



Imaxio announces the first human clinical trial using its pro-immunogenic technology IMX313, in tuberculosis

IMX313, Imaxio's antigen re-engineering technology, has been administered for the first time in humans as part of a tuberculosis vaccine phase I clinical trial managed by the Jenner Institute at Oxford University

Lyon, France – September 3rd, 2013 – Imaxio, a biopharmaceutical company specializing in vaccines and genomics, announces today that IMX313, its proprietary pro-immunogenic technology, has been administered for the first time to humans in a tuberculosis vaccine phase I clinical study. The trial is being conducted by the Jenner Institute at Oxford University, England.

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. The study will be performed in the UK and led by Prof. Helen McShane from the Jenner Institute at Oxford University.

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, and is currently used for the development of vaccine candidates indicated for influenza, *Staphylococcus aureus* infection, tuberculosis and malaria.

Tuberculosis remains a significant cause of mortality and morbidity throughout the developing world. Worldwide, there are two million deaths each year from TB. It is estimated that a third of the world's population are latently infected with *Mycobacterium tuberculosis*, the bacteria responsible for tuberculosis. The HIV epidemic and the emergence of multi-drug resistant strains of TB have made the need for improved tuberculosis control even more urgent.

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.¹

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 through the Grand Challenges in Global Health initiative, and is now starting to evaluate it in humans in combination with MVA85A.

"Following a number of successes with IMX313 in preclinical trials, we are really pleased to have reached this milestone: the first administration of IMX313 to human", explains

Dr. Fergal Hill, Chief Scientific Officer of Imaxio. "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."

"We are keen to find out whether this novel vaccine candidate will pave the way for new successes in addressing tuberculosis", said Prof. Helen McShane, Tuberculosis Program Leader and Professor of Vaccinology at the Jenner Institute at Oxford University. "We think IMX313 may be a key component to help MVA85A show even greater potency in humans."

About Imaxio SA

Imaxio SA is a biopharmaceutical company specialized in the areas of vaccines and genomics.

Using IMX313, its antigen re-engineering technology, Imaxio is developing, both individually and with its partners, recombinant vaccines with improved effectiveness for applications in both human and animal health. In France, Imaxio already markets Spirolept®, a human vaccine indicated for preventing a work-related infectious disease, and Trolovol®, an orphan drug indicated for a congenital metabolic disease.

Imaxio's genomics division undertakes diagnostic and therapeutic research in the field of oncology and immunology, as well as providing services in the areas of human health, the agro-food business and the environment.

Imaxio was created through the merger of Diagnogene and Avidis, a spin-off from the Medical Research Council and Cambridge University in the UK. The company owns well-founded intellectual property and collaborates with numerous academic partners, including the Jenner Institute at Oxford University.

Imaxio SA is based in Lyon and at Saint Beauzire, near Clermont-Ferrand in France. It has 24 employees, twelve of whom are engaged in R&D. In 2012 it delivered a turnover of EUR 2.7 million.

For more information, go to: <http://www.imaxio.com> and <http://www.genomics-imaxio.com>

About the Jenner Institute at Oxford University

The Jenner Institute was founded in November 2005 to develop innovative vaccines against major global diseases. Uniquely it focuses both on diseases of humans and livestock and tests new vaccine approaches in parallel in different species. A major theme is translational research involving the rapid early-stage development and assessment of new vaccines in clinical trials.

The Institute comprises the research activities of over 26 Jenner Investigators who head leading research groups spanning human and veterinary vaccine research and development. Together the Institute investigators comprise one of the largest non-profit sector research and development activities in vaccinology.

The Institute is a partnership between the University of Oxford and The Pirbright Institute. The Institute is supported by the Jenner Vaccine Foundation, a UK registered charity, and advised by the Jenner Institute Scientific Advisory Board.

For more information, go to: <http://www.jenner.ac.uk/>

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ⁱ McShane H et al. Boosting BCG with MVA85A: the first candidate subunit vaccine for tuberculosis in clinical trials. *Tuberculosis* (2005) 85, 47–52.

Tameris MD et al. Safety and efficacy of MVA85A, a new tuberculosis vaccine, in infants previously vaccinated with BCG: a randomised, placebo-controlled phase 2b trial. *The Lancet*, [Volume 381, Issue 9871](#), Pages 1021 - 1028, 23 March 2013.