



Press Release

The EMER-IT project led by Fab'entech, associating In Cell Art, has been granted a fund of 9, 5 million euros from OSEO.

Thanks to the developed immunoglobulins, in a near future it will be possible to fight against highly dangerous infectious emerging diseases and to develop new antiviral equine vaccines. This is an outcome of an original and innovative collaboration led by Fab'entech, engaging In Cell Art, Human Virology Department of ENS and l'institut du thorax of University of Nantes.

Paris, France, 22 February 2012 - The number of emerging infectious diseases is increasing notably over the last decades. Especially, the emergence or the reemergence of highly pathogenic viruses is observed, specifically those viruses with high pandemic potential like SARS, Ebola and Avian Flu H5N1, for which currently there is no satisfactory treatment option.

The **EMER-IT** project (IMMUNOTHERAPY against EMERGING diseases) supported by OSEO, will be able to serve a public health need and an economic necessity in a context where the sanitary shield needs to be reinforced and where the Governments promote an anti-infective political approach in order to be able to face the emerging health risks with a rapid employment of safe and innovative products supported by responsive and flexible industrial manufacturing processes.

The **EMER-IT** project is a promising collaboration which will spread over 5 years with a total budget of 20 million euros. An amount of 9,5 million euros of financial support will be provided by OSEO, 7,1 million euros of which will be received by Fab'entech, 1,2 million euros by In Cell Art and 1,2 million euros by the public laboratories.

Thus, the **EMER-IT** project will not only be able to accelerate the development of effective immunotherapy solutions against these emerging health risks but also pave the way for the production and the commercialization of these solutions.

A complete value chain will be employed for developing, producing and commercializing specific polyclonal immunoglobulins [F(ab')₂] against at least four emerging pathogens with no therapeutic solutions (such as Ebola hemorrhagic fever or Lassa, encephalitis of Nipah, SARS...). The specific polyclonal immunoglobulins in question are considered in the continuity of similar products against Crimean-Congo hemorrhagic fever virus (CCHFV) and avian influenza virus A(H5N1), currently in development at Fab'entech.

Specific polyclonal immunoglobulins directed against these emerging pathogens will be produced by Fab'entech through an ambitious immunization approach that will be implemented by using the methods of synthetic nano-vectorization of antigens in DNA form of In-Cell-Art. This process will be combined with the expertise of the Human Virology Laboratory of ENS of Lyon in the field of VLPs (Virus Like Particles) and that of the UMR-1087, University of Nantes in the field of adjuvants.

This project will also allow In-Cell-Art to initiate the development of equine influenza vaccine candidates by using these patented nanocarriers and it would lead to future applications for other species.

The production process of these immunoglobulins is historically validated, mastered and recognized internationally. The target of this project will be for Fab'entech to establish an autonomous and pilot production site in the Rhône-Alpes region. By doing so, a high-capacity purification unit of specific immunoglobulin polyclonal will be put in place by utilizing innovative and advanced equipment (disposable solutions, etc...) unique to this type of activity.

In regard to public health, the project has two main targets; on the one hand the project will produce immunotherapeutic solutions to the currently affected countries and thereby providing relief to public and health workers in their fight against a potential pandemic, on the other hand the project will function as a reinforcement of a sanitary shield for those countries which are threatened by the spread of the emerging infectious diseases in question.

Claude Pinault, Director of the *Strategic Industrial Innovation Program of OSEO* comments:

« *The assistance provided to the **EMER-IT** project is part of the ISI (Strategic Industrial Innovation) program whose purpose is to help collaborative projects engaging at least two French SME's which must contribute to create or to strengthen new European or world champions. This project proposed by Fab'entech alongside its three partners, ideally meets all the criteria required. We are very pleased to contribute to the advancement of this project that we deem extremely promising* ».

A national project of international standards, **EMER-IT** fosters the synergy and the complementarity between its partners that intervene at different phases of the value chain with their complementary expertise:

- **Fab'entech (Lyon)**, the leader of the **EMER-IT** project, brings its expertise in the development and the production of the specific polyclonal immunoglobulins [F(ab')₂] which will be later produced in an autonomous and pilot production site.
- The company **In-Cell-Art** (Nantes) employs its patented nanocarriers which can dramatically increase the expression and immunogenicity of the gene-encoded antigen to support this consortium. **In-Cell-Art** also contributes to the conceptualization and the development of new generation of immunogens for the production of specific polyclonal immunoglobulins and the development of veterinary DNA vaccines.
- **The INSERM Jean Mérieux BSL-4 Laboratory of Lyon** brings unrivaled scientific expertise on risk group 4 agents and also its technical capacity required for the implementation of experiments on highly pathogenic agents.

- **The Human Virology Laboratory, Inserm U758 - ENS of Lyon and l'institut du thorax, Inserm UMR 1087-CNRS UMR 6291 - University of Nantes** undertake the development of VLP (Virus-Like Particles) and new adjuvants in synergy with DNA vaccination of In -Cell-Art.

Beyond these project partners directly supported by OSEO, the **EMER-IT** project will also engage partners like IDD Biotech and other industrial partners in the region which will be intervening in the industrialization phase of the project.

*«The complementarity of these internationally recognized partners will enable us to respond rapidly to growing challenges in the fight against emerging diseases by retaining all the flexibility and the responsiveness required to control the infectious pathologies related to highly dangerous and potentially mutative viruses », underlines Dr. Bertrand Lépine, the founder and the CEO of Fab'entech, and adds: « I thank all the partners of the **EMER-IT** project, LyonBiopôle and the OSEO teams for their confidence and contribution to this ambitious project. We are assured that this project will bring effective and adapted solutions in our fight against emerging diseases ».*

About «Strategic Industrial Innovation » Program of OSEO

The "Strategic Industrial Innovation" (ISI) program promotes the emergence of European champions. It supports industry-oriented collaborative projects of innovation, proposed by innovative medium-sized companies and SMEs. These projects are very promising for success: they aim to market technological breakthrough products which could not be achieved without public funding. The aid is an amount of 3 to 10 million euros in the form of grants and repayable advances. In 2011, 13 ISI projects were funded by OSEO with an aid amounting to 107 million euros.

Between 2006 and 2010, since its inception, OSEO has funded 73 collaborative projects in the ISI program for a total aid of 1,477 million euros. These projects supported 356 companies and 198 public research organizations.

For further information, please go to www.oseo.fr

About Fab'entech

Founded in 2009 in Lyon and located at the heart of LyonBiopôle, Fab'entech is a biopharmaceutical company which develops and commercializes a range of innovative passive immunotherapeutic solutions based on specific polyclonal immunoglobulins [F(ab')₂] in the field of emerging infectious diseases, as well as certain drug intoxications.

Against increasing risks of emerging diseases such as Avian flu H5N1, CCHF, Ebola, Nipah, Lassa, SARS, Chikungunya, etc. and to risks of bioterrorism, Fab'entech proposes the development of flexible and tailored specific polyclonal immunoglobulins that can respond quickly, in a field with no or limited therapeutic solutions.

Thanks to its historical partners, namely Sanofi Pasteur, the vaccines divisions Sanofi and the Laboratory P4 Inserm, Jean-Mérieux, Fab'entech has the unique opportunity to capitalize on the well-established process developed by sanofi pasteur, and also could enjoy the indispensable collaboration of the Laboratory P4 Inserm, Jean Mérieux.

For further information, please go to www.fabentech.com

About In-Cell-Art

In-Cell-Art (Nantes, France) is a biopharmaceutical company specializing in the preclinical and pharmaceutical development of nanocarriers for macromolecules (DNA, RNA and Protein). Including a Nobel Prize Laureate among its founders and its research teams, the company has developed new classes of nanocarriers which enable macromolecules to cross the cell barrier efficiently and safely. In-Cell-Art employs its nanocarrier technologies to develop innovative prophylactic and therapeutic vaccines, and discover novel antibodies against challenging targets.

In-Cell-Art operates in an ideal environment to work for these innovative projects of public health. The company is linked to The Institute of Thorax from which the research teams and the founders of Atlanpôle Biotherapies Competitiveness Center are originated.

In-Cell-Art has partnerships with major pharmaceutical firms including Sanofi Pasteur and Merial. Today with these collaborations and over 150 different novel antibodies against challenging targets, In-Cell-Art possesses unique expertise in the development of innovative prophylactic and therapeutic vaccines and the discovery of novel antibodies.

For further information, please go to <http://www.incellart.com/>

About INSERM Jean Mérieux BSL-4 Laboratory

The INSERM Jean Mérieux BSL-4 Laboratory is a high containment laboratory, located in Lyon and dedicated to the study of risk group 4 pathogens. The biosafety level 4 is the highest biosafety containment which is designed and managed to protect workers from accidental contamination and to avoid any spread of the pathogens into the environment. Researchers are working equipped with a positive air pressure suit and the laboratory itself is maintained under negative pressure. This laboratory is still the structure of this containment level with the greatest capacity for experimentation in Europe.

Created in 1999 by the Foundation Mérieux, according to the will of Dr. Charles Mérieux then in the charge of Inserm in 2004, the laboratory became, at the initiative of Inserm, a major research infrastructure open to entire national and international scientific community who have the need, as part of their developments, to manipulate risk group 4 pathogens. The activities conducted in the laboratory P4 are in the areas of research referred to fundamental or much finalized, diagnosis and management of pathogen collections. Currently, more than a dozen scientific teams of French or foreign origin, active in public and private sector, utilize the Inserm Jean Mérieux BSL4 laboratory.

For further information, please go to <http://www.cervi-lyon.inserm.fr/>

About the Laboratory of Human Virology, Inserm U758 - ENS of Lyon

The Laboratory of Human Virology, directed by François-Loïc Cosset, is a joint unit of the National Institute of Health and Medical Research (INSERM) and the Ecole Normale Supérieure of Lyon (ENSL). The unit consisting of 8 teams work closely together with other institutes and laboratories of Lyon-Gerland campus conducts researches on the biology of several human viral pathogens: Epstein-Barr virus (EBV), Human Immunodeficiency Virus syndrome (HIV), adult leukemia virus (HTLV), Ebola virus, Nipah virus, measles virus and hepatitis C virus (HCV).

All the projects, particularly rich in terms of both approaches considered in regard to studied viruses, contributes greatly to elucidate the fundamental mechanisms and to identify new targets and therapeutic strategies. These different development programs are supported by ANRS (National Agency for AIDS Research), European Union, the National League against Cancer, ARC (Association for Research on Cancer), the NIH (National Institute of Health), the MENRT (Ministry of National Education, Research and Technology) or through contracts with industrial firms.

For further information, please go to <http://hvd.ens-lyon.fr/>

About l'institut du thorax, UMR 1087-CNRS 6291, University of Nantes

L'institut du thorax, UMR 1087-CNRS 6291 of University of Nantes was re-created on January 1st, 2012 in Nantes. Former UMR_S915, originating from the laboratory of Physiology, Pathophysiology and Molecular and cellular pharmacology of Inserm U533, was created on January 1st 2000 by Denis Escande.

The team Innovations in Biotherapies involved in the **EMER-IT** project aims at developing new tools for diagnosis and therapy. Led by Bruno Pitard, the team is dedicated to the rational development of nanovectors for intracellular transport of biological macromolecules and their clinical translation.

L'institut du thorax played a key role in the development of the company In-Cell-Art (founded in 2006), a major partner of the project that uses the patents taken by the scientific founders Bruno Pitard, Pierre and Jean-Marie Lehn.

For further information, please go to <http://www.umr1087.univ-nantes.fr/>

Note of Caution

This release and the information contained herein do not constitute an offer to sell or subscribe or a solicitation of an offer to buy or subscribe for shares of Fab'entech in any country. This press release contains forward looking statements about the objectives of the Company that are based on current expectations and assumptions of management of the company and are subject to risk factors and unpredictable uncertainties, which, if proved, could call into question the objectives mentioned above.

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