Minerva Neurosciences Announces Update on its New Drug Application (NDA) for Roluperidone for the Treatment of Negative Symptoms in Schizophrenia

May 10, 2023

FDA confirms acceptance of the filing of the NDA for roluperidone

Application has been granted a standard review

FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of February 26, 2024

BURLINGTON, Mass., May 10, 2023 (GLOBE NEWSWIRE) -- Minerva Neurosciences, Inc. (Nasdaq: NERV), a clinical-stage biopharmaceutical company focused on the development of therapies to treat central nervous system (CNS) disorders, today announced that on May 8, 2023, it received confirmation from the U.S. Food and Drug Administration (FDA) that the Company's New Drug Application (NDA) for roluperidone for the treatment of negative symptoms in patients with schizophrenia has been filed in accordance with the recent Appeal Granted letter dated April 27, 2023 and assigned a standard review classification. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of February 26, 2024. The FDA advised that it identified potential review issues that had been previously cited in the refuse-to-file decision letter, which included those discussed at the Type C meeting in March 2022.

"The filing of the NDA is an important event for Minerva and a step forward to our goal to treat those patients suffering negative symptoms of schizophrenia. If approved, we believe roluperidone could be an important new option to address the serious unmet need faced by that group of patients with schizophrenia whose negative symptoms are a major source of disability and adversely impact their daily quality of life," said Dr. Remy Luthringer, Executive Chairman and Chief Executive Officer of Minerva.

About Roluperidone
Roluperidone is an investigational drug that has been shown to block serotonin, sigma and α-adrenergic receptors that are all involved in the regulation of important brain functions, including mood, cognition, sleep, and anxiety.

Roluperidone was designed to avoid a direct blockade of dopaminergic receptors (the key pharmacological target for first- and second-generation antipsychotics), while maintaining blockade of a specific subtype of serotonin receptor called 5-HT_{2A} (an additional key target of second-generation antipsychotics) as well as additional pharmacological targets (sigma$_2$ and adrenergic-α_{1A}).

About Schizophrenia and Negative Symptoms
Schizophrenia is a chronic, severe, and debilitating type of mental illness characterized by distortions in thinking, perception, emotions, language, sense of self and behavior. Schizophrenia affects 20 million people worldwide. (World Health Organization).

Negative symptoms can cause individuals with schizophrenia to withdraw from society, become disinterested or unable to complete tasks or feel pleasure. Negative symptoms are characterized by five constructs: blunted affect, alogia, avolition, anhedonia, and asociality (Marder and Galderisi, 2017).

Negative symptoms are the main cause of the poor functional outcome of patients suffering from schizophrenia (Harvey et al., 2020) and may also be one of the main reasons ultra-high risk adolescents may develop full blown schizophrenia (Gomes and Grace, 2017). There are currently no treatments approved for negative symptoms of schizophrenia in the US.

Minerva believes that research continues to emerge indicating that there is a large subgroup of patients with schizophrenia who have moderate to severe primary negative symptoms and minimal positive symptoms (Galderisi 2021) and have a low risk of worsening of positive symptoms even in the absence of antipsychotic treatments (Harrow 2013; Moilanen 2016; Murray 2016; Wils 2017; Wunderink 2013; Landolt 2016).

About Minerva Neurosciences
Minerva Neurosciences, Inc. (Nasdaq: NERV) is a clinical-stage biopharmaceutical company focused on developing product candidates to treat central nervous system (CNS) diseases. Our goal is to transform the lives of patients with improved therapeutic options. Minerva's portfolio of compounds includes roluperidone (MIN-101), in clinical development for negative symptoms of schizophrenia, and MIN-301 for Parkinson's disease. For more information, please visit our website.

Forward-Looking Safe Harbor Statement
This press release contains forward-looking statements which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, reflect management's expectations as of the date of this press release, and involve certain risks and uncertainties. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements herein with respect to the regulatory progress and therapeutic potential of roluperidone for the treatment of negative symptoms in patients with schizophrenia. These forward-looking statements are based on our current expectations and may differ materially from actual results due to a variety of factors including, without limitation, whether the FDA will require additional trials or data which may significantly delay and put at risk our efforts to obtain regulatory approval; whether the FDA may meet expected review timelines for our NDA; whether roluperidone will be successfully marketed if approved; management's ability to successfully achieve its goals; our ability to raise additional capital to fund our operations and corporate objectives on terms acceptable to us; general economic conditions; and other factors that are described under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission on March 8, 2023. Copies of reports filed with

the SEC are posted on our website at www.minervaneurosciences.com. The forward-looking statements in this press release are based on information available to us as of the date hereof, and we expressly disclaim any obligation to update any forward-looking statements, except as required by law.

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