MinervaX appoints Lidia Oostvogels as Chief Medical Officer and provides clinical and regulatory update on its novel GBS vaccine

- *Newly appointed CMO with more than 25 years' experience in vaccine development*
- *Fast Track status granted by US Food and Drug Administration*
- *Completion of enrolment of its 2nd phase II clinical trial in pregnant women*

Copenhagen, Denmark, 5 January 2023 – MinervaX ApS, a privately held Danish biotechnology company developing a novel vaccine against Group B Streptococcus (GBS), today announces the appointment of Lidia Oostvogels as Chief Medical Officer and provides an update on its novel GBS vaccine.

Lidia Oostvogels brings a wealth of experience in vaccine development with more than 25 years' experience in clinical development. Prior to joining MinervaX, she was Senior Vice President, Area Head, Infectious Diseases and Senior Vice President, Clinical Development, for Prophylactic Vaccines CureVac AG. Oostvogels worked for GSK plc for more than 12 years, where she was Director of Vaccine Discovery and Development, Clinical, focused on Influenza and Zoster. Prior to GSK, she spent nine years Boehringer Ingelheim in a clinical development role. She gained her medical doctor qualification from Ghent University in Belgium. Oostvogels' experience will be instrumental as MinervaX progresses its GBS vaccine towards phase III clinical development.

MinervaX completed enrolment of its 2nd phase II clinical trial of its novel GBS vaccine in pregnant women across Denmark, the UK and South Africa. The randomized, multicenter trial will evaluate the safety, tolerability and immunogenicity of one and two doses of its GBS vaccine at different dosing regimens in healthy pregnant women. Details of MinervaX's clinical trials can be found at clinicaltrials.gov under the identifiers NCT04596878, NCT05154578 and NCT05005247.

MinervaX's GBS vaccine has been granted Fast Track regulatory status by the US Food and Drug Administration. The process is designed to facilitate the development of investigational treatments that demonstrate the potential to address unmet medical needs in serious or life-threatening conditions. Programs with Fast Track designation can benefit from early and frequent communication with the FDA throughout the entire drug development and review process and marketing application.

This follows the European Medicines Agency's decision to award Priority Medicine (PRIME) status to the vaccine in September, an initiative that optimizes development and evaluation of medicines targeting an unmet medical need.

Per Fischer, Chief Executive Officer of MinervaX, said: "I am delighted to welcome Lidia Oostvogels to the leadership team. Her extensive track record in vaccine development will be invaluable as we continue to make significant progress with our novel GBS vaccine. We are looking forward to an exciting and pivotal year of development milestones in 2023 as we continue to advance our vaccine for the prevention of the large unmet medical need, Group B Streptococcal infections."

Lidia Oostvogels, Chief Medical Officer of MinervaX, said: "I am hugely excited to join MinervaX and look forward to contributing to the further development of its GBS vaccine. There is a major need for more options to prevent this disease and I am delighted to be working with the experienced team at MinervaX to bring this important vaccine to populations at risk."

ENDS

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Notes to Editors:

About MinervaX
MinervaX is a Danish biotechnology company, established in 2010 to develop a prophylactic vaccine against Group B Streptococcus (GBS), based on research from Lund University. MinervaX is developing a GBS vaccine for maternal immunization, likely to have superior characteristics compared with other GBS vaccine candidates in development. The latter are based on traditional capsular polysaccharide (CPS) conjugate technology. By contrast, MinervaX's vaccine is a protein-only vaccine based on fusions of highly immunogenic and protective protein domains from selected surface proteins of GBS (the Alpha-like protein family). Given the broad distribution of proteins contained in the vaccine on GBS strains globally, it is expected that MinervaX's vaccine will confer protection against virtually 100% of all GBS isolates. www.minervax.com

About Group B Streptococcus (GBS)
GBS is responsible for nearly 50% of all life-threatening infections in newborns. At any given time, some 15-25% of women are spontaneously colonized with GBS, and they run the risk of transmitting the bacteria to their child in the womb, during birth and/or during the first months of life. GBS colonization may lead to late abortions, premature delivery, or stillbirth and, in the newborn child, may result in sepsis, pneumonia or meningitis, all of which carry a significant risk of severe morbidity, long- term disability or death.
Currently, the only preventative strategy available involves the use of intravenously delivered prophylactic antibiotics which do not comprehensively prevent GBS infection in utero or protect against late-onset infection in newborns. Not only is this approach expensive and logistically challenging, it fails to cover all, including the most severe cases in the US and Europe, and is rarely available in resource- limited settings.

The development of a GBS vaccine is also endorsed by Group B Strep Support and Group B Strep International, and GBS has been prioritized by a number of public health organizations. Both increased uptake of immunization among pregnant women and greater awareness of the implications of GBS suggest that a safe and effective vaccine targeting GBS would be well suited to address this unmet need.