Newron announces half-year 2020 results

Milan, Italy, September 15, 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 progress for the half-year ended June 30, 2020.

Highlights:

Evenamide (Schizophrenia)

- All evenamide pre-clinical studies requested by the US Food and Drug Administration (FDA) completed with no toxicity concerns identified
- First clinical safety study initiated despite industry wide delays caused by COVID-19
- Newron on track to initiate its pivotal Phase III program in 2021
- Newron currently evaluating potential options for partnering/co-developing evenamide

Xadago®/safinamide (Parkinson's disease)

- Newron noted Supernus Pharmaceuticals' acquisition of US WorldMeds' CNS portfolio, including the US rights to Xadago®/safinamide, effective June 2020
- 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

Sarizotan (Rett syndrome)

- Newron terminated development program, after the Sarizotan Treatment of Apneas in Rett Syndrome (STARS) clinical study did not demonstrate evidence of efficacy on the primary or secondary efficacy variables
- Company to share learnings from the Rett Syndrome International Burden of Illness study, and is evaluating passing on the study to another pharmaceutical company for completion

Corporate

- Newron received third tranche of EUR 7.5 million under financing agreement with the European Investment Bank (EIB)
- In light of COVID-19 pandemic, Newron reiterated its commitment to health and safety of patients, caregivers and employees
- Newron is evaluating opportunities to broaden its pipeline of treatments for central and peripheral nervous system diseases

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

"The first half of 2020 has presented some obstacles, but we move forward excited by our current pipeline of novel drugs and are confident in our ability to advance these through the clinic and improve their positioning in the market. We look forward to progressing towards our Phase III clinical program, evaluating evenamide in schizophrenia, to complete preparations towards the new label study with Xadago, and to potentially broaden our central nervous system pipeline. Newron's total available funding, including the EIB funds not yet drawn down, in addition to our royalty income and Italian R&D tax credits, will fund the Company's planned development programs and operations well into 2022."

Evenamide
In January 2020, Newron reached an agreement with the US FDA on the design and conduct of additional short-term pre-clinical explanatory studies with evenamide, as well as the protocol for a first, four-week safety study in patients with schizophrenia. The requested pre-clinical studies have already been successfully completed, with no toxicity issues reported.

Despite anticipated delays associated with COVID-19, Newron has initiated the first clinical safety study, an explanatory four-week randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability, 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. Newron intends to recruit approximately 120 patients. Patient recruitment is progressing well at sites in the US and India, with more than 75 patients enrolled, and contingent on no further COVID-19 restrictions, results from the study are currently expected in Q1 2021.

Together with the pre-clinical results confirming absence of toxicity that have been submitted to the FDA, the extensive explanatory study package should deliver robust, convincing clinical data to proceed with the next, pivotal phase of clinical development. Newron remains confident that it is on track to initiate the Phase III studies with evenamide in Q2 2021.

In key territories, the Company continues to expect to commercialize evenamide itself in the treatment-resistant schizophrenia indication. For the indication of patients showing inadequate response to their current atypical antipsychotics and experiencing worsening of psychosis, Newron is currently evaluating potential options for partnering/co-development.

Xadago®/safinamide
In April 2020, we noted the agreement between US WorldMeds and Supernus Pharmaceuticals, under which Supernus intended to acquire US WorldMeds' central nervous system (CNS) portfolio, including the US rights to Xadago®/safinamide. The transaction subsequently closed in June. Supernus' focus is the development and commercialization of products for the treatment of CNS diseases.

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.

Sarizotan
Unfortunately, in May 2020 Newron announced that the Sarizotan Treatment of Apneas in Rett Syndrome (STARS) study did not demonstrate evidence of efficacy on the primary or secondary efficacy variables. The study was well-designed and executed, based on highly promising data from a genetic model of Rett syndrome in mice. The results of the study demonstrate the inherent difficulties in translating effects in animal models, even if genetic, to human clinical studies. As a consequence, Newron has decided to terminate this development program. However, as part of its long-time commitment to the Rett syndrome community, the Company is evaluating how to share the learnings from the Rett Syndrome International Burden of Illness study (potentially by passing on the study to another pharmaceutical company for completion).

Financials:

- For the first six months of 2020, Newron reported a net loss of EUR 10.5 million, compared to EUR 14.0 million in the same period in 2019. The reduction is mostly due to the termination of the sarizotan development program in Rett syndrome.
- Cash used in operating activities has decreased to EUR 7 million from EUR 14.7 million in 2019.
- Xadago® revenues received from Zambon increased by 12.4% (EUR 2.5 million versus EUR 2.2 million in 2019).
- Newron's R&D expenses declined to EUR 7.8 million from EUR 10.3 million in 2019.
- G&A expenses were EUR 4.4 million in the first six months of 2020 versus EUR 5.9 million in 2019.
- Cash and Other current financial assets at June 30, 2020 were at EUR 39.4 million, compared to EUR 39.2 million at the beginning of the year.

Financial Summary (IFRS):

In thousand EUR (except per share information)

	HY1 2020	**HY1 2019**
Licence income/Royalties	2,509	2,232
Research and development expenses	(7,777)	(10,298)
General and administrative expenses	(4,374)	(5,934)
Net profit/loss	(10,503)	(14,046)
Profit/loss per share – Basic	(0.59)	(0.79)
Cash used in operating activities	(7,039)	(14,700)
	As of June 30, 2020	**As of Dec. 31, 2019** restated (1)
Cash and Other current financial assets	39,365	39,163
Total assets	57,834	60,288

(1): In 2020, Management restated the 2019 figures related to the R&D tax credit receivables. For additional information, please see Notes 2 and 12 of the Half-Year Report 2020.

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

Upcoming events:

- H.C. Wainwright 22nd Annual Global Investment Conference (virtual): September 15, 2020
- Investora 2020, Zurich: September 23, 2020
- Deutsches Eigenkapitalforum 2020 (virtual): November 16-18, 2020
- Jefferies Virtual Global Healthcare Conference: November 17-19, 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. Supernus Pharmaceuticals holds the commercialization rights in the US. 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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