NEWS

Nevrargenics Announces Successful Scientific Advice Meeting with the MHRA (the U.K.'s regulatory agency equivalent to the US FDA)

Date
20 November 2023

Nevrargenics Ltd, the UK biotech company focusing on developing novel drugs to treat neurodegenerative and other diseases, is pleased to announce that it had a scientific advice meeting with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) to discuss Nevrargenics' Motor Neurone Disease drug candidate, NVG0645. The meeting considered non-clinical and clinical data and justifications relevant to the commencement of human trials with NVG0645, including the planned preclinical evaluations and the protocol for the Combined Phase 1/2 open label multiple ascending escalating dose, basket design efficacy and tolerability study. The MHRA concluded that the preclinical and protocol design was sufficient for the Clinical Trial Application (CTA) submission. The MHRA meeting also provided an opportunity for the Company to outline its development plans for NVG0645.

NVG0645 is a novel Retinoic Acid Receptor-Modulator (RAR-M) ligand. NVG0645 is a product of a rational design process that has focussed on optimising the genomic and non-genomic activity of the retinoids. There is increasing evidence that retinoids and retinoic acid receptors play a major role in many neurodegenerative diseases.

Nevrargenics anticipates it will submit a CTA to the MHRA, for a combined regulatory and ethical review, in which formal authorisation will be sought from the MHRA and its UK ethics committee, to conduct the proposed clinical trial. This will be conditional upon a satisfactory review and evaluation of the information submitted by Nevrargenics in the CTA. Submission of the CTA application is planned for early 2024.

Contingent upon MHRA approval of the CTA, Nevrargenics expects to conduct its Phase 1/2 clinical trial in 2024. Following the successful completion of the trial, Nevrargenics plans to move forward with trials in patients with MND in a Phase 2/3 study to gather data necessary for market authorisation. Nevrargenics plans to bring to the market effective disease modifying therapeutics in MND by combining its lead drug candidate NVG0645 with an early prognostic disease related biomarker assay (Neurofilament Light Chain NfL).

Professor Andy Whiting, Nevrargenics' CEO, said: *"We are pleased with the decision of the MHRA to agree that we are in a green light position to submit a CTA. The Company is now well positioned to advance towards its clinical trial programme that is essential to market authorisation"*.

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Nevrargenics Ltd is a UK-based biotech company specialising in the discovery and development of novel medicines for the treatment of neurodegenerative disease, such as Alzheimer's, Parkinson's, Multiple Sclerosis, Amyotrophic Lateral Sclerosis and other neurological and psychiatric diseases.