MinervaX Announces Completion of Enrolment in Phase I Clinical Vaccine Trial as it Addresses the Global Burden of Group B Streptococcus in Older Adults

- *Full enrolment and dosing commenced with its novel, prophylactic GBS vaccine in both healthy older adults and older adult population with co-morbidities*

- *First immunological read-outs are anticipated in Q4, 2023*

Copenhagen, Denmark, 27 June 2023 – MinervaX ApS, a privately held Danish biotechnology company developing a novel, prophylactic vaccine against Group B Streptococcus (GBS), has today announced the completion of enrolment and initial dosing in its Phase 1, clinical vaccine trial in older adults. The trial is taking place at CEVAC (Centre for Vaccinology), Ghent University, Belgium.

GBS is most commonly associated with pregnant women and newborn babies. However, invasive GBS disease infections in the elderly population are continuously increasing. These can have devastating consequences – particularly if the person has a serious health condition such as diabetes mellitus, cancer, or a suppressed immune system.

To tackle this issue MinervaX has expanded the development pipeline of its novel GBS vaccine to include older adults, addressing the global burden and urgent need for the development of a vaccine to prevent and reduce deaths associated with GBS across the population. In pregnant women. MinervaX is currently progressing two Phase II clinical vaccine trials for the prevention of life-threatening infections in newborns. The trials are demonstrating that the vaccine has an acceptable safety profile, is highly immunogenic and gives rise to functionally active antibodies.

In April 2023, the Company commenced enrolment for its Phase I clinical vaccine trial in older adults. Enrolment and administration of the first dose to all participants is now complete. Details of MinervaX's ongoing clinical trials can be found at clinicaltrials.gov under the identifiers NCT04596878, NCT05154578 and NCT05782179.

The Phase I vaccine trial will investigate the vaccine's safety and immunogenicity in both healthy older adults and older adults with underlying medical conditions, i.e., diabetes and/or obesity, in an age range of 55 to 75. Two dose levels are being investigated: a lower dose level of 50 µg of fusion protein, which is also used in MinervaX's two Phase II clinical trials in pregnant women, as well as a higher dose level of 125 µg of fusion protein. In addition, all older adult participants will receive three doses of the vaccine. The administration of one more jab than in the Phase II clinical vaccine trial in pregnant women, as well as the investigation of a higher dose level, takes into account that older adults – especially those with comorbidities, tend to exhibit weaker immune responses. All participants have now received one dose and further dosing is progressing smoothly with first immunological read-outs anticipated in Q4, 2023.

Lidia Oostvogels, Chief Medical Officer of MinervaX, said: "The smooth completion of enrolment and dose escalation provides an indication of the overall acceptable reactogenicity profile of our novel GBS vaccine and replicates the findings in our two ongoing Phase II trials in pregnant women. This allows us to accelerate the development of this potentially lifesaving vaccine to address the global unmet medical need. I would like to thank the participants of the trial and the team at CEVAC who is being instrumental throughout the trial, and I look forward to providing initial results in Q4, 2023."

Prof. Isabel Leroux-Roels, Principal Investigator at CEVAC, commented: "We at CEVAC are very pleased to be contributing to this Phase I trial against this severe disease. Recruiting the many volunteers for this hugely

important trial is a step forward to demonstrate that MinervaX's novel vaccine works. We are very grateful to all the volunteers involved in the trial and will be following up with each participant accordingly. We are excited to see the data reported later this year."

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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, and now also for vaccination of older adults, 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)

Streptococcus agalactiae or Lancefield's Group B Streptococcus (GBS) is a common commensal in humans, approximately 25% of all adults will be colonised with GBS at any given time. Invasive GBS disease is normally associated with infection in pregnant women and new-born babies; however, invasive GBS disease in adults has been increasing over the last 40 years. The older adult population (>65 years of age) and adults with underlying chronic health conditions (diabetes mellitus, cancer, immune suppression, obesity) are at particular risk of invasive GBS disease.

Group B Streptococcus disease in non-pregnant adults causes secondary and primary bacteraemia, septic arthritis, endocarditis, prosthetic joint infection, and necrotising myositis and fasciitis.

It is apparent that outside of pregnancy and the neonatal period, GBS infection results in high morbidity and mortality rates. There is no preventative treatment, cases are managed with antibiotics when an infection is diagnosed. There is a clear unmet medical need for a preventative vaccine that could provide protection to all adults but particularly to the older adult population or those at risk of infection due to underlying medical or demographic conditions. In addition, the incidence is increasing and will probably continue to increase with an increasing older adult population and an increase in the prevalence of obesity and type 2 diabetes around the world.