diaxonhit
Specialty Diagnostic Solutions

Press Release

DIAXONHIT – Prosthetic joint infections test

DIAXONHIT announces the CE marking of the BJI InoPlex® test and its commercial launch

- The first and only non-invasive serological test with a simple blood sample
- Launched in France through InGen, DIAXONHIT Group's commercial affiliate
- Upcoming European launch through already selected distributors

Paris, France – January 14, 2015 - DIAXONHIT (Alternext : ALEHT, FR0004054427), a French leader in specialty in-vitro diagnostics for transplantation, infectious diseases and cancer, announces today that the CE marking of its BJI InoPlex® diagnostic test, the first blood test to aid in the diagnosis of prosthetic bone and joint infections, was completed late 2014 as scheduled. This regulatory step concludes the test development cycle, and opens the way to commercialization by DIAXONHIT. The launch of BJI InoPlex® is planned for the first quarter 2015, directly through InGen in France and through distributors in Europe.

BJI Inoplex® : a unique and innovative test

BJI InoPlex® is the first diagnostic test that can detect in patients' blood antibodies against several bacteria types frequently responsible for prosthetic infections, in particular staphylococcus, the most often encountered type in such infections.

BJI InoPlex® performance was confirmed in a clinical validation study conducted in two French reference centers for prosthetic joint infections, and were presented at the 34th RICAI meeting last November in Paris. During a symposium that gathered more than 200 participants, three specialists involved at different stages of prosthetic infections care presented the test and its use: Professor Eric Senneville, head of infectious and tropical diseases and infectiologist at the Tourcoing Hospital, Dr. Martin Rottman, microbiologist at the Raymond Poincaré Hospital (Paris Hospitals, AP-HP) and Dr. Thomas Bauer, orthopaedic surgeon at the Ambroise Paré Hospital (AP-HP) and study investigator. The speakers stressed the importance of improving current care of patients who developed prosthetic complications, whether mechanical or infectious. The speakers also stressed the importance of BJI InoPlex® in the diagnostic process in order to provide quick results and to propose a more appropriate therapy, treatments for mechanical complications being very different from those needed to treat infections.

BJI InoPlex®: in-house manufacturing

DIAXONHIT will manufacture in-house the BJI InoPlex® kit that includes all parts needed to perform the test on Luminex equipment. Kit manufacturing will be performed under quality assurance, based on compliance with ISO 13485 for which the DIAXONHIT Group is certified.

BJI InoPlex®: launch and initial commercialization in Q1 2015

DIAXONHIT is launching BJI InoPlex®. Commercialization in France is undertaken by its subsidiary InGen, leader in France for diagnostic tests related to transplantation and histocompatibility which, for the most part, are also performed on Luminex instruments. Beyond marketing the test, for which a medical expert was recruited, InGen will be in charge of sales administration, logistics for suppling kits to laboratories, reagent rental of Luminex instruments when necessary, and servicing.

For Europe, commercialization of the test will be undertaken through exclusive distribution agreements with distributors which DIAXONHIT already met and selected in November 2014 at the MEDICA convention in Düsseldorf, Germany, where the company had a booth.

BJI InoPlex®: an important step to accelerate DIAXONHIT's European Development

With the launch of this new proprietary test that strengthens its existing range of specialty diagnostic tests, DIAXONHIT further implements its development strategy.

In the coming years, the Group's objective is to become a European leader in specialty diagnostics and to achieve financial break-even by gradually increasing the share of proprietary products sales. This increase is directly linked to the innovation strategy and to R&D investments undertaken by DIAXONHIT in recent years.

After BJI InoPlex® should thus follow the DX15 test in thyroid cancer, but also the extension of the "InoPlex" range to other infectious indications.

"CE Marking BJI InoPlex® is a key step in the life of our group and a perfect illustration of our positioning in specialty in-vitro diagnostics. I would like to thank all our employees who participated in the development of this test, and took him to the gates of commercialization within the announced deadline. They demonstrate our ability to develop innovative high-value in-vitro diagnostic products and to strengthen our portfolio of marketed products. In early 2015, we will continue our innovation and business development by building on the strengths of our group, especially those that allow us to successfully implement our strategy. " concludes Dr. Loïc Maurel, President of the Management Board of Diaxonhit.

About BJI InoPlex® performance and clinical utility

Each year, nearly 3 million implants are placed in Europe and the United States, including more than 220,000 hip and knee replacements in France. About 10 to 20% of all patients undergoing replacements may experience pain or functional impairment, even long after implant surgery. Identifying whether the cause of such dysfunction is infectious or mechanical is key to prescribe the relevant treatment. Currently, diagnostic tools available to diagnose prosthetic infections have limited performances, resulting sometimes in unsuitable patient care and late diagnosis. Given that therapeutic strategies are quite different if the dysfunction is infectious or mechanical, it is critical for the surgeon, the infectiologist and the microbiologist to identify an infection prior to surgery.

BJI InoPlex® is a new test that provides qualitative information in a couple of hours for each targeted bacteria types, which enables caregivers, in association with the usual assessments, to accelerate and improve the care of patients. The performance of BJI InoPlex® compared with microbiological results on intraoperative samples are respectively 82.2% for specificity and 75.9% for sensitivity, all types of targeted staphylococci included. Other bacteria targeted by BJI InoPlex® are less frequent in the prevalence of prosthetic infections, and the incidence of proven intraoperative infections with these bacteria also ended up being limited in the study cohort. The high specificity of the test for these two families of bacteria (B-Streptococcus and Propionibacterium acnes) preferentially orients towards the absence of an immune response against these types of bacteria, BJI InoPlex® being used in addition to other tests performed.

This test requires a very small amount of serum (10 µl) taken by a simple blood draw and can be easily repeated. After adequate preparation, the test is carried out directly in the biology laboratory of the hospital with a standard Luminex instrument. The BJI InoPlex® kit contains various reagents necessary to perform the test, a 96-well filter plate, a calibration CD-ROM containing specific calibration information for each batch and a user manual. The BJI InoPlex® Software is used to interpret the data and report a result per family of bacteria.

BJI InoPlex® is protected by several patents covering the selected antigens.

About the CE mark and ISO 13485

The CE mark was created as part of European legislation. It materializes conformity of a product with EU requirements for the product manufacturer. Once CE marked, such a product can circulate freely in the European market, without any further requirement in terms of formalities, national safety standard or new testing. For Diaxonhit, BJI InoPlex® meets the requirements of Directive 98/79/CE of the European Parliament and the European Council with respect to medical devices for *in-vitro* diagnosis. Diaxonhit conducted the controls and tests that ensure compliance of BJI InoPlex® with the requirements set out in this Directive.

Diaxonhit drafted an EC declaration of conformity document in which Diaxonhit ensures that the product meets the "essential health and safety requirements" of relevant regulations, and by which it becomes liable.

The Diaxonhit Group is ISO 13485 : 2012 and ISO 9001 : 2008 since February 2014 (certification audit performed by the LNE, National Laboratory for Metrology and Testing, a french notified body). The Group meets the requirements of quality management systems (QMS) for the medical device industry, in its two areas of activity, Design of Medical Devices for *In-vitro* Diagnostics (reagent kit and associated software) in the area of infectious diseases, oncology and transplantation, and Distribution of Medical Devices for *In-vitro* Diagnostics (reagents and instruments) and associated services (training and maintenance).

About DIAXONHIT

Diaxonhit (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 Alternext OSEO Innovation and the Next Biotech indices. For more information, please visit: http://www.diaxonhit.com

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