



Novel tuberculosis vaccine shows promising immunogenicity and safety profile

- » The Danish Statens Serum Institut (SSI) and Intercell report promising data from a phase I clinical trial with a tuberculosis (TB) subunit vaccine
- » The vaccine is produced by SSI and contains Intercell's adjuvant IC31™
- » The project which is supported by the European Union aims to either replace the available TB vaccine "BCG"/"Calmette vaccine" or to boost its activity in adults.

Copenhagen (Denmark)/Vienna (Austria), March 14, 2007 – Statens Serum Institut (SSI) and Intercell announced today that their collaborative novel tuberculosis (TB) vaccine is safe and very immunogenic in healthy individuals in a phase I clinical trial. The preliminary data will be presented on the Keystone Symposia on Tuberculosis in Vancouver, March 24, 2007 by Prof. Peter Andersen from the SSI and April 12, 2007 at the 3rd Vienna Vaccines Conference by co-investigator Prof. Tom Ottenhoff, Leiden University Medical Center, Netherlands. Based on these results the partners will initiate a clinical trial with latent TB-infected and BCG-vaccinated individuals later in 2007.

The new H1 vaccine from SSI is a recombinant subunit vaccine based on two important TB antigens resulting from SSI's research pipeline combined with Intercell's proprietary adjuvant IC31™. The phase I clinical trial was performed at the Department of Infectious Diseases (headed by Prof. Jaap van Dissel) at Leiden University Medical Center in the Netherlands and was supported by the European Union-funded program "TB-VAC".

"The successful outcome of the phase I trial has paved the way to move our novel TB vaccine forward. It is designed to function in a stand alone schedule, as well as in combination with previous exposure(s) to BCG or other closely related mycobacteria. It seems that our decision to combine our antigen with IC31™ has been a sound judgement on the base of our preclinical data", explains Peter Andersen, Director of Vaccine Research and Development, SSI.

Intercell's CSO, Alexander von Gabain, commented: "Our adjuvant IC31™ proved an outstanding profile to stimulate a strong T-cell immune response in humans as already previously seen in a variety of animal models. These results prove the scientific concept of our adjuvant and encourage a broad and commercial use of IC31™ in a variety of prophylactic and therapeutic vaccines."

About tuberculosis

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)) vaccine 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.

About H1

H1 is a TB vaccine antigen in which two immuno dominant TB antigens (Ag85B and ESAT6) are fused together by recombinant technology and produced as a poly-protein.

About IC31™

Adjuvants enhance the effectiveness of vaccines. Existing adjuvants on the market induce antibodies but no or little T-cell immunity.

IC31™ is an adjuvant inducing both T-cell and B-cell responses with a unique synthetic formulation which combines the immunostimulating properties of an anti-microbial peptide, KKK, and an immunostimulatory oligodeoxynucleotide, ODN1a. The two component solution can be simply mixed with antigens, no conjugation is required.

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.
- 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 Institut 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 growing biotechnology company which focuses on the design and development of novel vaccines for prevention and treatment of infectious diseases with



substantial unmet medical need. The Company develops antigens and immunizers (adjuvants) which are derived from its proprietary technology platforms, and has in-house GMP manufacturing capability. Based on these technologies, Intercell has strategic partnerships with a number of global pharmaceutical companies, including Novartis, Merck&Co., Inc, sanofi pasteur, Kirin, Wyeth, and the Statens Serum Institut.

The company's lead product, a prophylactic vaccine against Japanese Encephalitis has successfully concluded pivotal Phase III clinical trials. The regulatory process towards a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) has been initiated. The broad development pipeline includes a therapeutic vaccine for Hepatitis C in Phase II, a Pseudomonas vaccine in Phase II, partnered vaccines for tuberculosis and S. aureus which are in Phase I, and five products focused on infectious diseases in pre-clinical development. Intercell is listed on the Vienna stock exchange under the symbol "ICLL".

For more information please visit: www.intercell.com

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