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New England Journal of Medicine Publishes Final Results from Innovative Phase 2 Study Showing Vaccines Can Reduce Rate of Sustained TB Infections in Adolescents at High Risk

Trial offers hope for new revaccination strategies with Bacille Calmette-Guerin (BCG) against Tuberculosis, the world's leading infectious disease killer

ROCKVILLE, MARYLAND (JULY 11, 2018) --Aeras, a nonprofit organization dedicated to developing vaccines against tuberculosis (TB), today announced the publication of the full results from a Phase 2, randomized, controlled clinical trial of two TB vaccines— the currently available BCG vaccine and an investigational vaccine, H4:IC31—in the *New England Journal of Medicine* (NEJM).

This proof-of-concept study showed that vaccination can reduce the rate of sustained TB infections in a high-transmission setting, such as in uninfected, healthy adolescents in the Western Cape of South Africa where the study was conducted. In the trial, revaccination with BCG significantly reduced sustained TB infections in adolescents with a 45.4% vaccine efficacy. H4:IC31 also reduced sustained infections, although not at statistically significant levels, showing 30.5% vaccine efficacy. However, the trend observed for H4:IC31 is the first time a subunit vaccine has shown any signal that it may be able to protect against TB infection or disease in humans. In the trial, TB infections were measured by a blood test (QuantIFERON-TB Gold In-Tube (QFT)) converting from negative to positive, and sustained infections were defined by a QFT test that remained positive for at least six months.

Jacqueline Shea, PhD, Chief Executive Officer at Aeras, said: “With this study, we showed that vaccines against TB infection can work. The results highlight the importance of investing in new approaches to fighting the leading infectious disease killer and to evaluating new concepts in clinical trials. Further, the collaborative effort established between industry leaders, nonprofits and clinical sites during this trial showed how powerful combining such forces can be for developing new interventions against a global health threat. The BCG results are important findings with significant public health implications that could lead to saving millions of lives. Likewise, the novel prevention-of-infection trial design can be used to inform clinical development of new vaccine candidates before entry into large-scale prevention-of-disease efficacy trials. We are very grateful to the trial participants and our partners and funders who enabled the conduct of this trial.”

Initial results from the study were presented at the 5th Global Forum in New Delhi, India in February 2018.

BCG is the only licensed tuberculosis vaccine available globally. H4:IC31 is an investigative subunit vaccine candidate being developed jointly by Aeras and Sanofi Pasteur, the vaccines business of Sanofi (EURONEXT: SAN) (NYSE: SNY), and the Statens Serum Institut. The clinical trial was funded by Sanofi

Pasteur, the United Kingdom's Department for International Development, The Bill & Melinda Gates Foundation and Aeras. The clinical trial was conducted at the South African Tuberculosis Vaccine Initiative (SATVI) at the University of Cape Town and at the Emavundleni Research Centre (part of the Desmond Tutu HIV Centre). The study was approved by the Medicines Control Council of South Africa and the relevant local independent ethics committees.

About TB

Tuberculosis is designated a priority infectious disease by the World Health Organization (www.who.int/tb/en/). It causes more deaths than any other single infectious agent and is increasingly characterized by antimicrobial resistance. There were 10.4 million new cases of TB in 2016 and 1.7 million deaths.

About Aeras

Aeras is a nonprofit organization advancing the development of new tuberculosis vaccines for the world in partnership with other biotech, pharmaceutical and academic organizations. Aeras is primarily funded by The Bill & Melinda Gates Foundation, the UK Department for International Development (DFID), and other parties committed to ending the TB epidemic. Aeras also receives support from the U.S. government and through partnerships and collaborations with universities and pharmaceutical companies around the world. Aeras is headquartered in Rockville, Maryland (USA), with a clinical development and operations office in Cape Town, South Africa. For more information, please visit www.aeras.org.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

About Statens Serum Institut (SSI)

Statens Serum Institut (SSI, Copenhagen, Denmark) is a public institution under the Danish Ministry of Health, with a mission to reinforce health through disease control and research. Since 1902, SSI has been an integrated part of Danish and international health services, ensuring preparedness against infectious diseases and biological threats as well as control of congenital disorders. With more than 600 employees, SSI is one of Denmark's largest research institutes.

About South African Tuberculosis Vaccine Institute (SATVI)

SATVI is a world leader in TB vaccine clinical research located within the Health Sciences Faculty at the University of Cape Town. The goal of SATVI is the development of new and effective vaccination strategies against TB through conduct of clinical trials of new vaccine candidates and immunology

studies to better understand risk for and protection against TB. For more information visit www.satvi.uct.ac.za.

About Desmond Tutu HIV Foundation

The Desmond Tutu HIV Foundation, housed within the Desmond Tutu HIV Centre at the University of Cape Town, is committed to the pursuit of excellence in research, treatment, training and prevention of HIV and related infections in South Africa.

Fully self-funded by grants and other investigator raised funds, its vision for the future includes the continuation of current TB/HIV related work of treatment, care, prevention and education particularly in the most vulnerable populations, whilst staying abreast of new developments and continuing to contribute to cutting edge information in HIV and TB public health, social and clinical research.

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