

New study shows predictive role of theranostics

in Inflammatory Bowel Disease

- Further validation of routine biotherapy monitoring in IBD patients
- Undetectable anti-TNF drug levels in IBD patients with long-term remission predicts relapse-free survival after drug withdrawal

Croissy-Beaubourg and Montpellier, June 17, 2015 – Theradiag (ISIN: FR0004197747, Ticker: ALTER), a company specializing in theranostics and *in vitro* diagnostics, announced today the publication of a study¹ in Alimentary Pharmacology and Therapeutics (AP&T) highlighting the predictive role of biotherapy monitoring in the clinical management of Inflammatory Bowel Disease (IBD) patients in deep remission treated with anti-TNF.

The study, conducted by Prof. S. Ben-Horin, M.D., of the Sheba Medical Center in Israel and Prof. X. Roblin, M.D., of Saint-Etienne Medical Center in France, shows that undetectable levels of anti-TNF at drug cessation in patients in long-term remission are associated with low risk of relapse for 12 months after interruption of the treatment. For these patients, anti-TNF discontinuation may be considered. Measurement of drug levels in patient plasma was made possible by theranostics tests².

Conversely, patients in remission with high anti-TNF titers at treatment interruption are at risk of imminent flare. Flares imply a return of disease symptoms and, depending on the situation, the need for patients to resume an anti-TNF treatment, switch to another biologic or undergo surgery.

Biotherapy monitoring, associated with biomarker analysis (CRP³ and calprotectin) and clinical parameters, thus forms a prediction model for long-lasting remission and risk for relapse after anti-TNF withdrawal in IBD.

"The results of this study show once again the need to adapt treatments to the specific need of every patient. This approach of personalized medicine has been adopted in cancer; it is gaining ground in the treatment of auto-immune diseases. The routine use of biotherapy monitoring kits can improve IBD patient care by identifying patients who are at a high or low risk of relapse after interrupting their treatment. It can also reduce the financial burden of IBD. Anti-TNF treatments cost thousands of euros per patient and per year, to which can be added the costs of hospitalization, surgery, and medical leave. We must adopt regular use of biological tools to better manage the treatment of patients suffering from auto-immune diseases." commented Gérard Tobelem, Chairman of Theradiag.

¹ S. Ben Horin et al. Undetectable anti-TNF drug levels in patients with long term remission predict successful drug withdrawal, AP&T, 2015.

² Measurements of drug levels in patients' plasma were performed by the Sheba Medical Center home-made anti-lambda ELISA test and by Theradiag's LISA TRACKER test. Good cross-comparability for anti-TNF drug levels between the two tests were showed by the investigators.

³ C Reactive Protein, CRP.



The study is available in full here: <u>http://onlinelibrary.wiley.com/doi/10.1111/apt.13268/epdf</u>

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.

For more information about Theradiag, please visit our website: www.theradiag.com



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