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GSK candidate vaccine shows protection against active TB

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Final results confirm the innovative TB candidate vaccine's efficacy level and acceptable safety profile in three-year clinical trial conducted in sub-Saharan African regions

GSK and IAVI reported that GSK's M72/AS01$_E$ candidate vaccine significantly reduced the incidence of pulmonary tuberculosis disease (TB) in HIV-negative adults with latent TB infection. These results demonstrate an overall vaccine efficacy of 50% during the three years after vaccination. The candidate vaccine has an acceptable safety and reactogenicity profile. The final results are consistent with the primary analysis done after two years of follow-up and published in New England Journal of Medicine in September 2018.

TB is the leading cause of death through infectious disease worldwide and represents a significant public health threat with 1.5 million attributed deaths in 2018[3]. It is estimated that one-quarter of the global population has latent TB infection, of whom approximately 10% will develop active pulmonary TB disease. Currently, multi-drug resistant strains of TB are emerging and spreading globally, and the only available TB vaccine, BCG, does not provide proven and consistent protection in adults in TB-endemic countries. Without a more effective vaccine, it will not be possible to achieve the World Health Organization target of decreasing the number of new cases by 90% and the number of TB deaths by 95% between 2015 and 2035.

Dr Thomas Breuer, Chief Medical Officer of GSK Vaccines, said: "These results demonstrate that for the first time in almost a century, the global community potentially has a new tool to help provide protection against TB. I want to thank our scientists for their dedicated effort and scientific innovation in developing this impactful vaccine candidate in partnership with IAVI and other key organisations."

The trial was conducted in TB-endemic regions (Kenya, South Africa and Zambia) and involved 3,573 HIV-negative adults between the ages of 18 and 50 years. Participants who received two doses of either M72/AS01$_E$ or placebo 30 days apart were followed for three years to detect evidence of pulmonary tuberculosis disease. In the final analysis, 13 participants in the vaccine group developed active pulmonary tuberculosis compared to 26 participants in the placebo group. Among participants who received the vaccine, an increased M72-specific immune response was sustained through three years.

Dr. Mark Feinberg, President and CEO of IAVI, said: "These final results show that M72/AS01$_E$ could be an important tool in the fight against pulmonary tuberculosis. While additional trials need to be conducted to confirm these findings in other

populations, we have never before seen a vaccine that provides protection in adults who are already infected with the bacteria that cause tuberculosis.”