MINERVAX ANNOUNCES POSITIVE RESULTS FROM PHASE I IN 240 HEALTHY ADULT WOMEN WITH ITS INNOVATIVE GROUP B STREPTOCOCCAL (GBS) VACCINE TO PREVENT LIFE-THREATENING INFECTIONS IN NEWBORNS

Copenhagen, January 5, 2017 - MinervaX, a privately held Danish biotech company, announces today positive results from a Phase I trial in 240 healthy adult women with its protein-only GBS vaccine, targeting pregnant women for the prevention of life-threatening infections in newborns.

GBS is responsible for 50% of life-threatening infections in newborns and affects 0.5-3 in 1,000 babies, depending on the geographical region. 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 infection in the unborn child may lead to premature delivery or stillbirth, and GBS infection 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. Annually, GBS is responsible for some 8,000 infections in newborns, 800 deaths and 1,000 life-long disabilities in Europe and the US.

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 almost 100% of GBS isolates.

The Phase I trial enrolled 240 healthy adult women in two Parts: Part A, a dose-escalation trial in 60 women and Part B, a dose-confirmation trial in 180 women. Primary endpoint was assessed 3 months' post first dose. The vaccine has proven to be well tolerated and highly immunogenic. The safety profile of the vaccine was similar to that of other protein vaccines administered with Alhydrogel® adjuvant. Adverse events were mainly injection site events (pain, erythema, bruising and reaction), which occurred following 40% of injections and 96% were assessed to be mild, 4% as moderate and none severe. No drug-related SAEs were observed.

The vaccine was found to be immunogenic, at all doses tested and appeared to reach a plateau at two doses of 50 µg given 4 weeks apart. All subjects who received that dose regimen, were found to seroconvert after administration of the vaccine, as assessed by a >2.5-fold increase over pre-immune levels at day 85 post first dose, with arithmetic mean fold-increase of 279 for this dose group at day 85. Arithmetic mean fold-increase was already >100 just 15 days after first dose. Geometric mean titers reached 19 µg/ml 14 days after the second dose, and stayed at 17 µg/ml until day 85. Analysis of individual responses revealed that approximately 50% of subjects

reached the maximum antibody titer already after the first dose, whereas the remaining 50% benefitted from a second dose. However, the latter group still reached in excess of 30-fold increases over pre-immune levels already after the first dose. The difference between the groups was in part related to higher levels of pre-existing immunity and likely the presence of B-cell memory from previous natural exposure to GBS. The antibody responses obtained in the immunized individuals were highly functional, being capable of inducing opsonophagocytic killing of and inhibiting epithelial cell invasion by both laboratory and clinical isolates of GBS. Geometric mean OPA titers ranged from 50-500, and inhibition of epithelial cell invasion was seen at antibody concentrations as low as 25 ng/ml.

The antibodies induced by the vaccine were predominantly IgG1 and IgA. The IgG1 subtype is actively transferred across the placenta to the fetus, such that the fetus may have up to to 125% of the concentration of the mother, as opposed to the IgG2 subtype, traditionally induced by Capsular Polysaccharide (CPS) based vaccines, which are only passively transferred across the placenta and achieves 70% of the concentration of the mother). The presence of high levels of IgA is also very encouraging as this might be transferred to mucosal surfaces and milk, the latter helping to project the newborns even after birth. Part B of the Phase I trial is continuing until 12 months' post first dose, in order to assess longer-term safety and duration of response to the vaccine.

According to Per Fischer, D.Phil., Chief Executive Officer of MinervaX, "The result of the Phase I trial is extremely encouraging, and represents a very significant milestone for the company in achieving preliminary clinical proof of concept by late 2016 as planned. In particular, the good safety profile and high immunogenicity of the vaccine, as well as the isotypes and functionality of the antibodies induced demonstrates the highly competitive profile of the vaccine compared to competing CPS-based vaccines".

The development of the company's GBS vaccine candidate is funded partly by the EU FP7 NeoStrep project, and Per Fischer adds "The results obtained from the Phase I trial is also a tribute to the support offered by the EU FP7 program and a testament to the excellent collaboration and contribution of NeoStrep project partners."

Group B Strep Support is the UK's only charity dedicated to eradicating group B Strep infections including meningitis in newborn babies. Chief Executive and Founder of the charity, Jane Plumb MBE, welcomes the news that Phase 1 of the clinical trial is now complete.

"We are delighted that MinervaX is developing a group B Strep vaccine. Group B Strep is the most common cause of severe infection in newborn babies and of meningitis in babies under 3 months, although most of these infections could be prevented. Despite the UK's risk-based prevention strategy, the rates of these infections have increased for more than a decade.

A safe and effective vaccine is the 'holy grail' of GBS prevention and could protect more babies from GBS infection than any other strategy. It is urgently needed and I'm delighted that the results of the Phase I trial are so encouraging.

Sadly, a vaccine being available is still many years away and the UK needs to improve its prevention strategy so that protective narrow-spectrum antibiotics can be targeted

in labour to those who will benefit the most – women who are carrying group B Strep."

Group B Strep International (GBSI), is a parent-based organization dedicated to reducing the burden of diseases caused by invasive group B Streptococcus. Marti Perhach, CEO and Cofounder of GBSI, is also pleased to hear about the positive results of MinervaX's Phase I trials for a GBS vaccine. "Even in countries where routine GBS screening and indicated treatment have greatly reduced the number of GBS infections acquired during birth, there are still gaps in prevention that cause much heartache to affected families. We concur that a cost-efficient vaccine boosting maternal, perinatal, and breast milk protective immunity may become a transformative advance in preventing GBS perinatal/newborn disease worldwide."

Shortcomings of current GBS prevention. Current GBS intervention, involving antibiotic prophylaxis during childbirth (known as intra-partum antibiotic prophylaxis or IAP) in women colonized with GBS or otherwise at risk of transmitting the bacteria to the newborn, has reduced the incidence of Early Onset Disease (EOD) occurring within the first 6 days of life by some 80% since its introduction. However,

1) IAP has failed to fully eradicate EOD for a number of practical reasons, and is not universally implemented in all countries, particularly in Europe and the developing world;
2) Current use of IAP has no impact on GBS-induced premature delivery and stillbirth caused by infection of the unborn child as it is administered only during labor;
3) IAP has no impact on Late Onset Disease occurring from 7 days to 3 months of age, where the burden of meningitis is highest. 50% of babies who recover from GBS meningitis have long-term sequelae, including brain damage, cerebral palsy, severe learning difficulties, hearing loss, and/or blindness;
4) IAP is currently only available in high-income countries and is unlikely to be implemented in low-income countries;
5) the efficacy of IAP is currently under threat from emerging antibiotic resistance in GBS, including the most commonly used antibiotics such as penicillin;
6) the wide spread use of broad-spectrum prophylactic antibiotic in birthing women has led to an increase in antibiotic resistance amongst other bacteria, which also can infect newborns, particularly in preterm babies;
7) and finally, wide-spread antibiotic prophylaxis in birthing women may negatively impact the developing intestinal microbiota of the newborn increasing the risk of eczema, asthma, ADHD, and learning disabilities.

The development of an efficacious GBS vaccine for maternal immunization capable of reducing this wide-spread use of antibiotic prophylaxis in birthing women and preventing more GBS infections both of early and late onset therefore addresses two significant medical needs. The annual market size for a GBS vaccine is expected to exceed 1 billion USD in Europe and US combined.

About MinervaX MinervaX is a Danish biotech company, established in 2010 in order to develop a prophylactic vaccine against Group B Streptococcus (GBS), based on research from Lund University. The company's investors include Novo A/S (Denmark, www.novo.dk), Sunstone Capital (Denmark,www.sunstone.eu), SEED Capital (Denmark, www.seedcapital.dk), LF Investment (Denmark, www.lauritzenfonden.com) and Lund University Innovation System (Sweden, www.luis.lu.se). www.minervax.com.

About NeoStrep - NeoStrep is an EU FP7 funded project, coordinated by Lund University (Sweden), partnered by MinervaX, BioKinetic Europe (Northern Ireland, www.biokineticeurope.com), CiToxLAB/Scantox (Denmark, www.citoxlab.com), and supported by Biovian Oy (Finland, www.biovian.com). www.neostrep.eu.

About Group B Strep Support – Group B Strep Support is a UK charity working to prevent preventable group B Strep infections in newborn babies. www.gbss.org.uk. Contact: Jane Plumb, Chief Executive & Founder: phone: +14 44 41 61 76. email: jplumb@gbss.org.uk

About Group B Strep International - Group B Strep International is a U.S. based nonprofit organization promoting awareness and prevention of GBS disease in babies before birth through early infancy. www.groupbstrepinternational.org. Contact: Marti Perhach, CEO/Cofounder: phone +1 909 993 2122. email: marti.perhach@gbs-intl.org

Contact:

Minervax:

Per Fischer, Chief Executive Officer, Phone: +45 20 25 20 38,
Email: pbf@minervax.com

NeoStrep
Development of Group B Streptococcal vaccine
SEVENTH FRAMEWORK PROGRAMME