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GSK TB vaccine shows promise in phII study

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Pharma giant GSK and Aeras reported that GSK's candidate vaccine significantly reduced the incidence of pulmonary tuberculosis disease in HIV-negative adults with latent tuberculosis infection in an ongoing phase IIb clinical trial testing. These primary results published in the *New England Journal of Medicine* after two years of trial demonstrate an overall vaccine efficacy of 54%, with varied response rates observed in different demographic sub-groups. The candidate vaccine had an acceptable safety and reactogenicity profile.

Tuberculosis is the leading cause of death through infectious disease worldwide and represents a significant public health threat with 1.6 million attributed deaths in 2017. It is estimated that one-quarter of the global population has latent tuberculosis infection, of whom approximately 10% will develop active pulmonary tuberculosis disease. Currently, multi-drug resistant strains of tuberculosis are emerging globally, and the only currently available vaccine against tuberculosis, BCG, does not provide proven and consistent protection in adults in tuberculosis endemic countries. Without a more effective vaccine, it will not be possible to achieve the WHO target of decreasing the number of new cases by 90% and the number of tuberculosis deaths by 95% between 2015 and 2035.

Dr Emmanuel Hanon, Senior Vice-President and Head of R&D, Global Vaccines GSK, said: "These initial findings represent a significant innovation in the development of a new and much-needed vaccine and advance the scientific understanding of

tuberculosis. This scientific breakthrough – one of the very few in tuberculosis vaccine development for almost 100 years – has been made possible by our strategic partnership with Aeras, in which GSK is providing the innovation expertise and technology platforms, such as the proprietary AS01 adjuvant."

Jacqui Shea, Chief Executive Officer of Aeras, which contributed to the partnership their decades long experience in tuberculosis vaccine clinical development, clinical operations capabilities and strong links with African clinical sites and patient communities, said: "This ground-breaking study shows – for the first time – that a subunit vaccine can significantly reduce the incidence of pulmonary tuberculosis in healthy, HIV-negative adults with latent tuberculosis infection, and that more effective vaccines against tuberculosis are achievable. Given the overwhelming public health need, the importance of these promising results, which need to be confirmed through additional clinical research, cannot be overstated. An effective vaccine, able to reduce transmission, would be by far the most impactful new intervention to end the global tuberculosis epidemic".

The study is still ongoing and a final analysis including all efficacy, safety, reactogenicity and immunogenicity data will be performed in 2019 after all participants have completed three years of follow up.