

## Biotherapy monitoring, a major area of interest at the European Crohn's and Colitis Organisation (ECCO) Congress

## Presentations of the results obtained with Lisa Tracker®

Croissy-Beaubourg and Montpellier, March 22, 2016 – Theradiag (ISIN: FR0004197747, Ticker: ALTER), a company specializing in *in vitro* diagnostics and theranostics, is announcing that the Eleventh ECCO (European Crohn's and Colitis Organisation) Congress held between March 16 and March 19, 2016 in Amsterdam (Netherlands) brought to light further evidence of the scientific community's interest in biotherapy monitoring.

A larger number of biotherapy monitoring data sets were presented at the ECCO 2016 Congress, including over 25 oral presentations and around 40 posters. This 2016 figure doubled compared to the previous year, backing up Theradiag's theranostic approach. Around 15 presentations and posters were based on Theradiag's Lisa Tracker® monitoring tests.

"The significant increase every year in the number of presentations at the ECCO Congress reflects the scientific community's growing interest in biotherapy monitoring and the major advance that it represents for personalized medicine. Our Lisa Tracker® range, the most extensive on the market, is very well-placed in these studies", commented Prof. Tobelem, Theradiag's Chairman.

An abstract¹ presented the preliminary results obtained by monitoring vedolizumab in a study by Prof. Xavier Roblin of Saint-Etienne CHU university hospital. This is the first study to demonstrate the benefit of monitoring vedolizumab (Entyvio®) in patients suffering from IBD (Crohn's disease and ulcerative colitis) and to propose a therapeutic threshold for vedolizumab. This therapeutic threshold emphasizes the benefit of early monitoring of circulating drug level and can be used to predict a long-term response. Vedolizumab is the latest of Theradiag's kits to have gained CE marking², and the only CE marked kit available on the market. Thanks to this kit, Theradiag is the only company that provides monitoring solutions for all the biotherapies used in gastroenterology.

Four abstracts³ presented the results of monitoring Inflectra™, a biosimilar for Remicade® (Infliximab), including data with Lisa Tracker®. Biosimilars are "similar" copies of biologic medical products with patents that have expired and that cost 20% to 30% less than the equivalent biotherapies. The abstracts are based on studies of close to 300 patients suffering from Crohn's disease and ulcerative colitis. These studies were performed in Hungary and the Czech Republic, the first countries to have had access to Inflectra™. The results presented confirm the validation of Lisa Tracker® tests on biosimilars and the data already published for the Remicade® originator molecule. Theradiag has a

DOP010 - Frequency and characteristics of infusion reactions during biosimilar infliximab treatment in inflammatory bowel diseases: results from a Central European nationwide cohort – Link to the presentation: http://bit.ly/1S4yv2I

<sup>&</sup>lt;sup>1</sup>P632 - Serum Vedolizumab assay at Week 6 predicts sustained clinical remission and lack of recourse to optimization – Link to the presentation: <a href="http://bit.ly/1Wr1X46">http://bit.ly/1Wr1X46</a>

<sup>&</sup>lt;sup>2</sup> See press release dated December 14, 2015: <u>Theradiag expands its biotherapy monitoring range, with a new CE marking</u> Obtained for its Entyvio® test

<sup>&</sup>lt;sup>3</sup> OP003 - Predicting short and medium-term efficacy of the biosimilar infliximab: trough levels/do anti-drug antibody's or clinical/biochemical markers play a more important role – Link to the presentation: <a href="http://bit.ly/1nOPYI4">http://bit.ly/1nOPYI4</a>

DOP031 - Efficacy of infliximab biosimilar CT-P13 therapy on mucosal healing in ulcerative colitis: data from 2 Central European countries – Link to the presentation: <a href="http://bit.ly/1M8oq5F">http://bit.ly/1M8oq5F</a>

DOP033 - Immunogenicity profile and predictors of TLs and ADA development of biosimilar infliximab during the first 6 months of the therapy: results from a prospective nationwide cohort – Link to the presentation: <a href="http://bit.ly/1RODe63">http://bit.ly/1RODe63</a>
DOP030 - Frequency and characteristics of influence resulting during hissimilar influence to the presentation in influence to the presentation of the pres



partnership agreement with Hospira⁴ covering Inflectra™, the first Infliximab biosimilar approved and marketed in Europe, Canada and Australia.

"The results presented confirm the benefits of Lisa Tracker® tests on biosimilars. With a fast-growing market, biosimilars are today a growing major area of interest for the pharmaceutical industry and thus represent a major driver for Theradiag's sales", added Michel Finance, Theradiag's Chief Executive Officer.

## **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, auto-immune and inflammatory diseases 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 75 employees.

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

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<sup>&</sup>lt;sup>4</sup> See press release dated May 20, 2015: <u>Theradiag and Hospira sign a partnership agreement</u>