

Bellerophon Project awarded EUR 5.5 million by EU to develop Staphylococcus aureus vaccine

A consortium comprising Imaxio, the Jenner Institute at Oxford University, the European Vaccine Initiative and Preclin Biosystems has been awarded a major FP7 grant to support development and phase I clinical trial of an S. aureus vaccine

Lyon, France, July 1, 2013 - Imaxio, a biopharmaceutical company specialized in vaccines, together with its partners from the Jenner Institute at Oxford University, the European Vaccine Initiative and Preclin Biosystems, is pleased to announce today a European Union award of EUR 5.5 million to support the 'Bellerophon Project' consortium to develop a vaccine against Staphylococcus aureus (S. aureus).

The EUR 5.5 million funding will be used to complete pre-clinical tests as well as a Phase I clinical trial in humans in 2016. The Bellerophon Project forms part of the 2012-2013 edition of the Seventh Framework Programme initiated by the European Community for Research, Technological Development and Demonstration Activities (FP7).

The bacterium *S. aureus* causes a range of serious infections in humans. It is responsible for approximately 16,000 deaths annually in Europe and 19,000 in the US. Additional studies suggest at least EUR 380 million annual European costs attributable to S. aureus, as well as several billion USD per annum in the USⁱ. The emergence of highly antibiotic resistant *S. aureus* strains, such as MRSA (Methicillin-resistant *S. aureus*), is creating a serious public health threat around the world and an increasing economic burden. There continues to be a high unmet medical need as recent vaccine candidates have not proven effective in large human clinical studies.

The pan-European Bellerophon Project is comprised of four European institutions involved in vaccine development, each contributing specialist expertise and technology. It includes Imaxio, a French biotech company focused in immunology, which has coordinated the grant application, and the Jenner Institute at Oxford University, UK, an academic institution with key expertise on S. aureus antigens and viral vector delivery systems, which will coordinate the overall project. email: neil@ala.com

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+44-1273 675100

ANDREW LLOYD & ASSOCIATES

+33-1 56 54 07 00

The consortium also includes the European Vaccine Initiative, a non-for-profit organization based in Germany specialized in vaccine development programs and coordination of European institutions. The fourth member is Preclin Biosystems, a Swiss contract research organization that has a strong expertise in preclinical efficacy models for infectious diseases.

"We are proud that the European Commission has chosen to support the Bellerophon Project and provide funding which will enable the consortium to progress our promising technologies and to conduct a phase I clinical trial," said Alexandre Le Vert, chief executive officer of Imaxio. "This reinforces the confidence we have in our proprietary pro-immunogenic technology, IMX313, which has been evaluated as part of this application."

"We are very enthusiastic about the Bellerophon Project and are pleased to have the opportunity to contribute the Institute's expertise in viral vector delivery systems and protective *S. aureus* antigens to consortium efforts to prevent *S. aureus* infections," said Dr. David Wyllie, *Staphylococcus aureus* program leader of the Jenner Institute at Oxford University and a consultant microbiologist in Public Health England.

"Once again, we are happy to see European research teams work effectively together, combining their skills to address difficult vaccine developments," said Dr. Odile Leroy, executive director of the European Vaccine Initiative. "We sincerely hope the Bellerophon Project will pave the way for new successes in fighting antibiotic resistant infectious diseases."

"We are very proud to be part of the Bellerophon Project consortium with such prestigious partners," said Dr. Bettina Ernst, chief executive officer of Preclin Biosystems. "We strongly believe our solid infectious models will successfully push this vaccine forward through preclinical trials up to 2015."

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(R), a human vaccine indicated for preventing a professional infectious disease, and Trolovol(R), 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 between Diagnogene and Avidis, a spinoff 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: <u>http://www.imaxio.com</u> and <u>http://www.genomics-imaxio.com</u>.

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 20 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 and is the successor to the former Edward Jenner Institute for Vaccine Research. 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: <u>http://www.jenner.ac.uk/</u>

About the European Vaccine Initiative

EVI was formally established as a European Economic Interest Grouping (EEIG) by a set of statutes signed in August 2009 between the founding Universities of Stockholm and Heidelberg. In 2010 the EEIG was augmented by the following four prominent institutions: the Biomedical Primate Research Centre, Rijswijk, the Jenner Vaccine Foundation, Oxford, the Netherlands Vaccine Institute, Bilthoven and the Royal College of Surgeons in Dublin, Ireland.

EVI's mission is to contribute to the global efforts to control diseases of poverty by creating an environment conducive to accelerating the development and clinical assessment of vaccine candidates for diseases of poverty, promoting the affordability and accessibility of vaccines for diseases of poverty in low-income populations, aligning all major stakeholders and acting as a focal point to ensure the successful development of vaccines for diseases of poverty for low-income populations, and communicating to stakeholders and public the importance of EVI's work and progress towards the deployment of affordable and efficacious vaccine candidates for diseases of poverty.

For more information, go to: <u>http://www.euvaccine.eu/</u>

About Preclin Biosystems AG

Preclin Biosystems AG is a privately owned company founded in June 2008 which offers a comprehensive in vivo preclinical testing platform for the identification and validation of lead candidate therapeutics.

Its extensive range of chronic inflammatory and infectious disease models are run routinely in its core facility providing a 'one stop shop' for preclinical drug efficacy testing. Its parallel testing approach for in vivo assessment of lead candidates can provide an overall efficacy, side effect and target market analysis condensing the preclinical phase of drug development dramatically. For more information, go to: <u>http://www.preclinbiosystems.com/</u>

For further information, please contact: Andrew Lloyd and Associates Celine Gonzalez / Neil Hunter <u>celine@ala.com</u> / <u>neil@ala.com</u> Tel : +44 1273 675100

¹ Lee BY et al 2013. The economic burden of community associated methicillin resistant *S. aureus*. Clin Micro Infect 2013: 19(6):528. <u>http://www.ncbi.nlm.nih.gov/pubmed/22712729</u>.

Köck R, et al. Methicillin-resistant *Staphylococcus aureus* (MRSA): burden of disease and control challenges in Europe. Euro Surveill. 2010;15(41):pii=19688. http://www.eurosurveillance.org/ViewArticle.aspx? ArticleId=1968.