

DIAXONHIT – HIV tests

Encouraging results of the first clinical study of the VAC-3S vaccine against HIV, for which DIAXONHIT develops a companion diagnostic

Paris, France – July 30, 2015 - DIAXONHIT (Alternext: ALEHT, FR0004054427), a French leader in specialty in-vitro diagnostics for transplantation, infectious diseases and cancer, announces that InnaVirVax, the company with which it currently develops a companion diagnostic for the VAC-3S vaccine within the PROTHEVIH program, released encouraging results of the IVVAC-3S/P1 clinical study during the International AIDS Society Symposium held in Vancouver on July 18 and 19, 2015.

Encouraging results of the IVVAC-3S/P1 study

The primary endpoint of this phase 1 study was met. The VAC-3S immunotherapy was well tolerated and immune response was observed as expected with a strength clearly linked to dose. Additionally, vaccination with VAC-3S triggered favorable immunovirologic effects, as measured by the leading four biomarkers of disease progression.

Correlated with immune response to VAC-3S, a decrease in proviral DNA, the most studied biomarker of viral load, was observed.

Furthermore, the following observations were made in responders 24 weeks after initial vaccination:

- The percentage of CD4+ T lymphocytes, usually destroyed by the HIV virus, increased (biomarker of such T lymphocytes reservoir);
- The percentage of CD8+ T lymphocytes decreased (biomarker of immune activation);
- The ratio CD4/CD8 increased (biomarker of immune system restoration in HIV infected patients).

Such results are promising. InnaVirVax indicated that if the favorable changes in these four biomarkers were confirmed in other studies with a higher number of patients, it could potentially lead to VAC-3S being used to restore immune functions in immunodeficient patients. This positions VAC-3S vaccination as a functional cure in order to enable HIV infected patients to control their viral load without antiretroviral treatments.

VAC-3S is currently in phase 2a within the IPROTECT1 clinical study which was initiated in December 2013.

Two diagnostic tests developed by DIAXONHIT

Synergistically with VAC-3S development, DIAXONHIT is currently developing two tests with its diagnostic know-how in the PROTHEVIH consortium:

- DIAG-3S, a diagnostic test for the detection of anti-3S antibodies naturally secreted by patients infected by the HIV-1 virus. One of DIAXONHIT's objectives is to validate the use of the level of natural anti-3S antibodies measured by this test as an early marker of disease progression, thus enabling optimized care of HIV-1 infected patients. The DIAG-3S prototype test should be completed during the first half of 2016. Upon completion and validation, commercialization of the test could start independently of the VAC-3S vaccine development;
- CO-3S, a companion diagnostic for the VAC-3S vaccine which measures the level of anti-3S antibodies in vaccinated patients. This test will enable doctors to measure the immune response to the vaccine therapy, and adjust it accordingly.

“These promising results with the VAC-3S vaccine are a strong encouragement to move ahead with its clinical development for a functional cure, the new frontier in this therapeutic indication, and we are looking forward to getting the results of the phase 2a study.” said Joel Cruzet, CEO of InnaVirVax.

“These first results are positive and are a real motivation for all members of the PROTHEVIH consortium, and DIAXONHIT in particular. If the VAC-3S vaccine confirms its potential to enable HIV infected patients to control their viral load without using the current antiretroviral treatments, the potential market for both tests under development would grow significantly. Like InnaVirVax, we are also looking forward to getting the results of the on-going phase 2a clinical study.” concludes Dr. Loïc Maurel, President of the Management Board of DIAXONHIT.

About InnaVirVax

Based in the Evry Genopole, InnaVirVax is a biopharmaceutical company dedicated to research and development of therapeutic solutions for major infectious and chronic pathologies. InnaVirVax lead project, VAC-3S, aims at developing an immunotherapy for HIV infections. Incorporated in 2008, the company received the support of the French Ministry for Higher Education and Research, BPIfrance, the French National Agency for Research, the Francilian Center for Innovation, the Essone General Council as well as the Isle-of-France Region and several funds including CapDecisif, G1J Isle-of-France, FaDiese, FRCI and Pradeyrol Research-Development. For more information, please visit: <http://www.innavirvax.fr>.

About DIAXONHIT

DIAXONHIT (NYSE Alternext, FR0004054427, ALEHT) is a French fully integrated leader in *in vitro* diagnostics, involved from research to commercialization of specialty diagnostic products in the fields of transplantation, infectious diseases and cancer. With many partnerships and a strong presence in hospitals, DIAXONHIT has an extensive commercialization network. Through its affiliate, InGen, it commercializes and services, mostly under exclusivity agreements, *in-vitro* diagnostic kits and advanced equipment, quality control products and rapid tests, including Tetanus Quick Stick®, a proprietary product. InGen is the leading supplier in France of HLA tests manufactured by Thermo-Fisher/One Lambda, of which it is the largest commercial partner worldwide. The group also owns a diversified portfolio of products in development, including both innovative molecular and non-molecular diagnostics, covering its three main specialty areas: transplantation, immuno-infection and cancer. DIAXONHIT headquarters are located in Paris and its affiliate in the Paris region. The Group is listed on NYSE Alternext in Paris and is part of both the NYSE Alternext OSEO Innovation and the Next Biotech indices. For more information, please visit: <http://www.diaxonhit.com>

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