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Novo Holdings invests 4.4M Euro in Minerva to combat AMR

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An additional investment of 0.8 mEUR was also obtained from SunStone Capital for Phase I development of the Company's protein-only GBS vaccine.

MinervaX, a privately held Danish biotech company has announced that is has been awarded an investment of 3.6 mEUR from the Novo Holdings REPAIR Impact Fund for development of therapies to combat antimicrobial resistance (AMR). An additional investment of 0.8 mEUR was obtained from SunStone Capital. The funding will be used to help finalize Phase I development of the Company's 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 estimated to be responsible for some 57,000 cases of stillbirth, 319,000 cases of invasive neonatal disease, 7,000 cases of meningitis, and up to 3.5 million preterm deliveries globally.

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.

MinervaX has previously reported positive results from an initial Phase I trial completed in 240 healthy adult women with a single component vaccine. The vaccine was demonstrated to have a favorable safety profile, give rise to high levels of long-lasting antibodies, which are capable of killing GBS bacteria and prevent invasion of epithelial and endothelial cell barriers. The current funding will be used to conduct a short Phase I trial to expand the coverage of the vaccine to close to 100% of all colonizing and invasive strains of GBS, by inclusion of a second vaccine component. In addition, funding will be used for

CMC development in preparation of Phase II clinical trials. The clinical trial was initiated in the UK on January 8, 2019.

According to Per Fischer, D.Phil., Chief Executive Officer of MinervaX, "The award from the REPAIR Impact Fund, represents external validation and recognition of MinervaX's GBS vaccine program by a group of key vaccine and bacteriology experts, and allows the company to advance the program towards Phase II clinical trials."

Group B Strep Support is the UK's only charity dedicated to eradicating group B Strep infection in newborn babies. **Chief Executive and Founder of the charity, Jane Plumb MBE,** welcomes the news that Phase 1 program of MinervaX's clinical trial of their GBS vaccine will now be finalised ahead of Phase II trials. "We welcome the news that MinervaX's Phase 1 program of their group B Strep vaccine will be finalised thanks to funding from the REPAIR Impact Fund. Group B Strep is the most common cause of severe infection in newborn babies and of meningitis in babies under 3 months. A safe and effective vaccine is the 'holy grail' of preventing group B Strep infection and could protect more than any other prevention strategy. It is urgently needed and I'm delighted that the research into MinervaX's vaccine candidate will continue."

Group B Strep International (GBSI) is a non-profit organization committed to promoting awareness and prevention of group B strep disease in babies during pregnancy through several months of age. **Marti Perhach, CEO and Cofounder of GBSI,** is glad to know that MinervaX has received funding from the REPAIR Impact Fund to finalize their Phase I clinical development of a GBS vaccine. "The current GBS disease prevention strategy of routine screening and indicated IV antibiotic treatment during labor and delivery adopted by many countries only targets GBS infections acquired during birth and, while highly effective, raises concerns about antibiotic overuse and how antibiotics affect the newborn's microbiome. An effective GBS vaccine replacing this strategy would obviate these concerns as well as provide a measure of protective coverage for unborn babies nearing term and babies up to several months of age, both periods of susceptibility without health agency recommended prevention strategies."

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.