in 2018.
- Cash used in operating activities has increased to EUR 22.2 million from EUR 16.0 million in 2018.
- Cash and Other current financial assets at December 31, 2019 were at EUR 39.2 million, compared to EUR 43.9 million at the beginning of the year.

Financial Summary (IFRS):

In thousand EUR (except per share information)

	2019	2018 (1)
Licence income contracts with customers	2,284	-
Royalties from contracts with customers	4,754	4,025
Revenues	**7,038**	**4,025**
Research and development expenses, net	17,440	9,835
Operating loss	**20,899**	**14,978**
Financial result, net	737	(41)
Net loss	**20,207**	**15,035**
Loss per share	1.13	0.84
Cash used in operating activities	22,210	15,954
Cash, cash equivalents and Other current financial assets	39,163	43,853
Total assets	60,288	59,999

(1): The Group adopted in 2019, for the first time, the new standard IFRS 16 Leases applying the full retrospective method that requires the restatement of previous financial statements.

Newron's full 2019 Annual Report is available on www.newron.com/financial-report-2019

Outlook for 2020:

"2020 will be an important year for Newron, with sarizotan in late-stage clinical development and Evenamide poised to enter a Phase III pivotal program. We look forward to reporting on our meeting with the FDA on the statistical plan for our STARS study and remain confident that we can address the FDA's questions around Evenamide. We are encouraged by the continued success of our global partners in the approvals and launches of safinamide and expect these to continue into 2020. We started 2020 with total available funds of up to EUR 61.7 million, including the EUR 22.5 million of EIB funds not yet drawn, which will cover the pursuit of Newron's development programs and operations as currently contemplated beyond 2021," outlined Stefan Weber, CEO of Newron.

2020 Shareholders' Meeting Agenda:

Newron's Board of Directors has approved the below agenda for the March 31, 2020, Shareholders' meeting, which will take place at the Company's registered office (Via Antonio Meucci 3) in Bresso (Mi), Italy, starting at 10:00 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 balance sheet as of 31 December 2019
2. Appointment of the members of the Board of Directors, after determination of the relevant number, for the financial years 2020, 2021 and 2022 and, therefore, until the approval of the financial statements as of December 31st, 2022, as follows:

   - Ulrich Köstlin, in quality of Chairman of the Board and non-executive director;
   - Stefan Weber, in quality of executive director;
   - Patrick Langlois, in quality of non-executive director;
   - Robert Leslie Holland, in quality of non-executive director;
   - Luca Benatti, in quality of non-executive director; and,
   - Donald deBethizy, in quality of non-executive director

   Determination of the remuneration of the Board of Directors

Dial-in details to the media/analyst/investor conference on March 5, 2020, 04:00 pm CET:

The Newron management team will present the 2019 full-year results and provide an update and guidance for 2020. 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

The slide deck for the call is available at www.newron.com/downloads/reports-presentations--webcasts/2020

Upcoming events:

- AGM 2020: March 31, 2020
- Half-year report 2020: September 15, 2020

About Newron Pharmaceuticals

Newron (SIX: NWRN, XETRA: NP5) 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, the USA, Australia, Canada, Brazil, Colombia, the United Arab Emirates and Japan, 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**

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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.

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.