diaxonhit
Specialty Diagnostic Solutions

Press Release

DIAXONHIT - AlloMap® Heart Transplant Surveillance Solution

Clinical utility and performance of the AlloMap® heart transplant test confirmed in European study

- CARGO II clinical study confirms performance of AlloMap® in European patients
- New opportunities for expanded use of AlloMap® in order to improve performance of rejection diagnostics

Paris, France – June 3, 2015 - DIAXONHIT (Alternext : ALEHT, FR0004054427), a French leader in specialty in-vitro diagnostics for transplantation, infectious diseases and cancer, today announced the results of a European-based clinical study confirming the utility and performance of the AlloMap® test. Results from the CARGO II study, which evaluated the use of AlloMap in 594 heart transplant patients, demonstrated performance similar to previously published experience in the United States.

AlloMap® is an innovative molecular blood test that was exclusively licensed to DIAXONHIT by CareDx, Inc. for commercialization in Europe. Following a heart transplant procedure, this test enables routine, non-invasive surveillance of acute cellular rejection, thereby assisting clinicians in the care and management of patients.

CARGO II clinical study confirms the utility of AlloMap®

CARGO II (Cardiac Allograft Rejection Gene Expression Observational II) is a prospective, observational, multicenter clinical study. Its main objective was to confirm the results of the first CARGO study, which was used to validate the performance of the AlloMap® test with US patients. CARGO II involved more than 17 centers, 13 of which were located in Europe. These results were the basis for the test's 510K filing with the FDA and CE marking.

In the study, blood samples for AlloMap® testing were collected during post-transplant surveillance visits beginning at least 55 days after heart transplantation, with or without cardiac biopsy. After analyzing the samples, the test result was provided as a unique score ranging from 0 to 40, with high values indicating a greater risk of acute cellular rejection.

Moderate to severe acute cellular rejection (i.e., histopathology analysis of biopsies showing a grade greater than or equal to 3A according to the ISHLT[1] grading system) were reported by pathologists in 106 out of 3324 biopsies (3.2%), in 79 out of 594 patients (13.0%). Taking into account these observations, the study shows that the negative predictive value of AlloMap® is greater or equal to 99.0% for AlloMap® scores less than 34. This threshold is therefore associated with a low risk of moderate to severe acute cellular heart graft rejection.

[1] International Society for Heart and Lung Transplantation

Ultimately, the CARGO II results confirm those of the initial CARGO study performed in the United States and demonstrate the utility of AlloMap in ruling out moderate to severe acute cellular allograft rejection.

"*The results of the CARGO II study show the value of performing the AlloMap® test on European heart-transplant patients, adding to the existing publications which have clearly demonstrated this in North America. This will certainly be helpful for centers in Europe that are planning to introduce AlloMap® as part of their surveillance on heart transplant patients.*" said Dr. Uwe Schulz, MD, Head of Transplant Unit, Dpt. of Thoracic and Cardiovascular Surgery, Heart and Diabetes Center NRW, Ruhr University of Bochum, in Bad Oeynhausen, Germany.

New opportunities for future use of AlloMap®

During a symposium organized by Diaxonhit and CareDx during the last annual meeting of ISHLT in Nice, France, several presentations were made by European and US transplant cardiologists:

- *Use of AlloMap® in the antibody mediated rejection era: application of EIMAGE results and Cedar-Sinai experience* by Jon Kobashigawa, MD, Director of the Heart Transplant Program of the Cedars-Sinai Heart Institute and Professor of Medicine at the Cedars-Sinai Medical Center, Los Angeles, California ;
- *New CARGO II results from Bad Oeynhausen* by Uwe Schultz, MD ;
- *Presentation of the PRME study, a multicenter AlloMap® trial* by Laurent Sebbag, MD, cardiologist in the heart transplant Center of the Hospices Civils in Lyon, France ;
- *Evolution of AlloMap® use at Baylor University Medical Center, Dallas* by Shelley Hall, MD, Medical Director Cardiac Transplant and Mechanical Circulatory Support Programs ;
- *Use of cell-free DNA in the detection of heart transplant rejection (and new findings with AllomMap®)* by Jon Kobashigawa, MD.

In parallel, several posters related to AlloMap® were presented during the scientific sessions of the congress.

Beyond analyses of the CARGO II study results, these presentations highlighted the growing use of AlloMap® in the US as a clinical tool for the surveillance of heart transplant patients. Also, several leads for new uses of the test were described, specifically the combination of AlloMap® with the measure of donor-specific cell-free DNA which improves the performance of the test, or an analysis of correlations between AlloMap® scores and long-term outcome for patients, which could give a new predictive role to the test.

"*With a central laboratory becoming operational soon in Strasbourg, France, DIAXONHIT will be able to duplicate the testing practice already conducted by CareDx in the US, and provide AlloMap® testing to European patients for whom the performance of the test was confirmed in the CARGO II study. The results that were presented during the second joint symposium at this year's ISHLT congress organized by DIAXONHIT and CareDx are quite encouraging as they confirm a more routine use of the test in several US centers and already present potential new uses of AlloMap® that should further benefit heart transplant patients.*" concludes Dr. Loïc Maurel, President of the Management Board of Diaxonhit.

About AlloMap®

AlloMap Molecular Testing is intended to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment. AlloMap is performed in the CLIA-certified and CAP-accredited clinical laboratory at CareDx and has been commercially available in the United States since 2005. AlloMap was cleared by the U.S. Food and Drug Administration in 2008 and was CE marked for the European Union in 2011. Recommended use of AlloMap for heart transplant rejection surveillance is included in the International Society for Heart and Lung Transplantation (ISHLT) Guidelines for the care of heart transplant recipients, published in August, 2010. These guidelines represent the worldwide standard for the care of heart transplant patients.

About CareDx

CareDx, Inc., based in Brisbane, California, is a molecular diagnostics company focused on the discovery, development, and commercialization of clinically differentiated, high-value, non-invasive diagnostic surveillance solutions for transplant recipients. The company has commercialized AlloMap, a gene expression test that aids clinicians in identifying heart transplant recipients with stable graft function.

For more information, please visit: www.caredx.com.

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

Symbol : ALEHT - ISIN Code: FR0004054427 - Reuters : ALEHT.PA - Bloomberg : ALEHT:FP

Disclaimer

This press release contains elements that are not historical facts including, without limitation, certain statements about future expectations and other forward-looking statements. Such statements are based on management's current views and assumptions and involve known and unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those anticipated. In addition, Diaxonhit, its shareholders, and its affiliates, directors, officers, advisors and employees have not verified the accuracy of, and make no representations or warranties in relation to, statistical data or predictions contained in this press release that were taken or derived from third party sources or industry publications, and such statistical data and predictions are used in this press release for information purposes only. Finally, this press release may be drafted in the French and English languages. If both versions are interpreted differently, the French language version shall prevail.

Contacts

DIAXONHIT
Hervé Duchesne de Lamotte, CFO, +33 (0)1 53 94 52 49, herve.delamotte@diaxonhit.com

CareDx, Inc.
Peter Maag, +1 415-287-2322, pmaag@caredx.com

NewCap
Julien Perez, Investors Relations & Financial Communication, +33 (0)1 44 71 98 52, jperez@newcap.fr
Annie-Florence Loyer, Media Relations, +33 (0)1 44 71 98 50, afloyer@newcap.fr