



New TB vaccine enters clinical trials

A new tuberculosis (TB) vaccine has been designed at Statens Serum Institut (SSI), Copenhagen. While the current TB vaccine, the Calmette (BCG) vaccine, efficiently protects children against TB, protection gradually decreases after 10-15 years and the vaccine provides limited protection against the disease in adults in the third world. In collaboration with Intercell AG and supported by the European Union, SSI now initiates clinical trials of a TB subunit vaccine that aims to either replace the Calmette vaccine or boost its activity in adults.

Copenhagen (Denmark)/Vienna (Austria), November 18, 2005 – TB causes the death of two-three million people every year and one-third of the world's population is infected by the bacteria *Mycobacterium Tuberculosis* which makes this disease one of the most severe global health problems.

The Calmette (*Bacillus Calmette-Guérin* (BCG)) is a live vaccine that, when given to newborns, provides good protection against TB for 10-15 years. However, when the protective effect decreases, yet another BCG vaccination does not provide sufficient TB protection. Therefore, a new type of TB vaccine is needed to address the need of TB protection in the adult population in the developing countries.

“Previous exposure to mycobacteria induces an immune response which seems to prevent the replication of BCG vaccine and the induction of immunity. The new vaccine is thus designed to protect against TB, even though an individual has previously been BCG vaccinated or exposed to other closely related mycobacteria often found in the environment in the third world”, explains Peter Andersen, Director of Vaccine Research and Development, SSI.

The new vaccine candidate from SSI is a recombinant subunit vaccine based on two important TB antigens combined with an adjuvant developed by the Austrian Biotech company Intercell AG.

Intercell's CSO, Alexander von Gabain, commented: “The new vaccine is based on our potent synthetic adjuvant IC31™, which has been shown to stimulate strong and long-lasting T cell immune responses, being crucial for an effective TB vaccine.”

The phase I clinical trial will start this week at the Department of Infectious Diseases at Leiden University Medical Center in the Netherlands supported by the European Union-funded program “TB-VAC”.

About Statens Serum Institut (SSI):

Statens Serum Institut (www.ssi.dk) is a public enterprise operating as a market-oriented production and service enterprise.

Statens Serum Institut is an enterprise under the Danish Ministry of the Interior and Health, and the Institute's duties are partly integrated in the national Danish health services.



Statens Serum Institut prevents and controls infectious diseases and congenital disorders. The expertise includes:

- Monitoring, advising and teaching on the incidence, prevention and treatment of infectious diseases and congenital disorders.
- Specializing in the diagnosis of infectious, autoimmune, congenital and genetic diseases.
- Ensuring the supply of vaccines, other biological products and diagnostic services through production and procurement.
- Preparedness against biological terrorism.
- Research and development in the Institute's areas of activity at an international level.

The Statens Serum Institute aims to ensure advanced control of infectious diseases, including new infections and biological threats. The Institute also strives to be a highly regarded and recognized national and international research, production and service enterprise.

About Intercell AG:

Intercell AG is a fast growing biotechnology company focusing on the design and development of novel vaccines for prevention and treatment of diseases with substantial unaddressed medical need. The Company's unique position is based on the combination of antigens and immunizers (adjuvants) derived from its proprietary technology platforms and its in-house GMP manufacturing facilities. Intercell's technology has been endorsed by collaborative agreements with a number of global pharmaceutical companies, including sanofi pasteur, Merck&Co., Inc., SciGen Ltd. and the Statens Serum Institut. The Company has a broad development pipeline with a vaccine for Japanese Encephalitis in Phase III, a vaccine for Hepatitis C undergoing Phase II trials, and five products focused on infectious diseases in the pre-clinical phase. Intercell is listed on the Vienna stock exchange under the symbol "ICLL".

For more information please visit: www.intercell.com

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