

MinervaX Commences First Phase 1 Clinical Study of Novel GBS Vaccine in Older Adults

- *Expands development of novel GBS vaccine in older adult population*
- *Targeting significant and growing unmet medical need of GBS infection*

Copenhagen, Denmark, 17 April 2023 – MinervaX ApS, a privately held Danish biotechnology company developing a novel vaccine against Group B Streptococcus (GBS), announces the first phase 1 clinical study in older adults of its novel GBS vaccine, at CEVAC (Centre for Vaccinology) in Ghent, Belgium.

GBS is a global unmet medical burden and can cause serious illness in people of all ages, worldwide. It 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. There is currently no vaccine available.

The clinical study will investigate the safety and immunogenicity of two dose levels on the MinervaX novel GBS vaccine in an older adult population from 55 to 75 years of age, with and without underlying medical conditions. The trial will investigate the safety and immune response to the dose level currently under development for use in pregnant women (50 µg of each fusion protein) and a higher dose of 125 µg of each fusion protein. Since older adults, certainly those with comorbidities, often mount a less strong immune response than a younger population, up to three doses will be investigated in this trial [clinicaltrials.gov under the identifier NCT05782179].

MinervaX has completed enrolment and dosing of its 2nd phase II clinical trial of its novel GBS vaccine in pregnant women across Denmark, the UK and South Africa. Details of MinervaX's ongoing clinical trials can be found at clinicaltrials.gov under the identifiers NCT04596878 and NCT05154578.

Lidia Oostvogels, Chief Medical Officer of MinervaX, said: “Expanding the development of our GBS vaccine for use in an older adult population, including people with increased risk for GBS due to underlying comorbidities, is a very important step for MinervaX in the battle against this pathogen. This builds on our efforts and experience to develop a product to provide protection to the most vulnerable populations, i.e., neonates in our maternal immunization program, and now older adults including those with certain comorbid conditions.”

Prof. Isabel Leroux-Roels, Principal Investigator at CEVAC, commented: “GBS is known to cause potentially life-threatening infections in Older Adults and currently there is no vaccine available to prevent this. All the team at CEVAC are very happy to contribute to the development of this vaccine for this high-risk population.”

Prof. Paul Heath, Director of the St George's Vaccine Institute, London and Lead Investigator of MinervaX's Phase IIb study across Denmark, the UK and South Africa, remarked: “Streptococcus agalactiae is a common commensal in humans and approximately 25% of all adults will be colonised with GBS in the gastrointestinal or genitourinary tracts at any given time. We are aware of the considerable global burden of this invasive GBS disease in babies and pregnant women and of the urgent need for a vaccine to prevent this. More recently, we have become aware of the burden of GBS in non-pregnant adults, particularly in older adults, and those with underlying health conditions such as diabetes mellitus. There is no current mechanism for preventing GBS disease in this growing population, and there is a well recognised morbidity and mortality. The need for a vaccine for this group of people is therefore urgent and the commencement of GBS vaccine trials in this population is therefore an important and welcome development.”

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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.