

Valneva: SSI and Aeras initiate Phase I/IIa Clinical Trial for Tuberculosis Vaccine Candidate Using IC31[®] Adjuvant

Lyon (France), November 8, 2013 – Valneva SE (“Valneva”, the Company) is pleased to distribute the following press release issued by the Statens Serum Institut (SSI) and Aeras about the initiation of a Phase I/IIa clinical trial for a tuberculosis (TB) vaccine candidate using Valneva’s IC31[®] proprietary adjuvant.

Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva, commented: “We are pleased to see the progress of this program for the development of a much needed vaccine against TB, reinforcing our collaboration with SSI.”

Three clinical vaccine candidates, all formulated with Valneva’s IC31[®] adjuvant, are currently being tested in Phase I and II clinical trials as part of the company’s agreement with SSI and their partners, including Aeras and Sanofi Pasteur.

Data from two of the trials is expected to be published by the fourth quarter of 2014.



SSI and Aeras Announce Initiation of Phase I/IIa Clinical Trial for Tuberculosis Vaccine Candidate

Clinical Testing Expanded for Vaccine Against Latent TB

COPENHAGEN, DENMARK/ROCKVILLE, MD, USA, November 8, 2013 – Statens Serum Institut (SSI) and Aeras today announced the initiation of a Phase I/IIa clinical trial for a candidate tuberculosis (TB) vaccine designed to protect people, especially those latently infected with TB, from developing active TB disease.

The decision builds on the outcome of a Phase I study that raised no safety concerns and demonstrated immunogenicity from the first clinical trial of the vaccine candidate, SSI H56:IC31/AERAS-456, formulated with Valneva’s IC31[®] proprietary adjuvant.

“With the results of our first study in hand, we can now test SSI H56:IC31/AERAS-456 for safety in a larger group of individuals, while looking for safety, the correct dose, and the needed immune responses that would lead us into the next phase,” said Thomas G. Evans, MD, Aeras President and CEO. “What continues to make this project so strong is the collaboration that brings together Aeras, with deep experience in clinical trials, and SSI, which has unparalleled expertise as an innovator in the basic sciences in TB vaccinology.”

The Phase I clinical trial of SSI H56:IC31/AERAS-456, concluded in December 2012, enrolled 25 people. It was the first time a South African research institute led a first-in-human clinical trial. With the second trial, the Phase I/IIa study now underway, the South African Tuberculosis Vaccine Initiative (SATVI) will continue its groundbreaking work.

“The current global TB epidemic requires novel approaches, new tools and sufficient resources to reverse what is now a more challenging and expensive disease to control than when the World Health Organization declared it a global emergency more than 20 years ago,” said Professor Peter Andersen at SSI. “The partnership with Aeras and SATVI provides a path to move the research beyond the laboratory and into communities that so desperately needs a safe effective vaccine against this deadly scourge.”

New vaccines are urgently needed to protect against all forms of TB and would represent the single greatest preventative tool in mitigating the epidemic, Evans said, noting that the spread of multi- and extensively drug-resistant strains are hobbling global efforts to halt the spread of TB and are placing an enormous economic burden on health systems globally.

In conducting the Phase I/IIa trial, SATVI will test the vaccine at three dosing levels to evaluate safety as well as immune response in HIV-negative adults—in groups with and without latent tuberculosis.

“We are up against one of the hardest vaccine targets science has ever taken on, but we accumulate more knowledge about protection against tuberculosis with every clinical trial,” said Associate Professor Mark Hatherill of SATVI. “That is why we need the sort of partnership we have working on this vaccine candidate, and scientists whose work is constantly influenced by what happens all along the pipeline, from the lab to the field and back again. Our strong partnership with the local community is crucial to the success of these tuberculosis vaccine trials.”

SSI H56: IC31/AERAS-456 is a subunit vaccine containing recombinant TB proteins formulated with the proprietary adjuvant IC31® of Valneva. The trial is approved by the Medicines Control Council of South Africa. It is being developed for both adolescent and adult populations.

The vaccine candidate has been shown to be immunogenic and protective before and after TB exposure in preclinical animal models.

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About Statens Serum Institut (SSI)

SSI is a state-owned enterprise under the Danish Ministry of Health and Prevention. The Institute is integrated in the national Danish health services. SSI's mission is to prevent and control infectious diseases, biological threats and congenital disorders. The institute strives to be a highly regarded and internationally recognized research, production and service enterprise. www.ssi.dk

About Aeras

Aeras is a nonprofit biotech advancing the development of tuberculosis vaccines for the world. In collaboration with global partners in Africa, Asia, North America and Europe, Aeras is supporting the clinical testing of six experimental vaccines as well as a robust portfolio of earlier stage candidates. Aeras receives funding from the Bill & Melinda Gates Foundation, the UK Department for International Development, the Netherlands' Ministry of Foreign Affairs, Australian AID, and a range of other governments. Aeras is based in Rockville, Maryland; Cape Town, South Africa; and Beijing, China. www.aeras.org

About SATVI

Established in 2001, the University of Cape Town's South African Tuberculosis Vaccine Initiative (SATVI) is the largest dedicated TB vaccine research group on the African continent. It is located within the Institute of Infectious Disease and Molecular Medicine of the University of Cape Town. Its mission is to conduct innovative, high-quality TB vaccine research in Africa to impact the global epidemic. A new, effective, affordable vaccine has the potential to save hundreds of thousands of lives worldwide. SATVI is conducting registration standard clinical trials of several novel TB vaccine candidates. It is also engaging in projects to address critical clinical, epidemiological, immunological and human genetic questions in TB vaccine development. <http://www.satvi.uct.ac.za/>

About Valneva SE

Valneva is a European biotech company focused on vaccine development and antibody discovery. It was formed in 2013 through the merger between Intercell AG and Vivalis SA. Valneva's mission is to excel in both antibody discovery and vaccine development and commercialization, either through in-house programs or collaborations with industrial partners using innovative technologies developed by the company. Valneva generates diversified revenue from its marketed product, a vaccine for the prevention of Japanese encephalitis (IXIARO®), commercial partnerships around a portfolio of product candidates (in-house and partnered), and licensed technology platforms (EB66® cell line, VIVA|Screen™ antibody discovery technology, and the IC31® adjuvant) that are becoming widely adopted by the biopharmaceutical industry worldwide. Headquartered in Lyon, France, the company employs approximately 350 people in France, Austria, Scotland, the United States and Japan. www.valneva.com

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