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Valneva: Aeras Initiates Phase II Clinical Trial of A Tuberculosis Vaccine Candidate Using IC31® Adjuvant

Lyon (France), March 11, 2014 – European Biotech company Valneva SE (Valneva) is pleased to distribute the following press release issued by Aeras about the initiation of a Phase II randomized clinical trial for their tuberculosis (TB) vaccine candidate Aeras-404 using Valneva's IC31® proprietary adjuvant.

Thomas Lingelbach, President and Chief Executive Officer and Franck Grimaud, President and Chief Business Officer of Valneva, commented, "The progress Aeras and its partners have made to date with the Aeras-404 vaccine candidate is impressive and we seek to further enable their studies under current agreement we have with them for the IC31® vaccine adjuvant."

Aeras-404 (also designated as H4IC) is a novel vaccine candidate developed jointly by Aeras, Statens Serum Institut (SSI) and Sanofi Pasteur. It has already been tested in four Phase I studies which showed an acceptable safety profile and immunogenicity. Aeras and its partners expect preliminary results of the study at the end of 2015.

AERAS

Novel Vaccine Trial Design Aims to Answer Key Tuberculosis Questions and Enhance Vaccine Development Strategy

Prevention of infection study underway in South Africa

ROCKVILLE, MD, USA & CAPE TOWN, ZA, March 11, 2014 – Aeras today announced the initiation of the first randomized, controlled tuberculosis (TB) vaccine trial designed to study prevention of *Mycobacterium tuberculosis (Mtb)* infection by vaccination. The Phase II study of the TB vaccine candidate, H4+IC31® (AERAS-404), will evaluate its safety, immunogenicity, and ability to prevent infection by *Mtb*, the bacterium that causes TB. The trial, which will be conducted in South Africa, will also evaluate BCG revaccination.

This novel trial design establishes a potential new paradigm in TB vaccine development. Clinical development of TB vaccines is hampered by the lack of biologic correlates of protection and lack of validated preclinical models, which could provide evidence of likely efficacy in early stages of development. The prevention of infection trial design enables a smaller, faster proof of concept to help in deciding on advancement into large-scale disease-prevention trials. While a TB vaccine would not need to prevent infection with *Mtb* to prevent TB disease, prevention of infection with *Mtb* would be an important marker of biologic impact.

“For the first time in a TB vaccine trial, we will be testing for infection by *Mtb*, rather than waiting to measure the occurrence of clinical disease, which is more expensive and requires much larger studies,” said Thomas G. Evans, MD, Aeras President and CEO. “This will enable us to obtain results much more quickly and with fewer subjects, and the data we generate will ensure that the entire field of TB vaccine R&D progresses in a more informed and streamlined way.”

The randomized, placebo-controlled, partially blinded trial will enroll 990 adolescents in the Western Cape Province. The South African Tuberculosis Vaccine Initiative (SATVI) will conduct this Phase II trial in healthy adolescents who have been previously vaccinated with BCG as infants. One-third of the participants will receive a revaccination with BCG; one-third will receive vaccination with H4+ IC31®, and one-third will receive a placebo. Infection will be determined with the use of commercially available interferon gamma release assays. Models indicate that an effective vaccine given to adolescents and adults, who bear the brunt of the TB burden, could have a dramatic impact on the global TB epidemic, preventing tens of millions of cases and millions of deaths from the disease.

Bacille Calmette-Guerin (BCG), the current TB vaccine, is one of the most widely administered vaccines globally. It prevents some forms of TB in children, but its widespread use in infants has failed to control the global epidemic. Recent studies of BCG suggest it may be effective at preventing infection, but this has not yet been tested in a randomized, controlled, prospective trial. H4 + IC31® is a novel vaccine candidate developed jointly by Aeras, Statens Serum Institut (SSI) and Sanofi Pasteur. It has already been tested in four Phase I studies—including one in South Africa—in adults, which showed an acceptable safety profile and immunogenicity.

“Right now, we do not have a reliable way to prevent people who are exposed to *Mtb* from becoming infected, and one out of 10 people who become infected will develop active TB disease at some point in their life,” said Associate Professor Mark Hatherill, Interim Director of SATVI. “Preventing new infections by vaccination, and interrupting the cycle of transmission, would make a tremendous impact on the TB epidemic.”

Preliminary results are expected at the end of 2015. If this initial study in adolescents shows that revaccination with BCG or vaccination with H4+ IC31® prevents infection with *Mtb*, then additional larger scale efficacy studies looking at the impact on TB disease in more diverse populations would be warranted.

H4+ IC31® uses SSI's H4 antigen (a fusion protein of *M.tuberculosis* antigens 85B and TB10.4), combined with the biotech company Valneva's IC31® adjuvant to stimulate T cell-mediated immunity. The vaccine candidate has been shown to be immunogenic and protective before and after TB exposure in preclinical animal models. The trial is approved by the Medicines Control Council of South Africa.

“We are thrilled that H4+ IC31® is being used in this groundbreaking trial that will impact the entire TB vaccine field,” said Peter Andersen, Vice President of Vaccine R&D at SSI. “It is only through continued partnerships and collaboration that we will discover the answers to basic scientific questions in order to expedite the development of effective TB vaccines for all who need them.”

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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 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 Valneva SE
Valneva is a European biotech company focused on vaccine development and antibody discovery. It was formed in 2013 through the merger of 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|ScreenTM 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 280 people in France, Austria, Scotland, the United States and Japan. www.valneva.com

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