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Minerva Announces Completion of Bridging Study to Select Improved Formulation of MIN-101 for Use in Phase 3 Trial for the Treatment of Negative Symptoms in Patients With Schizophrenia

New formulation observed to improve safety margin while offering bioequivalent exposure to prior formulation

Company to proceed with initiation of Phase 3 trial on schedule in second half of 2017

CMC scale-up work for NDA preparation initiated

WALTHAM, Mass., June 22, 2017 (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 the successful completion of a bridging trial to select an improved, gastric-resistant (GR) formulation of MIN-101. The Company plans to use the selected formulation in its upcoming Phase 3 clinical trial, which remains on schedule for initiation in the second half of 2017, as well as for the potential future submission of a New Drug Application (NDA).

The key objective of the bridging study was to identify an improved formulation of MIN-101 that would:

- Maintain similar exposure of MIN-101 based on area under the curve (AUC) as that shown in the Phase 2b study, which achieved its primary endpoint of improving negative symptoms in patients with schizophrenia with both doses tested, 64 milligrams (mg) and 32 mg;
- Reduce maximum concentration (C_{max}) of an inactive metabolite of MIN-101 known as BFB-520, thereby reducing the potential for transient QTc increases observed in the Phase 2b study at the higher dose but not the lower dose;
- Eliminate food effect to allow the Phase 3 doses to be administered with or without food.

In summary, data from the bridging study of the selected new formulation demonstrated:

- Bioequivalent exposures of MIN-101 as measured by AUC;
- Reduction of C_{max} of BFB-520 by approximately 30% compared to the formulation used in Phase 2b;
- No observations of QTc prolongations throughout the study;
- No observable food effect, thus allowing administration of the drug with or without food without changing its pharmacokinetic properties;
- Confirmation of the overall safety and tolerability profile of MIN-101.

"The successful completion of this bridging study should allow us to initiate Phase 3 clinical testing with MIN-101 on schedule in the second half of 2017 with the same doses used in the Phase 2b trial, while potentially enhancing the safety profile of MIN-101," said Dr. Remy Luthringer, president and chief executive officer of Minerva. "The results from this study should also help to ensure the coherent interpretation of results from both the Phase 2b trial and the Phase 3 trial."

The Company plans to immediately initiate CMC scale-up processes that will form part of the NDA in the future. As exposures of MIN-101 in the Phase 2b study and the formulation to be used in the forthcoming Phase 3 are comparable, the Company believes data from both studies can be aggregated for the purposes of evaluating efficacy. The Company has also filed a patent application for the GR formulation, which is in addition to an already granted patent in the U.S. that provides protection until 2035. If granted, the additional patent could potentially extend exclusivity beyond 2035.

The bridging study was an open-label, randomized, 3-treatment sequence, 3-period study to evaluate the plasma pharmacokinetic profile of MIN-101 and its metabolites (BFB-520 and BFB-999) after single oral administration of three formulations of MIN-101 (2 GR formulations and the formulation used in Phase 2b) under fasted condition to healthy volunteers. Upon completion of the 3-period testing, the GR formulation that will be used in Phase 3 was then advanced and tested with food.

About MIN-101

MIN-101 is a drug candidate with equipotent affinities for sigma$_2$ and 5-hydroxytryptamine-2A (5-HT$_{2A}$) and lower affinity at α1-adrenergic receptors. MIN-101 has no direct dopaminergic post-synaptic blocking effects, known to be involved in some side effects like extrapyramidal symptoms, sedation, prolactin increases and weight gain.

The Phase 2b trial with MIN-101, announced in 2016 and presented at the annual meeting of the American College of Neuropsychopharmacology, met its primary endpoint of statistically significant improvement in negative symptoms as measured by the PANSS pentagonal structure model and in the higher dose showed statistically significant benefit in multiple secondary endpoints that included general psychopathology.

MIN-101 is designed to improve negative symptoms and cognitive impairment in schizophrenia, thereby increasing the patient's ability to function socially and vocationally while preventing the exacerbation of intermittent positive symptoms.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of products to treat CNS diseases. Minerva's proprietary compounds include: MIN-101, in clinical development for schizophrenia; MIN-117, in clinical development for major depressive disorder (MDD); MIN-202 (JNJ-42847922), in clinical development for insomnia and MDD; and MIN-301, in pre-clinical development for Parkinson's disease. Minerva's common stock is listed on the NASDAQ Global Market under the symbol "NERV." For more information, please visit www.minervaneurosciences.com.

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. Forward-looking statements include statements herein with respect to: the improved formulation of MIN-101 to be used in the planned Phase 3 trial of MIN-101; the timing and results of future clinical milestones with MIN-101, including the planned Phase 3 trial of MIN-101, the timing and scope of future clinical trials and results of clinical trials with this compound; the potential for a single Phase 3 trial with supportive Phase 2b results to support the basis for an NDA; the timing and outcomes of future interactions with U.S. and foreign regulatory bodies; our ability to successfully develop and commercialize MIN-101; the sufficiency of our current cash position to fund our operations; and management's ability to successfully achieve its goals. 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 MIN-101 will advance further in the clinical trials process and whether and when, if at all, it will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether the results of future clinical trials of MIN-101, if any, will be consistent with the results of past clinical trials; whether MIN-101 will be successfully marketed if approved; whether any of our therapeutic product discovery and development efforts will be successful; our ability to achieve the results contemplated by our co-development agreements; management's ability to successfully achieve its goals; our ability to raise additional capital to fund our operations on terms acceptable to us; and general economic conditions. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, filed with the Securities and Exchange Commission on May 4, 2017. 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 disclaim any obligation to update any forward-looking statements, except as required by law.

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