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02 February 2016 | News | By BioSpectrum Bureau

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NASDAQ-listed Minerva Neurosciences Inc, a clinical-stage biopharmaceutical company focused on the development of therapies for central nervous system (CNS) disorders, has derived top line results from a phase I clinical trial conducted in Japan with MIN-202 (JNJ-42847922), a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV. MIN-202 is an innovative molecule acting as a selective orexin-2 receptor antagonist for the treatment of primary and secondary insomnia.

It was observed that single dose morning administration of MIN-202 was well tolerated at all three dose levels tested, 5 milligrams (mg), 20 mg and 40 mg. The observed plasma pharmacokinetic features were comparable to those observed in previous studies carried out in healthy non-Asian study participants. No clinically relevant safety concerns were observed based on the assessment of multiple safety endpoints.

Somnolence was the most frequently reported adverse event at the two higher doses, an expected finding as this compound is being developed as a treatment for patients suffering from insomnia disorder and as adjunctive treatment to concomitant antidepressant drug therapy in major depressive disorder (MDD).

This trial was a single center, double blind, placebo-controlled randomized single ascending dose study to investigate the safety, tolerability and pharmacokinetics of MIN-202 in 24 healthy Japanese adult male study participants.

Minerva entered into a co-development and license agreement with Janssen in February 2014 covering MIN-202 and any other orexin-2 compounds. Under this agreement, Minerva has an exclusive license to these compounds in the European Union, Switzerland, Liechtenstein, Iceland and Norway. Janssen has exclusive rights to these compounds worldwide outside of these territories.