

Imaxio starts human trials with re-engineered TB antigen

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Singapore: Vaccine firm Imaxio's proprietary pro-immunogenic technology, IMX313, has been administered for the first time in humans in a tuberculosis vaccine phase I clinical study. The trial is being conducted by the Jenner Institute at Oxford University, England, and is led by Professor Helen McShane, who is the tuberculosis program leader and professor of vaccinology at the institute.

This phase I trial is a dose escalation study that aims to assess the safety and immunogenicity of the tuberculosis vaccine candidate MVA85A-IMX313, a viral vector vaccine encoding the well-known tuberculosis antigen 85A, which is fused to Imaxio's IMX313.

Imaxio's proprietary antigen re-engineering technology, IMX313, is designed to enhance the immune response and, therefore, the effectiveness of each vaccine in which it is used. IMX313 brings significant potential as a solution to develop vaccines and immunotherapies for major indications. The technology was designed in response to the challenge in increasing the effectiveness of some human and animal health candidates. It is currently used for the development of vaccine candidates indicated for influenza, *Staphylococcus aureus* infection, tuberculosis and malaria.

As the currently available vaccine, BCG, is largely ineffective at protecting against adult pulmonary disease in endemic areas, the MVA85A vaccine candidate has been designed to enhance BCG's protective efficacy. Though first studies of MVA85A were promising, a recent phase II clinical trial revealed that the vaccine candidate did not offer extra protection against TB in South African infants who had already received the BCG vaccine. The Jenner Institute is investigating a number of options to see if the immune response generated by MVA85A can be improved.

The Jenner Institute identified IMX313 as one of the best vaccine technologies to enhance immune responses in a comparison study funded by a grant from the Foundation for the National Institutes of Health (NIH) through the Grand Challenges in Global Health initiative. It is now starting to evaluate it in humans in combination with MVA85A.

Dr Fergal Hill, chief scientific officer, Imaxio, said that, "Following a number of successes with IMX313 in preclinical trials, we are really pleased to have reached this milestone: the first administration of IMX313 in humans. We believe strongly that this will confirm fully that IMX313 is a real solution for developing more effective human vaccines and for addressing major

infectious diseases."

Professor McShane said that, "We are keen to find out whether this novel vaccine candidate will pave the way for new successes in addressing tuberculosis. We think IMX313 may be a key component to help MVA85A show even greater potency in humans."