TREATMENT OF THE FIRST HIV POSITIVE PATIENT IN ABIVAX'S PHASE IIA CLINICAL TRIAL WITH ABX464

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Details

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ABX464's innovative mechanism of action could produce a long lasting reduction in the viral load in patients

ABX464 could be administered less frequently and for shorter periods than current HIV treatments due to its long lasting impact on viral load

Paris, February 2nd, 2015 – ABIVAX, a leading clinical stage biotech company developing and commercialising anti-viral compounds and human vaccines, today announced that enrolment has been initiated and the first HIV positive patient dosed in a Phase IIa clinical trial of ABX464.

ABX464 is a novel, small molecule inhibiting HIV replication through an entirely new mechanism. For the first time in the treatment of AIDS, this molecule could deliver a long lasting reduction of the viral load after a treatment of only a few weeks.

In collaboration with the team of Professor Jamal Tazi at the CNRS in Montpellier, France, ABIVAX designed ABX464 to lead to a clinically relevant improvement in HIV therapy. ABX464 inhibits the biogenesis of viral RNA required for the replication of the HIV virus, a mechanism of action never before explored.

In pre-clinical reference models of HIV, ABX464 has proven its unique ability to induce a substantial reduction in viral load that persists for weeks after treatment arrest. Such an anti-viral effect has never been observed with existing treatments.

With current HIV treatments, the virus starts multiplying again as soon as the drugs are withdrawn, which typically means daily, life-long treatment for patients.

Additionally, in pre-clinical tests, the HIV virus did not develop any resistance to ABX464.

Pending confirmation in clinical trials, this unique mode of action and preclinical data to-date suggest that ABX464 could:

- Induce long term control of the viral load
- Not induce HIV mutants that are resistant to treatment
- Be less frequently administered over a shorter period than standard treatments; providing the potential to reduce healthcare costs and offer broader access to treatment

Having reviewed the complete current data package for ABX464, Professor Mark Wainberg, M.D., former President of the International AIDS Society and one of the top HIV experts worldwide, summarized his perspective on this novel candidate drug by saying: "If these unique features of ABX464 are confirmed in the clinical development program in HIV patients that is now underway, ABX464 could become the central element of a functional cure for AIDS."

The randomized, double-blind placebo-controlled clinical study, which is being conducted in Mauritius, is the first one of ABX464 in HIV patients and is designed to assess the safety and efficacy of the compound. It follows the successful completion of a Phase I clinical study in human volunteers in December 2014, which demonstrated that ABX464 was generally safe and well tolerated and had a favourable pharmacokinetic profile.

For the present study, 80 treatment-naïve patients will be enrolled into ten cohorts with six patients receiving ABX464 and two participants receiving placebo in each cohort. Five doses (25, 50, 75, 100 and 150mg) and two dosing frequencies (every day and every three days) will be tested. Treatment duration is two weeks and may be extended to three. The viral load will be monitored before, during and after treatment. The study's clinical endpoints are: safety, viral load in the blood and CD4 and CD8 cell counts.

The study aims to allow ABIVAX to narrow the dose and frequency of administration for the subsequent clinical phase IIb study development planned for the second half of 2015.

Professor Hartmut Ehrlich, M.D., CEO of ABIVAX, said: "We are pleased with the progress we are making with ABX464, and we are confident that 2015 will be a pivotal year for this flagship product. We look forward to reporting the data from this Phase IIa study, particularly ABX464's ability to produce a sustained reduction in viral load. With its unique mode of action, ABX464 could dramatically improve the treatment options for patients with HIV."

And Professor Tazi added: "Our platform targeting viral messenger RNA is a new approach in blocking the reproduction of a virus. It provides us with several very promising candidate molecules against HIV and other human pathogenic viruses."

ABX464 is the first candidate molecule coming from ABIVAX's proprietary technology platform and chemical library. It has been generated from an in-depth understanding of the processing of viral RNA within the human host cell and the ability of compounds from its novel library to block the biogenesis of viral RNA.

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About ABIVAX

ABIVAX is an advanced clinical stage biotech company focused on becoming a global leader in the discovery, development and commercialisation of anti-viral compounds and human vaccines to treat some of the world's most important infectious diseases, including HIV/AIDS and chronic Hepatitis B.

ABIVAX has 2 compounds in clinical stage research: ABX464 a novel small molecule against HIV with a number of important potential competitive advantages, and ABX203, a therapeutic vaccine candidate that could be a cure for chronic hepatitis B. The broader ABIVAX portfolio includes additional anti-viral compounds and vaccines that may enter the clinical stage in the coming 18 months.

ABX464 has been developed using ABIVAX' anti-viral platform that allows the Company to address a broad range of viral targets involved in the production and management of viral RNA within the host cell. ABIVAX also has access to a number of cutting edge technologies including complex molecular protein/RNA-pro interactions to discover and develop proprietary breakthrough therapies to help patients' clear important pathogenic viruses.

Headquartered in Paris, France, ABIVAX conducts its research and development in Évry (France) and Montpellier (France). In addition, ABIVAX benefits from long term partnerships with the Cuban Center for Genetic Engineering and Biotechnology (Havana, Cuba), The Finlay Institute (Havana, Cuba), the Molecular Genetics Institute of Montpellier (CNRS-Université de Montpellier, France), the Curie Institute (Paris, France), the Scripps Research Institute (La Jolla, CA, USA), the University of Chicago (Chicago, IL, USA), Brigham Young University (Provo, UT, USA), Institut Curie (Paris, France) and the Institut Pasteur (Paris, France). ABIVAX intends to pursue further business development opportunities to access commercial products as part of its overall corporate strategy.

ABIVAX was founded by Dr. Philippe Pouletty, M.D. , managing partner at Truffle Capital, the cornerstone investor in ABIVAX since its creation.

For more information, please visit the company's website: www.ABIVAX.com

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