Monitoring of infliximab and C-Reactive Protein can predict loss of response in inflammatory bowel disease

- **A study conducted at the Saint-Etienne University Hospital sustains the relevance of infliximab monitoring with LISA TRACKER kits and dosing of C-Reactive Protein (CRP) to predict loss of response in IBD patients**
- **Monitoring of biotherapies with LISA TRACKER combined to CRP dosing can guide clinical decision-making and improve patient care in IBD**
- **Recommendation for regular monitoring of IBD patients**

Croissy-Beaubourg and Montpellier, April 29, 2015 – Theradiag (ISIN: FR0004197747, Ticker: ALTER), a company specializing in theranostics and *in vitro* diagnostics, announced today that a study[1] published in the *Journal of Crohn's and Colitis* shows that monitoring of trough levels of infliximab, stable antibodies to infliximab and C-Reactive Protein (CRP) can predict loss of response in Inflammatory Bowel Disease (IBD) patients.

"Prediction of loss of response is a key aspect in IBD given the number of patients who become resistant to treatment in the course of the disease, sometimes in less than 12 months. We have identified optimal biological cut-off values which can be used in clinical practice to better manage IBD patients" commented Professor Xavier Roblin, M.D., the principal investigator of the study.

Prof. Roblin's team at Saint-Etienne University Hospital conducted a prospective study in 93 patients suffering from Crohn's Disease and Ulcerative Colitis, who had been treated by infliximab and had entered into clinical remission at the time of study. They identified a suggested algorithm predictive of loss of response based on three factors:

- Trough levels of infliximab (TRI) <5,5µg/ml;
- Presence of stable antibodies to infliximab (ATI)[2];
- Level of CRP >5mg/l.

Patients presenting all three factors were at a high risk of losing response to treatment. Loss of response implied the return of disease symptoms requiring an increase or a change in therapy or surgery.

Two of the three factors identified in the algorithm were measured using Theradiag's LISA TRACKER Infliximab kits.

[1] X. Roblin et al., *Combination of C-reactive Protein, infliximab trough levels and stable but not transient antibodies to infliximab are associated with loss of response to infliximab in inflammatory bowel disease,* Journal of Crohn's and Colitis, April 19, 2015 available at http://ecco-jcc.oxfordjournals.org/content/early/2015/04/17/ecco-jcc.jjv061

[2] Defined by two consecutive positive ATI levels

The study further emphasized the need to include regular monitoring of trough levels of infliximab and detect the presence of stable antibodies to infliximab when managing infliximab-treated IBD patients.

About Theradiag

Capitalizing on its expertise in the distribution, development and manufacturing of in vitro diagnostic tests, Theradiag innovates and develops theranostics tests (combining treatment and diagnosis) that measure the efficiency of biotherapies in the treatment of autoimmune diseases, cancer and AIDS. Theradiag notably markets the Lisa Tracker range (CE marked), which is a comprehensive multiparameter theranostic solution for patients with autoimmune diseases treated with biotherapies. With its subsidiary Prestizia, Theradiag is developing new biomarkers based on microRNAs for the diagnosis and monitoring of rectal cancer and HIV/AIDS. Theradiag is thus participating in the development of "customized treatment", which favors the individualization of treatments, the evaluation of their efficacy and the prevention of drug resistance. The Company is based in Marne-la-Vallée, near Paris, and in Montpellier, and has over 70 employees.

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