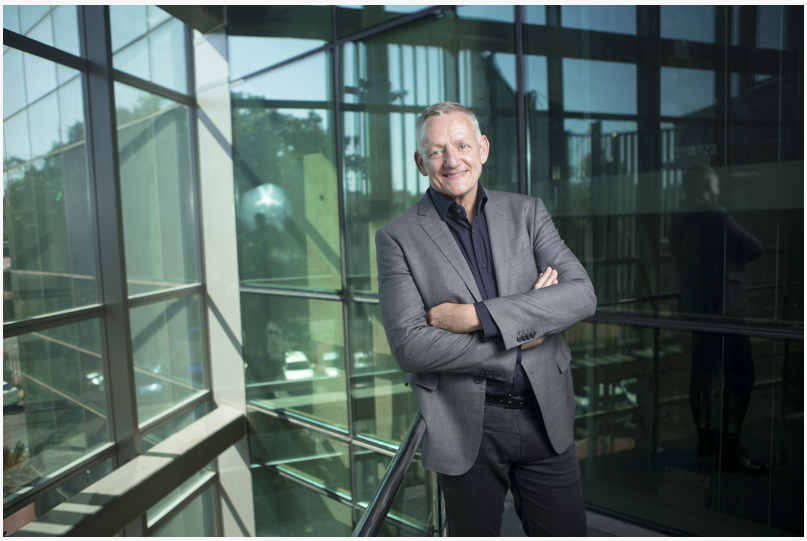
# This World TB Day, there is real hope – at last – for victory

*Africa plays a leading role in the development of the most promising vaccine in over a century*



TB vaccine expert Professor Willem Hanekom, executive director of the Africa Health Research Institute and the co-national principal investigator for the M72/AS01E trial in South Africa

SOUTH AFRICA, March 24, 2025 /EINPresswire.com/ -- About 3 500 people die of tuberculosis (TB) every day, according to the World Health Organization (WHO). But, finally, a new vaccine under development offers hope for triumph over the world's leading killer infectious disease.

This vaccine candidate, called M72/AS01E, is currently in a phase 3 clinical trial, which will definitively evaluate whether it can prevent TB disease. The trial is taking place in five countries: South Africa, Zambia, Malawi, Kenya and Indonesia, with the most trial sites situated in South Africa.

"TB is a pandemic that especially burdens the socio-economically dispossessed. The world's highest incidence rate is in sub-Saharan Africa and in particular Southern Africa, where hundreds of thousands become ill annually," says TB vaccine expert Professor Willem Hanekom, executive director of the Africa Health Research Institute and the co-national principal investigator for the M72/AS01E trial in South Africa.

"It is thus fitting that as we mark World TB Day on 24 March, we can proudly say that Africa, primarily South Africa, is playing an outsize role in the development of a TB vaccine that holds the greatest promise since the invention of the BCG vaccine in 1921," says Hanekom.

The BCG vaccine, however, is only effective at controlling TB in infants. A new vaccine has to be effective in those who spread TB the most: adults and adolescents.

The WHO lists several key benefits to successfully developing a new TB vaccine:

A significant reduction in TB incidence and deaths, as well as elimination of drug resistance to the disease
Economic benefit, in the sense that the cost of immunisation would be offset by savings in the future costs of TB treatment and macroeconomic gains. Cost-effectiveness would particularly benefit countries with a high TB incidence, such as South Africa
Improvement in health equity, by preventing TB in poorer, more vulnerable communities and promoting universal health coverage
Achievement of several UN Sustainable Development Goals (SDGs), including eradicating poverty (SDG 1), eradicating hunger (SDG 2), promoting good health and well-being (SDG 3), and promoting decent work and growth (SDG 8)
Greater investment in research and development, leading to quicker availability of TB vaccines, and from there strong public health and economic impacts

In initial trials, M72/AS01E was shown to have an acceptable safety profile, and a phase 2b trial indicated that it is 50% effective in prevention of laboratory-confirmed pulmonary TB; a subsequent sensitivity analysis showed potential efficacy of 68%. These results meet and potentially far exceed the WHO's 50% efficacy requirement for a novel TB vaccine.

But they must be confirmed by the definitive, scientifically rigorous phase 3 trial currently under way. It is a double-blind study involving 20 000 people (of whom more than 19 000 have already been enrolled), and it is anticipated to be completed in 2027 or 2028.

The Gates MRI, a non-profit organisation and subsidiary of the Gates Foundation, is sponsoring the phase 3 trial, which is supported by funding from the Gates Foundation and Wellcome. GSK is an active partner in the vaccine's development, providing Gates MRI with technical guidance and supplying the adjuvant (an ingredient used in some vaccines that can help create a stronger immune response) for the phase 3 trials and roll-out, should the trial be successful.

In addition to the work of developing the vaccine, says Hanekom, there are further challenges to overcome: incorporating adolescent and adult vaccinations into health systems that focus on administering the BCG to babies; vaccine hesitancy in target populations; and the requirements of some countries that vaccines be manufactured and tested in their jurisdictions. Also, it is difficult to quantify the potential demand for a vaccine while it is in development, which in turn could delay investment into manufacturing facilities once it is approved.

Nevertheless, Hanekom points out, vaccination is much easier – and simpler – to deploy than existing TB treatments or prevention strategies.

"There is no question: vaccination is the only way we can bring TB completely under control," he says. "The M72 trials show extraordinary promise, and it is tremendously exciting that Africa is at the forefront of developing a vaccine that may finally stop this killer in its tracks."

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