diaxonhit
Specialty Diagnostic Solutions

Press Release

DIAXONHIT – Thyroid cancer test

CITHY clinical study starts for Dx15 molecular test validation

- Diagnostic prospective multicenter study with approximately 1,000 patients
- European positioning of the test with about 20 clinical centers
- First patients already included
- At stake: a reduction in the number of unnecessary thyroid surgeries

Paris, France – November 18, 2014 - DIAXONHIT (Alternext : ALEHT, FR0004054427), a French leader in specialty in-vitro diagnostics for transplantation, infectious diseases and cancer, announces that the clinical study for the validation of Dx15, a molecular test for thyroid cancer, recently started. The goal of Dx15 is to enable surgeons to assess the benign or malignant status of a thyroid nodule when cytological analysis remains indeterminate. DIAXONHIT is the sponsor of this study entitled CITHY (Cytologie Indéterminée de la THYroïde - Indeterminate Thyroid Cytology), which received a favorable opinion from regulatory authorities. As of October 31, 2014, the first patients were already included in France.

In 2012, the Caisse Nationale d'Assurance Maladie (French CMS) found that 7,270 thyroid ablations were performed in France, while identified nodules that were analyzed post-surgery were benign. To avoid such unnecessary, costly and invasive surgeries, a sample from the suspicious nodule is collected by fine needle aspiration and analyzed by a cytopathologist. However, approximately 20% of such analyses remain inconclusive since the benign or malignant status cannot be determined. The objective of DX15 is to perform a more detailed molecular analysis of indeterminate samples in order to minimize unnecessary surgeries. In this context, such a test would bring considerable benefit to both patients and payers.

DIAXONHIT successfully completed the first two phases of development of DX15. During an initial feasibility study, more than 200 biomarkers that showed a statistically significant difference between benign and malignant nodules, were first identified. It was followed by an identification phase in which several very promising transcriptomic signatures were selected, with different molecular profiles than those of US competitors. With the CITHY clinical study, the final stage of development aims at determining DX15 clinical performance on a statistically significant basis.

In this context, the CITHY study will recruit approximately 1,000 patients in twenty European clinical centers, all experts in the diagnosis and monitoring of thyroid cancer. This positioning, deliberately expanded at the beginning of the validation study, allows DIAXONHIT to collaborate at onset with a panel of leading experts in Europe. It should also enable a greater number of patients to rapidly benefit from DX15 as soon as validated.

"*I want to congratulate our teams who completed on schedule the steps required to initiate the CITHY study. The enthusiasm of clinicians for DX15 is an encouragement to focus our efforts so that this test be made quickly available to thyroid cancer specialists. DX15 will strengthen our portfolio of diagnostic tests in the growing specialty field of oncology.*" said Dr. Loïc Maurel, President of the Management Board of Diaxonhit.

Professor Jean-Louis Wémeau of the University Hospital in Lille, CITHY study coordinator for France, added: "*The cytology of thyroid nodules, now codified according to the Bethesda classification, has become a key examination in order to define subsequent patient care. However, in a significant number of cases, this analysis ends up being indeterminate, and the benign or malignant nature of the thyroid sample cannot be identified. In this context, the contribution of a new molecular test such as DX15 could be very valuable, and the CITHY study will allow us to evaluate its clinical utility*. "

About the CITHY study

The CITHY clinical study (Cytologie Indéterminée de la THYroïde - indeterminate thyroid cytology) is a multicenter prospective diagnostic study. The main objective of this blind study is to validate the diagnostic performance of DIAXONHIT's DX15 molecular test on transcriptomic signatures, previously identified on separate cohorts of samples, for the determination of the malignant or benign status of thyroid nodules which cytology proved indeterminate. The target population includes categories III (atypia of indeterminate significance or follicular lesion of indeterminate significance (AUS / FLUS)) and IV (follicular neoplasm or suspicion of follicular neoplasm (FN / SFN)) of the Bethesda classification. This study received a favorable opinion from the Ethics Committee on July 1, 2014 and authorization from ANSM (French health authority) on August 6, 2014.

The study plans to include about 1000 patients in twenty European investigation centers, all experts in the diagnosis and monitoring of thyroid cancer. All patients will be followed until obtaining the malignancy or benignity status of nodules, that will be subject to cytology following a fine needle aspiration, by histological analysis of the surgical specimen or, in its absence, of clinical monitoring. The duration of the inclusion period is estimated at about 14 months.

Monitoring of patients who underwent surgery will be performed until histological results are provided. For no-surgery patients, monitoring will last for a minimum of one year from inclusion. The clinical assessment of patients without surgery will continue for up to 12 months after the last patient enters the study in order to benefit from extended follow-up for patients entering early into the study. Given the length of monitoring, the total duration of the study should be approximately 26 months from the first recruitment.

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

Contacts

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

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.