
Press Release

FAB'ENTECH launches a Phase I clinical trial in Singapore for its new product against H5N1 Avian Influenza

Specific anti-H5N1 polyclonal immunoglobulins developed by Fab'entech raise the prospect of a new approach to the treatment of H5N1 Avian Influenza in humans.

Lyon, France, 11 October 2012 - Fab'entech, a French biopharmaceutical company specialized in developing specific polyclonal immunoglobulins against emerging infectious diseases announces that the company is launching its first clinical trial in humans for its product against the H5N1 Avian Influenza virus. If promising results from animal testing are confirmed, these immunoglobulins may provide a new specific approach for the treatment of subjects infected by or exposed to the H5N1 virus.

This approach is based on passive immunotherapy which consists in injecting patients with specific antibodies (immunoglobulins) capable of recognizing, targeting and neutralizing the virus. Based on an already validated and well-established production process at industrial scale, Fab'entech is able to provide highly purified immunoglobulins to neutralize the virus .

"The phase 1 clinical trial represents an important milestone in providing a potential innovative solution to combat H5N1 virus infections in humans," said founder and CEO of Fab'entech, Dr Bertrand Lépine, MD. "The clinical trial will take place in Singapore, located in the Asia-Pacific region where the risk of propagation of H5N1 virus is one of the highest in the world. The injection of specific anti-H5N1 polyclonal immunoglobulins is likely to provide immediate protection for people who have been infected with or exposed to the virus."

The good safety profile and the efficacy of this product have been extensively documented in animal studies conducted in collaboration with the INSERM Jean Mérieux BSL-4 Laboratory of Lyon (France). The clinical trial in Singapore will involve 16 healthy adult volunteers who will be monitored for 5 weeks. It will be a double blinded, placebo controlled study, performed in strict compliance with Good Clinical Practices (GCP).

About Avian Influenza H5N1

Avian influenza is an infectious disease caused by the A(H5N1) strain of the influenza virus, which occurs primarily in birds (particularly wild water birds, but sometimes also poultry). Historically, human infections with avian influenza viruses have been extremely rare but certain H5N1 strains can cause serious infections in humans with a mortality rate that can reach 60-80% in some regions, particularly in Asia.

According to World Health Organisation (WHO), 608 human cases have been reported since 2003, including 30 human cases in the first half of 2012. The scientific community estimates that an H5N1 influenza pandemic remains a real threat, particularly if the H5N1 virus were to mutate and become transmissible between humans.

About Fab'entech

Fab'entech is a biopharmaceutical company founded in 2009 in Lyon and located at the heart of LyonBiopôle. **Fab'entech** develops and commercializes a range of innovative passive immunotherapeutic solutions based on specific polyclonal immunoglobulins using a well-established technology set up by Sanofi Pasteur, the vaccines division of Sanofi, and in collaboration with the Inserm – BSL-4 Jean Mérieux Laboratory (Lyon, France) : this approach allows Fab'entech to provide rapid responses to address public health requirements in the context of increasing risks of emerging infectious diseases with no or limited therapeutic solutions (such as H5N1 Avian flu, Crimea-Congo-Hemorrhagic Fever (CCHF) , Ebola, Nipah, Lassa, SARS, Chikungunya,...).

In collaboration with internationally recognized experts and specialist partners, **Fab'entech** has developed several innovative programmes of worldwide scope with support from public and private finance, in order to provide flexible and tailored solutions to these public health concerns.

More information at www.fabentech.com

For any further information, please contact:

- **Bertrand Lépine**, CEO, +33 (0)4 37 70 67 67
Immeuble Domilyon, 321 Avenue Jean Jaurès, 69007, Lyon, FRANCE
- Press contact : **Azizé Merle**, +33 (0)4 37 70 13 11, azize.merle@fabentech.com

Note of Caution

This press release contains forward-looking statements referring to the clinical trial and development and commercial potential of the product. Clinical testing and successful product development and commercialization depend on a variety of factors, including the timing and success of future patient enrolment, the risk of unanticipated adverse patient reactions, regulatory approval and the level of demand for the product by the medical community. Results from future studies with more data may show less favorable outcomes than prior studies, and there is no certainty that product candidates will ever demonstrate adequate therapeutic efficacy or achieve regulatory approval or commercial success. In addition, forward-looking statements regarding product development, testing and marketing costs are by the nature subject to uncertainties as a result of unforeseen difficulties and expenses which may arise.

References

- WHO. Avian influenza. Factsheet. Updated April 2011.
http://www.who.int/mediacentre/factsheets/avian_influenza/en/index.html (accessed 28/09/2012)
- CDC. Information on Avian Influenza. <http://www.cdc.gov/flu/avianflu/>. (accessed 28/09/2012)
- WHO. Cumulative number of confirmed human cases of avian influenza A(H5N1) reported to WHO as of 10 August 2012:
http://www.who.int/influenza/human_animal_interface/EN_GIP_20120810CumulativeNumberH5N1cases.pdf. (accessed 28/09/2012)
- WHO. Avian influenza: assessing the pandemic threat. January 2005 – WHO/CDS/2005.29.
http://whqlibdoc.who.int/hq/2005/WHO_CDS_2005.29.pdf. (accessed 28/09/2012)