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Specialty Diagnostic Solutions

Press Release

DIAXONHIT – Prosthetic joint infections test

Diaxonhit announces the good performance of BJI InoPlex® its test for the diagnosis of prosthetic infections at the 34th RICAI meeting

- The first non-invasive, quick and objective test for identification of antibacterial antibodies from a simple blood sample
- A test targeting different families of bacteria, particularly staphylococci, most responsible for prosthetic joint infections and a major public health issue
- A diagnosis contributing to early detection of prosthetic infections and optimization of patients care by orthopedic surgeons and infectiologists

Paris, France – November 27, 2014 - DIAXONHIT (Alternext : ALEHT, FR0004054427), a French leader in specialty in-vitro diagnostics for transplantation, infectious diseases and cancer, announces the good performance of BJI InoPlex®, the first blood test for the diagnosis of prosthetic joint infections at a symposium held during the 34th RICAI meeting in Paris, France.

This performance was derived from BJI InoPlex® clinical validation study conducted in two French reference centers for prosthetic joint infections. A large cohort of 455 patients was recruited for this study.

Prosthetic joint infections, a major public health issue

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 becomes necessary. If the diagnosis of prosthetic infections in the weeks or first few months following surgery is usually not a problem because clinical signs are visible, it becomes more difficult with time, thus delaying relevant care of the patient. Infections may indeed become serious complications depending on the pathogenicity of the identified bacterium and the duration of the infection.

As a result, a faster detection of prosthetic infection is capital. This is particularly the case for infections by staphilococci, the most often identified bacteria and among the most aggressive.

" Staphylococci are the most frequently observed bacteria in prosthetic joint infections and represent more than half of such infections. Staphylococci infections can be particularly severe especially in the case of Staphylococcus aureus, and difficult to diagnose when dealing with skin staphylococci. It is therefore interesting to have an easy-to-use serum test that can help assert the existence of an infection and guide the microbiological diagnosis. " said Professor Eric Senneville, Head of Infectious and Tropical Diseases and Infectiologist in the Tourcoing hospital.

A new test that, together with the standard assessments, allows practitioners to provide earlier and more tailored patient care

Currently, diagnostic tools available to diagnose prosthetic infections have limited performances, resulting sometimes in unsuitable patient care and late diagnosis.

BJI InoPlex® is the first test able to detect, directly in the patient's blood, antibodies against bacteria types

frequently responsible for prostetic infections, including staphylococci that are the most often encountered bacteria in such infections.

With this test, the result of which is made available in a few hours, whereas conventional bacteriological culture requires from several days to over a week, the practitioner receives quick qualitative information by targeted types of bacteria, which enables him, in association with conventional assessments, to accelerate initiation of relevant patient care, particularly in terms of antibiotic therapy.

BJI InoPlex® only requires a single patient blood sample. After proper preparation, the test is carried out directly in the biology laboratory of the hospital with a standard Luminex instrument. It provides a quick result to the prescriber who is then able to offer a more personalized support to the patient.

According to Dr. Thomas Bauer, Orthopaedic Surgeon at the Ambroise Paré Hospital in Paris and study investigator: " *Today, the diagnosis of prosthetic infection is difficult because it is based on a combination of clinical, radiological and biological assessments. Despite progress in recent years, the best conventional tests taken individually display limited performance. The clinical exam can remain somewhat evocative, laboratory tests, including ESR and CRP, lack specificity, and often the radiographic signals prove to be too late. BJI InoPlex® is a noninvasive test that complement existing tools by characterizing the presence of antibodies directed against carefully selected bacterial antigens. It allows to determine, on a simple blood sample, specific biologic responses to the most frequently encountered bacterial types in orthopedic implant infections.* "

" *The good performance achieved in this validation study reinforces our confidence in the qualities of BJI InoPlex®, our test that addresses a significant unmet medical need, particularly in the fight against infections by staphylococci which represent a major public health problem. These results represent another important move towards the commercialization of BJI InoPlex® for which the next step is the CE mark by the end of 2014.* " concludes Dr. Loïc Maurel, President of the Management Board of Diaxonhit.

Detailed results of BJI InoPlex® clinical validation study

BJI InoPlex® clinical validation study was conducted prospectively in two French reference centers for bone and joint infections (CRIOA) and focused on a large cohort of 455 patients for whom prosthetic reintervention was planned, with or without suspicion of an infection. The average age of patients was 71 years. The location of prostheses was respectively 66% at the hip, 30% at the knee and 4% at the shoulder. The prostheses were implanted on average 7.5 years before surgical reintervention. Cases of proven prosthetic infections were observed in one third of recruited patients.

As expected, staphylococci were the bacterial type most frequently represented in confirmed cases of infection with a respective frequency of 30% for S. aureus, 26% for S. epidermidis, and 6% for S. lugdunensis. BJI InoPlex® assay performances compared to microbiological results on intraoperative samples cultures are respectively 82.2% for specificity and 75.9% for sensitivity, all types of targeted staphylococci included.

Other bacteria (B-Streptococcus and Propionibacterium acnes) 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 preferentially orients towards the absence of an immune response against these types of bacteria, BJI InoPlex® being used in addition to other tests performed.

BJI InoPlex® development

The first phase of BJI InoPlex® development was to engineer the test by selecting the bacterial types most involved in prosthetic joint infections, and identifying antigens characterizing these types. This identification work was based on a differential approach between sera from patients with a confirmed prosthetic infection and sera from clinically healthy control patients. The selected antigens were those recognized by antibodies present in the blood of patients whose prosthesis was infected, and unrecognized in the blood of healthy patients. As a result, BJI InoPlex® identifies, in the blood of patients, antibodies targeting several antigens characterizing three bacterial types: staphylococcus, streptococcus group B, and Propionibacterium acnes.

The second phase of the development was undertaken to validate the performance of the test with an independent cohort of patients in a specific clinical trial.

About the BJI InoPlex® diagnostic test

BJI InoPlex® is a multiplex assay based on the detection, in the serum of patients wearing an osteoarticular prosthesis, of antibodies directed against key bacterial antigens recognized by the immune system during prosthetic infections. Developed with the Luminex technology using highly specific recombinant antigens, this test allows individual and simultaneous characterization of antibodies directed against three types or species of bacteria covering the majority of prosthetic infections. BJI InoPlex® notably allows the identification of serum antibodies directed against staphylococci, most often responsible for prosthetic joint infections. This test requires a very small amount of serum (10 µl) taken by a simple blood draw and can be easily repeated. BJI InoPlex® is protected by several patents covering the selected antigens and the algorithm for interpretation of results.

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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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

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