MinervaX Provides Clinical Update on its Maternal GBS Vaccine

- *Completed enrolment of all pregnant women in a Phase 2 study in South Africa and Uganda*
- *Following clearance from the US FDA, Danish Medicines Agency and UK MRHA, started enrolment of pregnant women in a Phase 2 study in Denmark and the UK*
- *Completed enrolment of a Phase 1 booster study in the UK*

Copenhagen, Denmark, 14 February 2022 – MinervaX, a privately held Danish biotechnology company developing a novel vaccine against Group B Streptococcus (GBS), today announces significant clinical progress on its maternal GBS vaccine.

MinervaX is developing a maternal vaccine for the prevention of adverse pregnancy outcomes and life-threating infections caused by Group B streptococcus . GBS is responsible for nearly half of all life-threatening infections in newborns during the first 3 months of life as well as a portion of late-term abortions, premature deliveries, or stillbirths during pregnancy. As current preventive strategies are insufficient, there is an urgent need for a maternal vaccine to reduce the burden of GBS globally.. MinervaX's maternal GBS vaccine is based on adjuvanted protein antigens covering close to 100% of clinical GBS isolates.

MinervaX announces today that the enrolment of all 200 pregnant women in a Phase 2 study in South Africa and Uganda has been completed. Furthermore, all babies in the South Africa study population have been delivered and no product related serious adverse events have been reported to date. The study is sponsored by the European Developing Countries Trial Partnership and is listed on clinicaltrials.gov under NCT04596878.

Furthermore, MinervaX announces today that it has started enrolment of 270 pregnant women in a Phase 2 study in Denmark and the United Kingdom. The study is run under an open US FDA IND and is listed on clinicaltrials.gov under NCT05154578.

Finally, MinervaX has also completed dosing healthy adult women previously receiving the company's GBS vaccine in a Phase 1 booster study in the United Kingdom. The study is listed on clinicaltrials.gov under NCT05005247.

Commenting on the announcement, Per Fischer, Chief Executive Officer of MinervaX, said: "We are very pleased to have completed enrolment of all subjects in our Phase 2 study in Africa, and to have received positive feedback from the US FDA resulting in IND clearance and enrolment for the Phase 2 in Denmark and the UK, and to have completed dosing of the Phase 1 booster study in the UK. The vaccine has, to date, demonstrated high immune responses even in individuals with low levels of preexisting immunity to GBS who are most at risk of invasive disease. The vaccine has also demonstrated a very promising safety profile in both non-pregnant and pregnant women in past and ongoing clinical studies. The progress represents a significant advancement towards initiating Phase 3 clinical studies."

Gerd Zettlmeissl, Chairman of MinervaX Board of Directors said: "I would also like to congratulate, on behalf of my Board colleagues, the MinervaX team for this outstanding progress towards a potential future GBS vaccine. We are convinced that our vaccine candidate could provide a major global contribution to the health of pregnant women and newborns."

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Enquiries

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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.
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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 does 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.