Newron announces H1 2023 results and provides R&D update

Ad hoc announcement pursuant to Art. 53 LR

Milan, Italy, August 4, 2023, 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, 2023, and provided an update on its R&D and business activities.

Highlights H1 2023:

Evenamide

- Results from study 014/015, the first international trial of an antipsychotic new chemical entity (NCE) as an add-on therapy to a single antipsychotic in patients with treatment-resistant schizophrenia (TRS)
    - demonstrated evenamide's efficacy on multiple measures of psychopathology
    - support movement to potentially pivotal, multinational, randomized, placebo-controlled trial
    - suggest a potential new strategy for the management of TRS patients
- Presentation of data to the medical community at several international psychiatry conferences, highlighting the multi-modal, clinically important response to evenamide in TRS patients, across various domains and multiple timepoints
- Publication of data from study 014/015 in the peer-reviewed *International Journal of Neuropsychopharmacology*, outlining the continued improvement in symptoms of psychosis in TRS patients receiving evenamide
- Following the publication of this encouraging data, the Company is working towards initiation of study 003, a potentially pivotal, multinational, randomized, double-blind, twelve-week, placebo-controlled study assessing the efficacy, safety and tolerability of evenamide (15/30 mg bid) as an add-on treatment in patients with TRS
- Evenamide (30 mg bid) is also being evaluated as a treatment in patients with chronic schizophrenia demonstrating inadequate benefit to their current second-generation antipsychotic, in study 008A, a potentially pivotal four-week, randomized, double-blind and placebo-controlled study; patient recruitment is ongoing and on track to report full results by end of 2023/early 2024

Corporate

- As per July 2023, two key promotions strengthening Newron's senior management team: Laura Faravelli, Director Business Development at Newron since 2019, was promoted to Vice President Business Development, and Roberto Galli, Vice President Finance since 2012, was appointed Chief Financial Officer
- Gillian Dines was elected as a Non-Executive Director to the Board of Newron, following J. Donald (Don) deBethizy stepping down as per the AGM 2023 from the Board after a nine-year tenure
- Implementation of 2023 ESG goals well on track

Stefan Weber, CEO of Newron, commented:

"The first half of 2023 has been a period of enormous progress for Newron. We have reported three striking sets of data from our evenamide development program for treatment-resistant schizophrenia (TRS), presented these results at international psychiatry scientific conferences, and published key results in a peer-reviewed journal. Newron is on track to report more crucial data in the second half of 2023 and early next year from the Phase II study in TRS as well as data from its Phase III trial in non-treatment resistant schizophrenia. Finally, we are progressing towards the initiation of the potentially pivotal study assessing the efficacy, safety and tolerability of evenamide (15/30 mg bid) as an add-on treatment in patients with TRS. The exciting results

triggered substantial interest from potential partners on future collaboration opportunities for the development of evenamide."

Evenamide (Schizophrenia)

In Q1 2023, Newron announced three exciting new sets of data evaluating evenamide as an add-on treatment for patients with TRS.

- In January, the Company presented data from the first 100 patients to complete six months (30 weeks) of treatment with evenamide in study 014/015, the first, international, multi-centre, randomized, open label, rater-blinded study of NCE evenamide (7.5/15/30 mg bid) as an add-on to an antipsychotic (excluding clozapine) in patients with moderate to severe TRS not responding to their current antipsychotic medication
- This announcement was followed in February by further data from the same cohort at the one-year (52 weeks) timepoint
- In March Newron also reported topline data from all 161 patients at the six-week timepoint

Overall, data from study 014 has demonstrated that evenamide was safe and well-tolerated at all doses, with 97% of patients completing six weeks of treatment. The incidence of treatment-emergent adverse events was very low, and more than 90% of the completers chose to continue with evenamide treatment into the long-term extension study (study 015).

The results at the six-week, six-month and one-year timepoints demonstrated a statistically significant improvement of symptoms compared to baseline in patients with TRS after treatment with evenamide. Moreover, comparison of both the six-month and one-year data with the six-week data shows that not only was there a sustained improvement in all key measures of psychosis, but this benefit increased over time. Further evidence of the increasing proportion of patients who experienced a clinically meaningful benefit over time was provided by the proportion of patients considered as "multi-domain-responders", increasing 2.5-fold from six weeks to 38% at one year. This continued, sustained improvement is unprecedented for an antipsychotic treatment in patients with TRS and demonstrates the potential of evenamide to offer a genuinely innovative therapeutic option for patients struggling with debilitating schizophrenia symptoms who have exhausted other antipsychotic treatments.

Newron presented these data sets at three key conferences in the CNS space during H1 2023; furthermore, they were published in the peer reviewed journal *International Journal of Neuropsychopharmacology* at the end of the reporting period. The Company will be presenting the full results from extension study 015 of all 161 patients after six months in October at the 36th European College of Neuropsychopharmacology (ECNP) Congress, in Barcelona, Spain, in October.

Newron's key focus now is on initiating study 003, a randomized, placebo-controlled and potentially pivotal Phase III study of evenamide, which will hopefully confirm its potential as a new add-on for TRS patients. Newron is also investigating evenamide in patients with chronic schizophrenia who experience an inadequate response to their current antipsychotics but who are not classed as having TRS. Study 008A is continuing to enroll patients in this indication, and results are expected by end of 2023/early in 2024.

If approved, evenamide would be the first medication added to existing antipsychotics that improves the symptoms of TRS, offering a much-needed new treatment option for those who are not responding to existing second-generation antipsychotics. Evenamide is revolutionary in its glutamatergic mechanism of action, working through modulation of glutamate and voltage-gated sodium channel blockade. Evenamide modulates sustained repetitive firing, without inducing impairment of normal neuronal excitability, and normalizes glutamate release induced by aberrant sodium channel activity. The results seen validate the rule of glutamate release inhibition in repairing disturbed neural connectivity in the TRS population.

Xadago®/safinamide (Parkinson's disease)

In partnership with its partners Zambon and Supernus, Newron continues to further develop and market its product, Xadago®/safinamide. 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), seeking approval to engage in the commercial manufacture, use or sale of safinamide mesylate drug product in the US before expiration of certain US patents, Newron and its partners Zambon and Supernus had filed an infringement case against these manufacturers to secure its intellectual property rights. The companies continue to challenge these submissions and note that the patents on Xadago® (safinamide) tablets remain protected by three patents in the FDA Approved Drugs Product List (Orange Book) until at least 2027.

Financial Summary (IFRS) H1 2023 and H1 2022:

In thousand EUR (except per share information)

	H1 2023	**H1 2022**
Licence income/Royalties/Other income	5,494	2,830
Research and development expenses	(5,685)	(5,324)
General and administrative expenses	(4,062)	(3,894)
Net profit/loss	(6,950)	(8,636)
Profit/loss per share	(0.39)	(0.48)
Cash used in operating activities	(5,603)	(5,630)
	As of June 30, 2023	**As of December 31, 2022**
Cash and Other current financial assets	17,139	22,774
Total assets	31,494	37,195

Outlook 2023:

The second half of 2023 and early 2024 will bring further crucial data sets and proof points in Newron's evenamide development program. In the TRS indication, this includes the presentation of full data from all patients in study 014/015 after six months at the ECNP Congress in October, and for the 12 months, as well as the preparations towards initiation of study 003, a potentially pivotal trial. The Company remains on track to report full results from study 008A in patients with chronic schizophrenia who are inadequate responders to their current antipsychotic. Newron's total available cash resources, in addition to its royalty income and Italian R&D tax credits, will fund the Company's planned development programs and operations well into 2024.

Newron's Half-Report 2023 with further details and information is available for download on https://www.newron.com/investors/reports-and-presentation/year/2023

Financial calendar

- Investora 2023, Zurich — September 13-14, 2023
- 36th ECNP Congress, Barcelona — October 7-10, 2023
- Jefferies 2023 London Healthcare Conference — November 14-16, 2023
- Deutsches Eigenkapitalforum, Frankfurt — November 27-29, 2023

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 symptoms of schizophrenia. For more information, please visit: www.newron.com

For more information, please contact:

Newron
Stefan Weber – CEO, +39 02 6103 46 26, pr@newron.com

UK/Europe
Simon Conway / Ciara Martin / Natalie Garland-Collins, FTI Consulting, +44 20 3727 1000, SCnewron@fticonsulting.com

Switzerland
Valentin Handschin, IRF , +41 43 244 81 54, handschin@irf-reputation.ch

Germany/Europe
Anne Hennecke / Caroline Bergmann, MC Services, +49 211 52925222, newron@mc-services.eu

USA
Paul Sagan, LaVoieHealthScience, +1 617 374 8800, Ext. 112, psagan@lavoiehealthscience.com

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