Ad hoc announcement pursuant to Art. 53 LR

# Newron announces Half-Year 2021 results

**Milan, Italy, September 16, 2021, 07:00 am CEST** – 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 operational highlights and financial results for the half-year ended June 30, 2021.

**Highlights:**

**Evenamide (Schizophrenia)**

- The primary objective of two short-term explanatory studies of evenamide was met on all safety variables: study 010, in healthy volunteers, and study 008, in patients with schizophrenia
- Post-period, Newron initiated study 008A, the first potentially pivotal study with evenamide in patients with schizophrenia, results from which are expected by Q4 2022
- Newron continues to evaluate strategic commercial and development partnering options for evenamide

**Xadago®/safinamide (Parkinson's disease)**

- Newron signed an agreement with its partner Zambon to commence a potentially pivotal study with safinamide in Parkinson's disease patients with levodopa-induced dyskinesia (PD LID)
- Newron is currently working on finalizing the design of the study with international clinical experts and regulatory authorities and intends to initiate the study in Q1 2022
- Newron and its partners Zambon and Supernus are responding appropriately to protect the intellectual property rights relating to Xadago®/safinamide in the US, following some Paragraph IV Notice Letters regarding Abbreviated New Drug Applications that have been submitted by generic manufacturers

**Corporate**

- Newron is in the process of conducting value assessments on several potential opportunities to broaden its pipeline of treatments for central and peripheral nervous system diseases
- Post-period, Newron received a fourth tranche of EUR 7.5 million under its financing agreement with the European Investment Bank (EIB)

**Stefan Weber, CEO of Newron, commented:**

"As we move forward into the remainder of 2021, we are pleased with the progress we are making with our innovative products. In particular, we look forward to advancing our potentially pivotal studies with evenamide in patients with schizophrenia and with safinamide in PD LID. We are evaluating opportunities to broaden our pipeline of treatments for central and peripheral nervous system diseases, as well as exploring opportunities to partner, where appropriate. Newron's total available cash resources, including the EIB funds not yet drawn down, in addition to its royalty income and Italian R&D tax credits, will fund our planned development programs and operations well into 2023."

**Evenamide**

In April, Newron announced encouraging results from two short-term explanatory studies in evenamide: study 010 in 56 healthy volunteers, and study 008 in 138 outpatients with chronic schizophrenia, receiving treatment with a second-generation atypical antipsychotic. These promising results showed that evenamide is devoid of any arrhythmic effect, a risk generally associated with antipsychotics, even at twice the therapeutic dose, and can be safely added to any other antipsychotic. The results also demonstrated that the drug is safe at all doses investigated, due to the lack of any systemic pattern of adverse effects relating to the central nervous system.

Based on this encouraging data and supported by the pre-clinical results published last year confirming the absence of toxicity, Newron, on September 6, 2021, initiated study 008A, the first potentially pivotal study with evenamide in patients with chronic schizophrenia. Study 008A, a four-week, randomized, double-blind

placebo-controlled international study, is designed to evaluate the efficacy, tolerability, and safety – including electroencephalography (EEG) effects – of the 30mg BID therapeutic dose of evenamide in patients with chronic schizophrenia, currently being treated with a second-generation antipsychotic.

Results from the study are expected by Q4 2022. Newron believes that positive results from this study would qualify the trial as the first adequate and well-controlled (pivotal) study with evenamide in patients with schizophrenia who are inadequate responders to antipsychotics.

**Xadago®/safinamide**

For the continued clinical development of its marketed product Xadago®/safinamide, Newron has signed an agreement with its partner Zambon to commence a potentially pivotal study with safinamide in PD LID. This double-blind, placebo-controlled study is intended to be performed in the US, Europe and Asia/Australia, with a potential label extension for safinamide in key markets. Newron currently expects to initiate the study in Q1 2022.

In May, Newron received some Paragraph IV Notice Letters regarding the submission by generic manufacturers of an Abbreviated New Drug Application to the US FDA, seeking approval to engage in the commercial manufacture, use or sale of safinamide mesylate drug product in the US before the expiration of certain US patents. Newron and its partners Zambon and Supernus have responded in filing an infringement suit against the generic manufacturers to secure a 30-month stay of the ANDAs approval, and thus to protect its intellectual property rights relating to Xadago®/safinamide tablets. The compound is currently protected by three patents listed in the FDA's Approved Drugs Product List (Orange Book) that expire no earlier than 2027.

**Financial Key Takeaways:**

- For the first six months of 2021, Newron reported a net loss of EUR 9.1 million, compared to EUR 10.5 million in the same period in 2020
- Cash used in operating activities has increased to EUR 8.8 million from EUR 7.0 million in H1 2020
- Xadago® revenues received from Zambon slightly increased from EUR 2.5 million in H1 2020 to EUR 2.7 million in the reporting period
- Newron's R&D expenses have fallen to EUR 6.8 million from EUR 7.8 million in H1 2020
- G&A expenses were EUR 3.7 million in the first six months of 2021 versus EUR 4.4 million in the same period in 2020
- Cash and Other current financial assets at June 30, 2021 were at EUR 21.9 million, compared to EUR 31.3 million at the beginning of the year
- Post-period, on September 6, Newron received the fourth tranche of funds under its financing agreement with the EIB that was announced in 2018 and comprised of funding up to EUR 40 million. Tranche 4 consisted of EUR 7.5 million and will primarily be used to support the Company's development programs in CNS diseases

**Financial Summary (IFRS):**

In thousand EUR (except per share information)

| | **H1 2021** | **H1 2020** |
|---|---|---|
| Licence income/Royalties | 2,671 | 2,509 |
| Research and development expenses | (6,783) | (7,777) |
| General and administrative expenses | (3,747) | (4,374) |
| Net profit/loss | (9,063) | (10,503) |
| Profit/loss per share | (0.51) | (0.59) |
| Cash used in operating activities | (8,750) | (7,039) |
| | **As of June 30, 2021** | **As of Dec. 31, 2020** |
| Cash and Other current financial assets | 21,906 | 31,250 |
| Total assets | 39,886 | 51,198 |

Newron's Half-Year Report 2021 is available for download on the Company's website:
https://www.newron.com/investors/reports-and-presentation/year/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, Brazil, Colombia, 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 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**

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**Important Notices**