MinervaX provides clinical and leadership update

- *Completed enrolment of 150 pregnant women in a Phase 2 study in South Africa and dosing started in an additional 50 pregnant women in Uganda, as part of same study*
- *Phase 1 booster study started in the United Kingdom*
- *Regulatory approval obtained from Danish Medicines Agency and UK MHRA for the initiation of a Phase 2 study in pregnant women, in Denmark and United Kingdom*
- *Vaccine Expert and Biotech Entrepreneur Gerd Zettlmeissl appointed new Chairman of the Board of Directors*
- *Leading vaccine industry veterans join Scientific Advisory Board*

Copenhagen, Denmark, 7 October 2021 – MinervaX, a privately held Danish biotechnology company developing a novel vaccine against Group B Streptococcus (GBS), today announces clinical progress on its maternal GBS vaccine as well as multiple additions to its leadership teams.

MinervaX is developing a maternal vaccine for the prevention of adverse pregnancy outcomes and life-threating infections caused by Group B streptococcus (GBS). 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. Current preventative strategy is insufficient, and great medical needs exist, which may be addressed by a maternal GBS vaccine. MinervaX's maternal GBS vaccine is based on adjuvanted proteins antigens covering close to 100% of clinical GBS isolates.

Clinical Update:

MinervaX announces today completed enrolment of 150 pregnant women in a Phase 2 study in South Africa, sponsored by the European Developing Countries Trial Partnership. Dosing of an additional 50 pregnant women in the same study has started in Uganda. The study is listed on clinicaltrials.gov under NCT04596878.

MinervaX has also started 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.

Finally, MinervaX has received regulatory approval from the Danish Medicines Agency and UK MHRA to initiate a Phase 2 study in 270 pregnant women in Denmark and the United Kingdom.

Corporate Update:

Gerd Zettlmeissl joins MinervaX as new Chairman of the Board of Directors. Gerd brings a wealth of experience from the vaccine and broader biotech industry, including several successful biotech exits.

MinervaX announces the addition of Ralf Clemens, Jean-Paul Prieels, Peter Patriarca, Jean Smal, Clement Lewin, and Inca Kusters as new members of its Scientific Advisory Board (SAB).

Commenting on the announcement, Per Fischer, Chief Executive Officer of MinervaX, said: "We are very pleased with the progress in clinical development of our maternal GBS vaccine since closing our last financing round in December 2020. 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"

"We are also very pleased to welcome Gerd Zettlmeissl as new Chairman of the Board of Directors as well as the members of the expanded Scientific Advisory Board. The additions bring valuable business and development expertise to the Company."

Gerd Zettlmeissl, Chairman of MinervaX Board of Directors said: "I am very excited about the outstanding progress MinervaX is making in the development of one of the globally most promising GBS vaccine candidates and about the opportunity to support the company towards future success."

Ralf Clemens, MinervaX Scientific Advisory Board member said: "Group B Streptococcus is a leading cause of neonatal sepsis and despite efforts since many years by academia and industry to develop a prophylactic vaccine progress so far is limited. The MinervaX phase 2 candidate has shown very promising immunogenicity data and an excellent safety profile, and the company has a clear plan of path to licensure. The studies in Uganda, UK and Denmark are a critical piece of that plan."

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Enquiries

For more information on MinervaX, please contact:

Per Fischer, CEO: pbf@minervax.com

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 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.

About Gerd Zettlmeissl, Chairman

Gerd has more than 30 years of R&D and General Management leadership experience in the biopharmaceutical industry. Since 2012 he served on the Board of Directors of several non-profit organizations and biotech companies. Until 2015 he was chairman of GlycoVaxyn (Switzerland) sold to GSK, and until 2020 chairman of Themis (Austria) sold to MSD. He is the former CEO of the Austria-based Intercell (now Valneva). Prior to that, he was Managing Director of Chiron-Behring (Germany) and held senior management roles in biopharmaceutical R&D and Technical Operations at Chiron (USA) and Behringwerke (Germany). In 2010, he was named Vaccine Biotech CEO of the Year at the World Vaccine Congress. Gerd Zettlmeissl holds a doctoral degree in biochemistry of the University of Regensburg and did a post-doctoral fellowship at the Institut Pasteur Paris in virology. Current key positions: Chairman of the Supervisory Board for Medigene (Germany) & Hilleman Laboratories (Singapore) and Member of the Strategic and Scientific Advisory Board for Biological E (India).

About Ralf Clemens, SAB

Ralf Clemens, MD PhD, is a long-time leader in vaccine industry and academia. He is currently serving as Advisor to the Bill & Melinda Gates Foundation and is Member/ Chair of various scientific and management boards including IVI, GHIT, CEPI as well as Clover Biopharmaceuticals, China, Curevac AG, Germany, and

Valneva SE, France. Prior to this he was Head Global Vaccines Development at GSK, Novartis and Takeda Vaccines. At GSK Vaccines he was additionally in charge of developing country business strategies and technology transfers to developing country manufacturers. During his almost 30 years in vaccine industry, he developed and brought to licensure over 25 different vaccines. Ralf graduated in medicine from the University of Mainz, Germany, and he holds an executive degree in Management from the Wharton Business School. Ralf has more than 180 publications and given more than 250 scientific presentations mainly on vaccines, immunization and pharmaceutical development.

About Jean-Paul Prieels, SAB

Jean-Paul Prieels holds a Ph.D. in biochemistry from Université Libre de Bruxelles in Belgium. He started his industrial career at Petrofina in 1983 as biotechnology manager and joined GSK Vaccines in 1987. His responsibilities gradually expanded to lead the vaccine preclinical R&D development activities as Senior Vice President of Research and Development at GlaxoSmithKline Biologicals in Rixensart, Belgium, until 2011. His career spans from basic research to applied research and product development. He was instrumental in the development of several commercially available vaccines, including Rotarix, Cervarix, Synflorix and Shingrix. Today, he is director at Quantoom Bioscience, NCardia, Nouscom, Leukocare, Bone Therapeutics and PDC*Line Pharma. He is a member of the scientific advisory board of CureVac, Imcyse, and Vaximm, and a member of the European Vaccine Initiative Board of Stakeholders.

About Peter Patriarca, SAB

Peter A. Patriarca, MD, is the Principal of Immuno-Vax, LLC, and a senior affiliate consultant with the Biologics Consulting Group, Inc. (Alexandria, Virginia). He has provided technical and regulatory consulting services for all phases of vaccine and drug development for the past 14 years, including approximately 400 IND submissions and 12 successful Biologics License Applications (BLAs) or NDAs. Prior to consulting, Dr. Patriarca was Corporate Head and Vice President, Worldwide Regulatory Affairs and Pharmacovigilance at MedImmune, Inc. (2001-2005) and also served as Medical Officer in the U.S. Public Health Service at the Centers for Disease Control and Prevention (1980-1992) and the US Food and Drug Administration (1993-2001). At FDA, Dr. Patriarca served, among other positions, as Director of the Division of Viral Products in the Office of Vaccines Research and Review (OVRR), CBER. In that capacity, he was responsible for laboratory-based research and review activities of more than 100 scientific staff in eight laboratories and was intimately involved with regulatory decisions and policy affecting vaccine development and licensure. While at CDC, Dr. Patriarca was assigned to the National Immunization Program, where, among other positions, he served as the Chief Medical Epidemiologist in the Influenza Division and the first head of CDC's program in support of the Global Poliomyelitis Eradication Initiative. He has authored more than 100 peer-review publications and has served on multiple scientific advisory bodies for CDC, WHO, the Bill and Melinda Gates Foundation, the American Academy of Pediatrics, the National Academy of Sciences, and numerous pharmaceutical companies.

Jean Smal, SAB

Jean Smal is a Senior Consultant with global experience in the R&D and Manufacturing Vaccine Industry. He is currently supporting the vaccine projects of various companies and serves as a member of the WHO Advisory Panel for the Polio Eradication Program. He is chairman or independent board member of several biotech companies. He has previously served as Vice-President, Head of New Product Development at GSK Vaccines, covering development and scale-up of manufacturing processes, analytical methods, manufacturing for Phase I-III clinical trials, development strategy and organizational development. In this role, he directly contributed to the development and the launch of 12 new vaccines from 1998 to 2016, totaling over €4bn in sales in 2020. Prior to joining GSK, Jean served in roles from Project Leader to General

Manager of Eurogentec CDMO Division, a Company offering development and GMP services for biopharmaceutical products. Jean Smal holds a degree in Bio Engineering, a PhD in Biochemistry and Prost-graduate degree in Business Management. He has published over 50 peer reviewed scientific papers/communications in the biochemical field.

About Clement Lewin, SAB

Clement Lewin, PhD MBA, is a Principal at CSL Vaccine Consulting with expertise in medical affairs, policy and strategy. Clem has 25 years of experience from vaccine development at Merck, Chiron, Acambis, Novartis and Sanofi Pasteur. He served as VP Strategic Planning & Business Intelligence and then VP Government Affairs & Immunization Policy for the US at Chiron. He served as Head of Government Affairs, Strategic Planning and Marketing at Acambis, helping to secure large government contracts for a small-pox vaccine. He headed Medical Affairs & Immunization Policy for North America, at Novartis Vaccines, where he was responsible for Medical Affairs activities and the CDC and National Vaccine Program Office helping launch several vaccines and manage the response to the 2009 pandemic. He served as AVP of R&D Strategy and headed the BARDA Office and NV Stakeholder Engagement for Sanofi Pasteur, securing and managing over $2 billion in BARDA funding for pandemic influenza and COVID-19 vaccines development. Clem obtained his BSc and PhD from the University of London, and an MBA with distinction from Cornell University. He served as the Biotechnology Innovation Organization liaison to the Advisory Committee on Immunization Practices from 2004 to 2014, and served on the National Vaccine Advisory Committee from 2009-2012. He has published over 50 papers in peer reviewed journals.

About Inca Kusters, SAB

Inca C. Kusters, Ph.D. has been at Sanofi Pasteur for more than 20 years and currently heads External Research and Development for Sanofi Pasteur in Europe. This group is responsible for evaluating the scientific value of external vaccine opportunities. Prior to her current role, Inca was responsible for several vaccine projects including pandemic H1N1 vaccine development in 2009 and the SARS-CoV1 vaccine development in 2003. She is a guest lecturer at several French universities (Lyon I, Paris IX, Paris XIII).