

## **EANS-News: Intercell AG / Intercell and Statens Serum Institut (SSI) progress vaccine clinical development to fight Tuberculosis**

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Wien (euro adhoc) - » The combination of SSI's novel tuberculosis subunit vaccine candidate and Intercell's proprietary IC31® adjuvant enters Phase II clinical trial in HIV-positive individuals  
» First results expected in 2013, a second Phase II study is planned for 2012

Vienna (Austria) / Copenhagen (Denmark), January 11, 2012 - Intercell AG (VSE; "ICLL") and Statens Serum Institut (SSI) today announced the start of the first Phase II study within their collaboration to develop vaccines against Tuberculosis (TB). The randomised, double-blind, clinical trial evaluating the immunogenicity and safety of two doses of an adjuvanted TB subunit vaccine candidate, H1IC (a combination of SSI's Ag85B-ESAT-6 + Intercell's IC31®), in HIV-positive individuals, will be conducted in South Africa and Tanzania. The study is funded by EDCTP (European and Developing Countries Clinical Trials Partnership) and conducted in collaboration with Aurum Institute, Ifakara Health Institute, Swiss Tropical and Public Health Institute, London School of Hygiene and Tropical Medicine and the South African TB Vaccine Initiative. First results are expected in 2013. A second Phase II clinical study is being planned to assess the safety and immunogenicity of the vaccine candidate in healthy adolescents.

Previous Phase I clinical trials in Europe and Africa have demonstrated that SSI and Intercell's collaborative novel investigational TB vaccine is safe and very immunogenic in different populations. The new H1IC vaccine candidate 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® and ultimately targeted against adults and adolescents.

"We are very proud that the clinical evaluation of the H1IC vaccine is progressing so well and that this vaccine is playing a key role in the development of a much-needed novel efficient TB vaccine", says Peter Lawætz Andersen, Vice President Vaccine R&D, SSI.

"The start of this Phase II clinical trial is not only a further validation of Intercell's proprietary IC31® adjuvant technology, it is foremost an notable

step towards addressing an important medical need with a novel vaccine against TB", says Thomas Lingelbach, CEO of Intercell AG.

The collaboration between SSI and Intercell in the field of Tuberculosis currently includes three clinical vaccine candidates, all formulated with Intercell's IC31® adjuvant: H1IC, now entering Phase II, H4IC, currently in Phase I (partnered with Sanofi and AERAS, "AERAS 404"), and H56IC, currently in a Bill and Melinda Gates Foundation-funded Phase I in partnership with AERAS and the South African Tuberculosis Vaccine Initiative.

Further inquiry note:

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