

MINERVAX INITIATES PHASE I CLINICAL TRIAL WITH INNOVATIVE GROUP B STREPTOCOCCAL (GBS) VACCINE TO PREVENT LIFE-THREATENING INFECTIONS IN NEWBORNS

NOVEL, SINGLE COMPONENT VACCINE PREDICTED TO PROTECT AGAINST UP TO 95% OF GBS ISOLATES

Copenhagen, June 2, 2015 - MinervaX, a privately held Danish biotech company, announced today that the company has initiated a Phase I clinical trial with its innovative Group B Streptococcal (GBS) vaccine candidate, GBS-NN, 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 such 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 both to their child in the womb, during birth and 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 US.

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 in year 2000. However,

- 1) IAP has failed to fully eradicate EOD for a number of practical reasons, and is not universally implemented in all countries;
- 2) IAP has no impact on GBS-induced premature delivery and stillbirth caused by infection of the unborn child;
- 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 also infecting 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.

MinervaX believes its vaccine is 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, GBS-NN is a single component, protein-only vaccine based on a fusion of two highly immunogenic and protective protein domains from selected surface proteins of GBS (N-terminals of AlphaC and Rib). Given the broad distribution of proteins from which the vaccine originates as well as cross-reactive proteins, it is expected that MinervaX's single component vaccine will protect against up to 95% of GBS isolates.

The Phase I trial will enroll up to 310 healthy adult women in two parts. Part A will enroll up to 70 women to investigate safety and initial dose-escalation and Part B will enroll up to 240 women to further evaluate safety and confirm dose and regimen. The trial will take place in Belfast, Northern Ireland. In addition to important safety data, the trial will provide information towards defining an optimal dose and schedule for the vaccine as well as response rates, magnitude and duration of the immune response. Exploratory endpoints will include an assessment of the vaccine's potential ability to protect women against spontaneous vaginal colonization with GBS and provide preliminary data on the breadth of coverage of the vaccine (ability to neutralize different isolates of GBS).

According to Per Fischer, D.Phil., Chief Executive Officer of MinervaX, "The initiation of the Phase I clinical trial represents a very significant milestone for the company, towards its goal of achieving preliminary clinical proof of concept by late 2016".

The development of the company's GBS vaccine candidate is funded partly by the EU FP7 NeoStrep project, and Per Fischer adds " The initiation of the clinical 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 preventing group B Strep infections in newborn babies. Chief Executive and Founder of the charity, Jane Plumb MBE, welcomes the news that Phase 1 of the clinical trial has now begun.

"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, although most of these infections are preventable. The UK's prevention strategy has failed to reduce the rates of these infections for more than a decade.

A safe and effective vaccine is the 'holy grail' of GBS prevention as it could protect more babies from GBS infection than any other strategy, though is still years away. In the meantime, the UK needs to identify women carrying GBS late in pregnancy so that protective antibiotics in labour can be targeted at those who will benefit the most – the babies of women carrying group B Strep."

Group B Strep International (GBSI), a parent-based organization dedicated to reducing the burden of diseases caused by invasive group B Streptococcus. Marti Perhach, CEO/Cofounder is also pleased to hear that MinervaX is developing 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."

According to Dr Paul Heath, Professor of Paediatric Infectious Diseases, St. Georges Vaccine Institute, University of London, UK "There is an urgent need for an effective GBS vaccine. Our previous work has shown that there is a significant global burden of GBS disease in infants, both in Developed as well as Developing countries", and he continues "The vaccine appears to elicit strong and long lasting immune responses in animals, to protect against invasive disease in animals and to cover a wide range of clinical isolates. The latter is important because the current conjugate vaccines will be limited in coverage to 3-5 of the 10 possible serotypes that can cause disease in infants".

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

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NeoStrep
Development of Group B
Streptococcal vaccine

