Newron provides H1 2022 results and updates on R&D and business activities

Ad hoc announcement pursuant to Art. 53 LR

Milan, Italy, September 15, 2022, 7 am CET – 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 half year ended June 30, 2022 and provided an update on its R&D and business activities.

Highlights H1 2022:
Evenamide (Schizophrenia)

- Key data presented at the 33rd CINP Hybrid World Congress of Neuropsychopharmacology, Taipei, Taiwan, including:
  - Encouraging interim data from the first 100 patients in study 014, a world-first, randomized, open-label trial of evenamide as an add-on to an antipsychotic in patients with chronic, treatment-resistant schizophrenia (TRS). Results showed the addition of evenamide improved symptoms of psychosis. Enrollment in this study is expected to be completed by end of 2022 and results are expected in QI 2023
  - Study design for an upcoming potentially pivotal, randomized, double-blind, placebo-controlled, eight-week, global study (003) assessing the safety and efficacy of evenamide as an add-on treatment in patients with TRS, which is expected to commence in 2023
  - Safety data from more than 400 healthy volunteers and patients with schizophrenia treated with evenamide, showing that the compound is safe and well tolerated
- The first potentially pivotal study of the Phase II/III evenamide development program, study 008A with evenamide as add on therapy in patients with chronic schizophrenia experiencing inadequate response to their current antipsychotics, is continuing to enroll patients, and results are expected in first half of 2023
- Newron continues to evaluate strategic commercial and development partnering options for evenamide

Xadago®/Safinamide (Parkinson's disease)

- Newron and its partners Zambon and Supernus continue to work to protect intellectual property rights associated with Xadago®/safinamide in the US, responding to Paragraph IV Notice Letters regarding Abbreviated New Drug Applications submitted from generic pharmaceutical manufacturers
- Newron continues to plan a potentially pivotal study with safinamide in Parkinson's disease patients with levodopa-induced dyskinesia (PD LID) in partnership with Zambon

Corporate

- Reaffirmed commitment to Environmental, Social and Governance (ESG) reporting and standards through the establishment of an ESG board committee, which is undertaking a comprehensive assessment of key ESG areas to identify measurable targets for Newron
- Strengthened senior leadership team with the appointment of Filippo Moriggia as Vice President Operations, who will also lead Newron's operational ESG activities
- Newron continues to explore a number of potential opportunities to expand its pipeline in central nervous system diseases

Stefan Weber, CEO of Newron, commented:
"In particular, we are very excited about the encouraging progress made in the first half of 2022 with our ongoing evenamide development program. This includes the interim results from study 014 – the first ever randomized international trial with a New Chemical Entity, evenamide, as add-on therapy in patients with treatment-resistant schizophrenia – as well as the continued progress in study 008A, the first potentially pivotal study with evenamide as add-on therapy in patients with schizophrenia who are inadequate responders to

atypical antipsychotics. We also strengthened our senior leadership team and furthered our commitments to ESG standards, principles and outcomes."

Evenamide
In June 2022, Newron presented key scientific data of evenamide at the 33rd Collegium Internationale Neuro-Psychopharmacologicum (CINP) Hybrid World Congress of Neuropsychopharmacology, in Taipei, Taiwan.

Among others, the Company presented interim results from the first 100 patients in study 014, an open-label study of evenamide as an add-on antipsychotic in patients with moderate to severe treatment resistant schizophrenia (TRS), who were not responding to current antipsychotic medication. The primary objective of the study was to evaluate the safety and tolerability of evenamide given orally at three fixed doses (7.5, 15 and 30 mg bid). The vast majority of these patients were treated with 7.5mg and 15mg bid doses, as an Independent Safety Monitoring Board first reviewed the safety data from the lower doses before allowing randomization to a 30mg bid dose. The assessment of preliminary efficacy was a secondary objective and was based on changes from baseline in the Positive and Negative Syndrome Scale (PANSS); Clinical Global Impression - Change from baseline (CGI-C); Severity of illness (CGI-S); and Strauss-Carpenter Level of Functioning (LOF) scale.

The interim results from this world-first, international, six-week, open-label, randomized, rater-blinded and multi-center trial showed that the addition of evenamide improved symptoms of psychosis in patients with chronic TRS. This was reflected by an approximately 12% reduction in the PANSS score, CGI-S improvement of 0.7, and CGI-C ratings, indicating that 77% of patients were considered to have improved. The results confirm the potential of evenamide as an add-on therapy to antipsychotics to improve the lives of patients who continue to experience severe symptoms of psychosis under their current medication.

Newron sees significant progress in the enrolment of patients for study 014 and expects to complete the process by the end of 2022, with results from the study due in QI/2023. Newron is especially excited by the impressive rate (> 90%) of treatment resistant patients deciding to continue treatment with evenamide by entering into the long-term extension study 015. At the CINP congress, the Company had also outlined safety data from more than 400 healthy volunteers and patients with schizophrenia who were treated with evenamide. The results showed that evenamide was well tolerated, with no safety issues identified.

Finally, Newron presented the study design for an upcoming randomised, double-blind, placebo-controlled, eight-week, global study (003) assessing the safety and efficacy of evenamide (15/30mg bid) as an add-on treatment in patients with TRS not responding to their current atypical antipsychotics. This second potentially pivotal study 003 is expected to commence in 2023. Study 003, together with study 008A, form Newron's promising Phase II/III evenamide development program.

The ongoing Study 008A is a four-week, randomised, double-blind and placebo-controlled study assessing the efficacy, tolerability, and safety (including electroencephalogram effects) of evenamide (30mg bid) in patients with chronic schizophrenia currently being treated with a second-generation antipsychotic, but who are not classed as having TRS. The study is enrolling patients in treatment centers in Europe, Asia and Latin America. Recently, an additional 10 study centers have been added in Europe, to arrive at a total of more than 50 centers, globally. This will help enrol patients to the study and ensure timely progress in the study. The results from study 008A are expected in the first half of 2023. If positive, the study would mark the first well-controlled, potentially pivotal study of evenamide in schizophrenic patients who do not adequately respond to treatment with atypical anti-psychotics.

If approved, evenamide would be the first add-on therapy for schizophrenia. It acts through selective attenuation of the abnormal release of glutamate, which is a novel, alternative mechanism of action to the common dopaminergic or serotonergic anti-psychotics. It would also offer a new therapeutic option for TRS patients, who make up roughly one-third of patients suffering from schizophrenia. This would represent a significant advancement in the approach to schizophrenia and TRS specifically, especially as there are currently no new drugs in development for TRS.

Newron continues to evaluate opportunities to partner on the development and commercialisation of evenamide.

Xadago®/safinamide
Newron continues to further develop and market its product, Xadago®/safinamide, with its partners, Zambon and Meiji Seika.The Company also continues to plan a potentially pivotal study with safinamide in Parkinson's disease patients with levodopa-induced dyskinesia (PD LID) in partnership with Zambon.

In reference to the receipt of several Paragraph IV Notice Letters in May 2021 regarding the submission by generic manufacturers of an Abbreviated New Drug Application to the US Food and Drug Administration (FDA), Newron and its partners Zambon and Supernus continue to challenge these submissions and note that Newron's patents on Xadago® (safinamide) tablets remain protected by three patents in the FDA Approved Drugs Product List (Orange Book) until at least 2027.

Corporate
Post period, in July 2022, Newron announced the strengthening of its Senior Management team through the appointment of Filippo Moriggia to the newly created position of Vice President of Operations. Filippo joined Newron in November 2016 as IT Director and became Director of Operations in January 2022.

Newron also reaffirmed its commitment to Environmental, Social and Governance (ESG) through the initiation of a comprehensive assessment of key ESG topics that impact the company and its shareholders, in order to identify measurable targets for its sustainability activities. To effectively pursue these targets and track their progress, the Board of Directors also in July 2022 established an ESG Committee, with Filippo Moriggia, newly appointed VP of Operations, leading the ESG work on an operational level. Newron's material ESG topics and the corresponding KPI's and reporting framework should be communicated by the end of 2022, while annual ESG reporting will commence in spring 2023 with the publication of the 2022 Annual Report.

Financial Summary (IFRS):
In thousand EUR (except per share information)

	H1 2022	**H1 2021**
Licence income/Royalties	2,830	2,671
Research and development expenses	(5,324)	(6,783)
General and administrative expenses	(3,894)	(3,747)
Net profit/loss	(8,636)	(9,063)
Profit/loss per share	(0.48)	(0.51)
Cash used in operating activities	(5,630)	(8,750)
	As of June 30, 2022	**As of December 31, 2021**
Cash and Other current financial assets	28,358	34,594
Total assets	43,543	50,486

Newron's Half-Report 2022 is available for download on the Company's website:
https://www.newron.com/investors/reports-and-presentation/year/2022

Outlook:
"Looking ahead to the next months, we remain dedicated to our mission of developing novel treatments for diseases of the central and peripheral nervous system. We also remain on track to publish full results from study 014 in QI/2023 and from study 008A in the first half of 2023. We will continue to explore commercial partnerships as well as opportunities to in-licence drugs. The total available cash resources, in addition to royalty income and Italian R&D tax credits, will fund the planned development programs and operations of our Company well into 2024," outlined Stefan Weber, CEO of Newron.

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