



NeoStrep

Development of Group B
Streptococcal vaccine

Funded by the
European Commission
FP7 Programme HEALTH



Group B Streptococcal vaccine for the prevention of life-threatening infections in newborns secures funding to reach clinical proof of concept.

Copenhagen, January 8, 2014 – NeoStrep, a consortium consisting of Lund University (Sweden), MinervaX ApS (Denmark), CiToxLAB A/S (Denmark), and BioKinetic Europe Ltd. (UK), announced today that it has been awarded EUR 6 million in funding under the European Commission FP7 Programme HEALTH, for the development of a novel innovative Group B Streptococcal Vaccine candidate, owned by MinervaX. The consortium is coordinated by Lund University and MinervaX is responsible for project management. Together with co-funding provided by the individual partners, the funding will allow for the advancement of the GBS vaccine candidate to clinical proof of concept in Phase IIa by late 2016.

Despite the introduction of extensive use of antibiotic prophylaxis, GBS is responsible for up to 50% of life-threatening bacterial infections in newborn infants and carries a significant risk of either long-term disability or death. Approximately 15-25 % of women are colonized with GBS in their vaginal flora, from which GBS may spread to the child before or during childbirth. Newborn infants are also at increased risk of contracting GBS infections up to 3 months after birth. Infection of the unborn child may lead to premature labour or stillbirth, and infection of the newborn infant may result in severe infections such as pneumonia, septicaemia and meningitis, which all carry a high risk of long-term disability or death. In addition to newborns, GBS infections are also a growing concern in the elderly.

The extensive use of GBS antibiotic prophylaxis in birthing women has resulted in the emergence of antibiotic resistance. The development of wide spread antibiotic resistance in GBS will significantly impair the effectiveness of current preventive strategies, as well as the effectiveness of treatment options in the remaining GBS infections. The development of a GBS vaccine will prevent GBS infections without the need for antibiotic prophylaxis and hence reduce the risk of widespread antibiotic resistance developing in GBS. A GBS vaccine therefore addresses a major medical need, and will help protect pregnant women, newborn infants and the elderly against stillbirths, severe disease, long-term disability or death.

The NeoStrep vaccine candidate employs a novel innovative protein-only strategy, and is based on a fusion protein (GBS-NN) containing the N-terminal domains of the Rib and Alpha surface glycoproteins of GBS. The vaccine candidate has been shown to elicit a highly protective immune response in animal models of GBS infection, and is capable of neutralizing the clinically most relevant strains of GBS responsible for up to 95% of all infections (Serotypes Ia, Ib, II, III, & V) all in a single vaccine component.

The vaccine candidate is currently undergoing GMP manufacturing in preparation for clinical trials to be initiated early 2015. For further details see www.neostrep.eu

About Lund University - Lund University is a research intensive university belonging to the League of European Universities (LERU) and the international Universitas 21. With eight faculties covering engineering, science, medicine, economics, social sciences, fine and performing arts, law and humanities, together with a number of specialised research centres, Lund University has a breadth of research and a strong cross-disciplinary approach to finding solutions to today's world problems. Over SEK 4 billion is awarded annually to research at eight faculties, which gives Lund University one of the strongest and broadest ranges of research in Sweden. The University has 47 000 students and 7 200 staff based in Lund, Helsingborg and Malmö. We are united in our efforts to understand, explain and improve our world and the human condition. For further details see, www.lunduniversity.lu.se

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About MinervaX - MinervaX is a Danish biotech company, established in 2010 in order to develop a novel vaccine candidate against Group B Streptococcus (GBS), invented at Lund University. The company's investors include Novo A/S (Denmark, www.novo.dk), Sunstone Capital (Denmark, www.sunstone.eu), LF Investment (Denmark, www.lauritzenfonden.com), Seed Capital (Denmark, www.seedcapital.dk) and Lund University Innovation System (Sweden, <http://innovation.lu.se/en>). For further details see, www.minervax.com.

Per Fischer, Chief Executive Officer, pbf@minervax.com

About CiToxLAB - CiToxLAB is a multi-national non-clinical Contract Research Organisation providing a wide range of testing services to companies in the Pharmaceutical, Biopharmaceutical, Medical Device, Chemical, Agrochemical, Veterinary and Food industries. CiToxLAB carries out studies in general and reproductive toxicology, carcinogenicity, bioanalysis, immunology and safety pharmacology. The group has particular expertise in areas such as toxicology and reprotoxicology in NHPs and minipigs, inhalation, genomics, radiation studies and environmental studies. CiToxLAB has more than 850 employees working on five sites in four countries (France, Denmark, Canada and Hungary). For further details see, www.citoxlab.com

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About BioKinetic Europe – BioKinetic is an independent, owner-managed Phase I-III Clinical Pharmacology Unit based in Belfast, UK. The company was established in 1996 to provide error-free clinical trials on behalf of the pharma and biotech industries. BioKinetic has specific expertise in Vaccines, Women's Health, Asthma/COPD, Arthritis and Dermatology. For further details see, www.biokinetic europe.com

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