

## MinervaX and Wacker Biotech Announce Manufacturing Collaboration for Prophylactic Vaccine Targeting Group B Streptococcus

- *MinervaX scaling up supply of novel GBS vaccine, ahead of phase III studies*
- *Wacker Biotech to manufacture active vaccine protein ingredients and prepare for commercial supply after regulatory approval*
- *Vaccine to address the unmet medical burden of GBS, both by maternal vaccination to prevent adverse pregnancy outcomes and life-threatening infections in infants and by vaccination of older/at risk adults*

**Copenhagen/Munich, September 17, 2024** – MinervaX ApS, a privately held Danish biotechnology company developing a novel, prophylactic vaccine against Group B Streptococcus (GBS) and Wacker Biotech, a contract development and manufacturing organization (CDMO), wholly owned subsidiary of Wacker Chemie AG, today announce a collaboration to manufacture MinervaX's active protein ingredients of its GBS vaccine.

GBS is responsible for nearly 50 percent of all life-threatening infections in newborns. At any given time, some 15-25 percent of the population, including pregnant people are spontaneously colonized with GBS, and during pregnancy 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. With no general implemented and fully protective preventative treatment available for GBS, this underlines the unmet medical need of developing and providing a vaccine to prevent adverse pregnancy outcomes and life-threatening infections in infants caused by GBS. Furthermore, older adults and adults with certain co-morbidities such as diabetes or obesity are also at an increased risk of severe GBS infections and form a second population which would benefit from a prophylactic vaccine against this potentially fatal disease.

MinervaX's lead vaccine candidate, is a novel protein-only vaccine, based on fusions of highly immunogenic and proactive protein domains from selected surface proteins of GBS. The company is strongly committed and dedicated to advancing its novel vaccine and has successfully completed two Phase II clinical trials of its maternal vaccine against GBS and is in preparation to commence Phase III clinical trials in this indication. Data from MinervaX's GBS vaccine is very positive, demonstrating an acceptable safety profile in pregnant people and their infants, with high immunogenicity, leading to functionally active antibodies, with the potential for broad coverage and protection, alleviating the need for excessive use of antibiotics.

Wacker Biotech will manufacture the active ingredients of MinervaX's novel vaccine candidate, alongside performing the technology transfer, process validation and process characterization activities for later commercial manufacturing. Subsequently, Wacker Biotech will perform all key functions critical to ensure stable commercial supply at its site in Amsterdam, The Netherlands.

**Per Fischer, CEO of MinervaX, said:** "GBS can be life-threatening for newborn babies and is linked to over half a million preterm births annually. Following the EUR 54 million financing last year, our team is advancing the development of our novel prophylactic vaccine against GBS for the benefit of all populations at risk, worldwide. Wacker Biotech is a robust manufacturing partner with a strong track record in late clinical and commercial supply and we look forward to collaborating with the team ahead of commencing Phase III studies."



**Ronald Eulenberger, Managing Director of Wacker Biotech B.V. in Amsterdam, stated:** “With our strong background in E. coli processes, process characterization, and process validation experiences, we at Wacker Biotech are perfectly suited to support MinervaX with its ongoing program for the prevention of invasive GBS disease.”

Details of MinervaX’s completed Phase II clinical trials in pregnant people can be found at <https://clinicaltrials.gov/> under the identifiers NCT04596878 and NCT05154578. In addition to pregnant people, MinervaX is also pursuing Phase I development of its novel GBS vaccine in older adults, under identifier NCT05782179.

**ENDS**

**For further information please contact:**

**MinervaX**

Per Fischer | Chief Executive Officer  
Email: [info@minervax.com](mailto:info@minervax.com)

**Optimum Strategic Communications**

Mary Clark / Zoe Bolt / Vareen Outhonesack  
Email: [minervax@optimumcomms.com](mailto:minervax@optimumcomms.com)  
Tel: +44 (0) 203 882 9621

**Wacker Chemie AG**

Dr. Karsten Werth  
Email: [karsten.werth@wacker.com](mailto:karsten.werth@wacker.com)  
Tel: +49 89 (0) 6279-1573

**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 also for vaccination of older/at risk adults. Phase II clinical data from its maternal vaccination program suggest a high efficacy, based on the preliminary Correlate of Protection data from a natural history study. MinervaX’s GBS 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 (AlpN). Given the broad distribution of proteins contained in the vaccine on GBS strains globally, it is expected that MinervaX’s GBS vaccine will confer protection against virtually 100% of all GBS isolates.

[www.minervax.com](http://www.minervax.com)

**About Wacker Biotech**

Wacker Biotech is a full-service contract manufacturer of therapeutic proteins, live biopharmaceutical products (LBPs), plasmid DNA (pDNA), messenger ribonucleic acid (mRNA) and vaccines based on microbial systems. Wacker Biotech’s portfolio extends from strain/process development and analytical testing through to production for clinical and commercial applications. Wacker Biotech operates three GMP-compliant, FDA- and EMA-certified production plants at its Jena and Halle sites in Germany and in Amsterdam in the Netherlands. In addition, Wacker Biotech has had a plant in San Diego (Wacker Biotech US Inc.) since



February 2021. Wacker Biotech GmbH, Wacker Biotech B.V. and Wacker Biotech US Inc. are wholly owned subsidiaries of Munich-based Wacker Chemie AG.