Newron announces 2020 financial results and provides outlook for 2021

Milan, Italy, March 16, 2021 – 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, 2020, and provided an outlook for 2021.

Highlights 2020:

Evenamide (Schizophrenia)

- All evenamide pre-clinical studies requested by the US Food and Drug Administration (FDA) have been completed with no toxicity concerns identified
- Despite the COVID-19 pandemic, the Company has successfully completed enrolment for explanatory study 008 with evenamide in patients with schizophrenia, with results expected by the end of March 2021
- Newron remains on track to initiate its pivotal Phase III program in Q3 2021 and continues to evaluate potential options for partnering/co-developing evenamide

Xadago®/safinamide (Parkinson's disease)

- Newron noted that Supernus Pharmaceuticals acquired the CNS portfolio of US WorldMeds, including the US rights to Xadago®/safinamide, effective June 2020
- Agreement signed with Zambon for potentially pivotal study with safinamide in patients suffering from Parkinson's disease levodopa-induced dyskinesia (PD LID)

Corporate

- Newron continues to evaluate opportunities to broaden its pipeline of treatments for central and peripheral nervous system diseases
- The Company received third tranche of EUR 7.5 million out of a potential EUR 40 million total funding amount under its financing agreement with the European Investment Bank (EIB)
- Cash (incl. Other current financial assets) as of December 31, 2020 is EUR 31.3 million

Stefan Weber, CEO of Newron, commented:

"The onset of the COVID-19 pandemic in 2020 presented enormous challenges for societies across the world. The healthcare industry, in particular, was challenged with identifying the resources to cope with the pandemic and with finding ways to fight it. We are proud of the way that Newron has adapted to this fast-evolving situation and of our ability to continue making operational progress, despite the pandemic and the difficulties it presents. 2020 has demonstrated that Newron's business remains resilient, and we move into 2021 and beyond confident in our strategy for the future. In addition, we enter into this year assessing a number of exciting strategic opportunities and additional compounds to expand our pipeline of novel therapies, and we will update the market accordingly."

Evenamide

Present treatments are unsatisfactory for most people suffering from schizophrenia and some 30% of patients with schizophrenia do not respond adequately to conventional therapy. Evenamide, as potentially the first add-on therapy to currently marketed antipsychotics, holds promise to change the treatment management paradigm: improving functioning and allowing patients to continue longer on their maintenance antipsychotic treatment. This would likely translate into lower rates of relapse, thus helping reduce the personal, societal, and economic burden to patients, their families, and

society. In the reporting year, Newron made significant progress with evenamide for the treatment of patients with inadequately treated or clozapine treatment-resistant schizophrenia. The additional short-term pre-clinical explanatory studies with evenamide requested by the US FDA were successfully completed, and no toxicity concerns were identified.

Additionally, Newron has initiated explanatory study 008, a clinical study designed to evaluate the safety, tolerability, electroencephalography (EEG) effects and preliminary efficacy of two fixed doses of evenamide in outpatients suffering from chronic schizophrenia receiving treatment with a second-generation atypical antipsychotic. Despite anticipated delays associated with the COVID-19 pandemic, the study was ongoing during 2020 and in January 2021, Newron announced that enrolment has been completed with 138 patients randomized to treatment with placebo, 7.5 mg BID, or 15 mg BID of evenamide at study centers in the US and India. Results from this four-week, randomized, double-blind placebo-controlled study are expected by the end of March 2021.

Newron remains on track to initiate the Phase III studies with evenamide in Q3 2021, contingent on no delays due to COVID-19 restrictions. The proposed Phase III clinical trial program with evenamide targets patients with schizophrenia experiencing worsening of psychosis while on atypical antipsychotics, and treatment-resistant patients not responding to clozapine. The latter represents an orphan-like indication with approximately 25,000 patients in the US (with similar numbers in the EU).

Xadago®/safinamide

Newron's partner Zambon had previously held discussions with the US FDA on the design of a potentially pivotal study to evaluate the efficacy of the compound in Parkinson's disease patients with levodopa induced dyskinesia (PD LID). The intention is to perform the study in centers in the US, Europe, and Asia/Australia, aiming at a label extension for PD LID in key global markets. Given Newron's extensive experience in the development of Xadago®/safinamide, Newron and Zambon have agreed on Newron taking responsibility for conducting the study. Zambon will remain associated with the study; Newron and Zambon will share the cost of the study equally, and Newron will qualify for a one-time milestone payment and a greater share of royalties, should the outcome of the trial lead to a label extension. Newron is currently working on finalizing the design of the study with international clinical experts and regulatory authorities.

To date, safinamide has received marketing authorization for the treatment of Parkinson's disease in the European Union, Switzerland, the United Kingdom, the United States, Canada, Australia, countries in Latin America, Israel, the United Arab Emirates, Japan and South Korea. It is commercialized by Newron's partner Zambon, their partners, and Meiji Seika and Eisai under the brand names Onstryv® in Canada, Equfina® in Japan and South Korea, and Xadago® in the rest of the world.

Financial Key takeaways 2020:

- In 2020, Newron reported a net loss of EUR 21.0 million, compared to EUR 20.2 million in 2019
- Cash used in operating activities has been reduced to EUR 15.6 million from EUR 22.0 million in 2019
- Xadago® royalty income increased by 10% to EUR 5.2 million versus EUR 4.8 million in 2019, when a one-time milestone payment for approval in Japan of net EUR 2.0 million was incurred, on top
- Newron's net R&D expenses have seen a reduction to EUR 14.9 million from EUR 17.4 million in 2019, largely due to the termination of the development program in Rett syndrome.
- Due to substantial changes of the regulations covering the Italian R&D tax credits, the Company could only accrue an additional EUR 1.4 million in 2020 versus EUR 5.0 million in 2019. The

cumulated tax credits of EUR 15.9 million can be offset with future tax and social contribution payments by Newron

- In 2020, G&A expenses have been reduced to EUR 8.1 million compared to EUR 9.9 million in 2019
- Cash and Other current financial assets at December 31, 2020, were at EUR 31.3 million, compared to EUR 39.2 million at the beginning of the year.

Financial Summary (IFRS) 2020 and 2019:

In thousand EUR (except per share information)

	2020	**2019**
Licence income contracts with customers	23	2,284
Royalties from contracts with customers	5,235	4,754
Revenues	**5,258**	**7,038**
Research and development expenses, net	14,853	17,440
Operating loss	**18,066**	**20,899**
Financial result, net	(1,552)	737
Net loss	**20,998**	**20,207**
Loss per share	1.18	1.13
Cash used in operating activities	15,588	21,976
Cash, cash equivalents and Other current financial assets	31,250	39,163
Total assets	51,198	60,288

Newron's Annual Report 2020 is available for download on the Company's website: https://www.newron.com/investors/reports-and-presentation/year/2020

Outlook 2021:

"We move forward into 2021 confident in our vision for the future, and excited by our current pipeline of novel drugs. We continue to evaluate opportunities to broaden our pipeline of treatments for central and peripheral nervous system diseases, as well as exploring partnering opportunities. In particular, we look forward to initiating our Phase III clinical program evaluating evenamide in schizophrenia and progressing in our preparations towards the new label study with Xadago®/safinamide. Newron's total available funding, including the EIB funds not yet drawn down, in addition to its royalty income and Italian R&D tax credits, will fund the planned development programs and operations of our Company to early 2023," outlined Stefan Weber, CEO of Newron.

2021 Shareholders' Meeting Agenda:

Newron's Board of Directors has approved the below agenda for the April 13, 2021, Shareholders' meeting, which will take place at the Company's registered office (Via Antonio Meucci 3) in Bresso (Mi), Italy, starting at 10:30 am CET. The formal invitation to shareholders will be issued and disclosed in the statutory papers on or around March 16.

The full invitation and supporting material will be made available on the Company's website (https://www.newron.com/investors/shareholders-meeting) on the same date. The agenda is as follows:

1. Approval of the balance sheet as at 31 December 2020. Related and consequent resolutions

Dial-in details to the media/analyst/investor conference on March 16, 2021, 03:00 pm CET

The Newron management team will present the 2020 full-year results and provide an update and guidance for 2021. 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 06 13
- United States: +1 (1)631 570 56 13

The slide deck is available at
https://www.newron.com/investors/reports-and-presentation/year/2021

Upcoming events

- AGM 2021: April 13, 2021
- Half-year report 2021: September 16, 2021

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 UK, the USA, Australia, Canada, Latin America, Israel, the United Arab Emirates, Japan and South Korea, and is commercialized by Newron's Partner Zambon. Supernus Pharmaceuticals 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. 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.