Newron Pharmaceuticals hosts its 2018 R&D Day in New York City

- *Leading clinicians presented new evidence on treatment options for patients suffering from Rett syndrome and treatment resistant schizophrenia*

- *Company provided update on its innovative pivotal stage development programs in Rett syndrome and schizophrenia*

Milan, Italy and Morristown, NJ, USA – October 31, 2018 – Newron Pharmaceuticals S.p.A. ("Newron") (SIX: NWRN), a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central nervous system, welcomed investors, analysts and media today to its well-attended research and development (R&D) day in New York City, featuring leading medical experts presenting on schizophrenia, treatment resistant schizophrenia and Rett syndrome.

Stefan Weber, Chief Executive Officer of Newron Pharmaceuticals, commented: "We were delighted to host presentations from leading clinicians on the treatment options for Rett syndrome and treatment resistant schizophrenia at today's R&D event, as well as to provide an update on our clinical development programs. We expect to use our financial resources for the clinical studies presented today to advance our drugs towards the market in orphan or orphan-like indications, which we then intend to commercialize ourselves. In addition, we plan to use a proportion of our funds to help advance the potentially pivotal study that will evaluate our commercial stage Parkinson's disease treatment, Xadago®, in patients with levodopa induced dyskinesia, a study that will be performed by our partner Zambon."

Schizophrenia

John Kane, MD, Professor and Chairman of the Department of Psychiatry at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell presented the current status of management of patients with treatment resistant schizophrenia (TRS) in a talk entitled, "Spectrum of treatment resistant schizophrenia: new therapeutic mechanisms."

Dr. Kane stated: "There's clearly a huge unmet medical need for patients suffering from treatments resistant schizophrenia, as no new drug has been approved in more than three decades. Clozapine, the only available treatment for treatment resistant patients, is only infrequently used. Evenamide's voltage-gated sodium channel blockade produces benefits that have been shown to be additive to current antipsychotics in pre-clinical studies as well demonstrating Proof of Concept in a Phase IIa placebo-controlled study. If confirmed in the upcoming Phase III program, Evenamide could offer a new treatment option for patients with schizophrenia showing inadequate response to their current medication as well as in treatment resistant schizophrenia patients not responding to clozapine."

Ravi Anand, MD, Newron's Chief Medical Officer, presented the Evenamide Phase III development program, with enrollment expected to be initiated in Q2 2019. The overall program has been discussed and agreed upon with the regulatory authorities in Europe and the United States. The program includes two pivotal studies: the first one will be a 52-week

randomized, double-blind, placebo-controlled, parallel-group, multi-center study with the primary analysis of efficacy, safety, and tolerability of three fixed doses of Evenamide (7.5, 15 and 30 mg BID) or placebo as add-on in patients with chronic schizophrenia not responding adequately to their current single atypical antipsychotic medication at therapeutic doses despite adequate duration of treatment, performed after 6-weeks of randomized treatment. Patients completing 6 weeks of treatment will continue on their randomized treatment for an additional 46-week, double-blind, placebo-controlled extension. The study will be performed in approximately 520 patients (130/group) in about 30 study centers in Canada, Europe, India, Latin America and North America.

The second Phase III trial will be a randomized, double-blind, parallel-group, multi-center, 8-week study, to determine the efficacy, safety, and tolerability of add-on treatment with Evenamide (15 or 30 mg BID) or placebo in patients with treatment resistant schizophrenia not responding adequately to clozapine. The study will be performed in approximately 450 patients (150/group) in about 30 centers in Canada, Europe, India, Latin America and the US.*

Dr. Anand stated: “We look forward to initiating the Phase III program for Evenamide next year. If proven safe and effective, we are excited by the prospect of a new treatment paradigm that Evanamide could offer to schizophrenia patients. Regulatory discussions suggest that positive results in the clozapine treatment resistant population could lead to expedited approvability of Evenamide in that indication, while positive results from both studies could lead to approval of Evenamide as an add-on treatment in patients with chronic schizophrenia.”

Newron estimates that approximately 20,000 to 35,000 patients in the US are treatment resistant to clozapine, a patient population that could be easily accessed by a small commercial organization. Newron plans to commercialize Evenamide in this orphan-like indication itself.

*Patients with treatment resistant schizophrenia show increases in glutamate in the anterior cingulate cortex. Evenamide antagonizes the effects of the excess of glutamate; animal studies have demonstrated that the addition of Evenamide to ineffective doses of clozapine is associated with efficacy.

Rett syndrome

Daniel Glaze, MD, Neurologist and Professor at Baylor College of Medicine in Houston, Texas, presented the topic “Rett Syndrome: Natural History of Awake Breathing Dysfunction and Emerging Data.” Dr. Glaze in his talk summarized current knowledge on Awake Breathing Dysfunction in Rett Syndrome, stemming from the Natural History Study and accruing new evidence from the STARS study with sarizotan.

Dr. Glaze stated: “The STARS (Sarizotan Treatment of Apneas in Rett Syndrome) study for the first time provides objective measure of breathing dysfunction in the home environment over a long period of wakefulness. It is a quantitative as well as qualitative assessment of breathing dysfunction in Rett. The STARS base line data from more than 100 patients suggest that up to 70 percent of patients experience clinical significant apnea and minimally

10 percent of their time is spent without breathing. In these patients, oxygen saturation falls below 90 percent between 4.2 to 24 times per hour, and the cumulative duration of this state may last as long as 48 minutes per hour. It will be very important to determine the type and extent of symptoms a reduction in apnea will improve. The Rett community is eagerly awaiting the results from the STARS study, which could be the first treatment ever to be approved for treatment of Rett Syndrome."

Ravi Anand, MD, Newron's Chief Medical Officer, presented the status of the STARS study. By the third week of October, 116 patients had been randomized to treatment, with another four qualifying for randomization. Newron is therefore on track to reach its target of enrolling 129 patients during the remaining months of 2018 and now expects to report results from the study in Q3 2019.

The STARS study is focused on patients suffering from Rett syndrome who present with clinically significant daytime apneas during the course of the disease, which present in approximately 70% of patients. Treatment with sarizotan has been well tolerated with a very low rate of discontinuation due to adverse events or lack of efficacy. To date, nearly 90% of patients who have completed the 24-week double-blind period have continued in the long-term open-label extension.

Newron management believes that positive study results may lead to the approval of the first drug to benefit key symptoms of Rett syndrome. Newron intends to commercialize sarizotan itself in key markets.

Finally, Stefan Weber, Chief Executive Officer of Newron Pharmaceuticals, commented on the financial outlook of the Company, in light of the EUR 40 million long-term loan facility that the Company and the European Investment Bank (EIB) announced on October 30, 2018: "We are very pleased that the EIB has recognized the potential of Newron's R&D activities. This loan, coming on top of the approximately EUR 51 million in cash that we showed on our balance sheet at June 30 of this year, will provide us with material additional financial flexibility over the coming years and significantly enhance our resources."

A replay of the event is available in the 2018 R&D Day section of the Company's website at https://www.newron.com/home/newron-rd-day.

About schizophrenia

Schizophrenia is a long-term mental health condition that causes a range of different psychological symptoms. It is one of the most common serious mental health conditions. About 1 in 100 people will experience schizophrenia in their lifetime, with many continuing to lead normal lives. Schizophrenia is most often diagnosed between the ages of 15 and 35. Men and women are affected equally. There is no single test for schizophrenia. It is most often diagnosed after an assessment by a mental health care professional, such as a psychiatrist. It is important to diagnose schizophrenia as early as possible, as the chances of recovery improve the earlier it is treated. Schizophrenia is often described in terms of positive and negative (or deficit) symptoms. Positive symptoms are those that most individuals do not normally experience but are present in people with schizophrenia. They can include delusions, disordered thoughts and speech, and tactile, auditory, visual, olfactory and gustatory hallucinations, typically regarded as manifestations of psychosis. Hallucinations are also typically related to the content of the delusional theme. Positive symptoms generally respond well to medication. Negative symptoms are deficits of normal emotional responses or of other thought processes, and are less responsive to medication.

About Rett Syndrome
Rett syndrome is a severe neurodevelopmental disorder primarily affecting females, with an estimated prevalence of one in 10,000 females. There are no approved treatments available. Rett syndrome is characterized by a loss of acquired fine and gross motor skills and the development of neurological, cognitive and autonomic dysfunction, which leads to loss of ability to conduct daily life activities, walk or communicate. Rett syndrome also is associated with a reduced life expectancy. Approximately 25 percent of the deaths in patients with Rett syndrome are possibly related to multiple cardio-respiratory dysrhythmias that result from brain stem immaturity and autonomic failure. More than 95 percent of these patients have a random mutation in the MeCP2 gene. Episodes of apnea, hyperventilation and disordered breathing are found in approximately 70 percent of patients with Rett syndrome at some stage of their life. For more information on Rett syndrome, visit http://www.rettsyndrome.org.

About Newron Pharmaceuticals
Newron (SIX: NWRN) is a biopharmaceutical company focused on the development of novel therapies for patients with diseases of the central 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 and the USA, and is commercialized by Newron's partner Zambon. US WorldMeds 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. In addition to Xadago® for Parkinson's disease, Newron has a strong pipeline of promising treatments for rare disease patients at various stages of clinical development, including sarizotan for patients with Rett syndrome and ralfinamide for patients with specific rare pain indications. 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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