

Theradiag presents at JFHOD the results of a microRNA signature predicting a patient's therapeutic response in locally advanced rectal cancer

- Identification conducted as part of the miCRA project, in conjunction with ICM
- Results presented at the JFHOD (Francophone Gastroenterology, Liver-Disease and Digestive Cancer) congress

Croissy-Beaubourg and Montpellier, March 15, 2016 – Theradiag (ISIN: FR0004197747, Ticker: ALTER), a company specializing in *in vitro* diagnostics and theranostics, is presenting at the JFHOD congress the preliminary results of identification of a microRNA signature that can predict response to neoadjuvant therapy¹ in patients with locally advanced rectal cancer.

With over 175,000 new cases diagnosed in 2013, including more than 102,000 locally advanced cases (stages II and III), rectal cancer is the fifth most common cancer in the world. Prestizia, a wholly-owned subsidiary of Theradiag, and the Regional Cancer Institute of Montpellier (ICM) are working together as part of the miCRA project, which was awarded the 2014 Worldwide Innovation Challenge prize², on a simple, reliable, rapid and non-invasive theranostic solution that provides an early prediction of patient response to chemoradiotherapy and of metastatic recurrence in locally advanced rectal cancer.

"Locally advanced rectal cancer is treated by means of neoadjuvant chemoradiotherapy followed by surgery. And there is significant inter-subject variability in patient response to neoadjuvant therapy. It's crucial to develop a theranostic test as a genuine decision-making tool for clinicians to ensure that the most suitable treatment is offered to patients", commented Professor Gérard Tobelem, Theradiag's Chairman.

Based on the results of the study, Theradiag and ICM have identified a classifier consisting of eight circulating microRNA markers. As a result, through the analysis of a combination of microRNA done using a simple blood sample taken prior to treatment, the clinician is able to evaluate the specific response of locally advanced rectal cancer patients to neoadjuvant therapy and adapt the treatment to each patient.

This classifier's performance is currently undergoing clinical validation on a larger cohort consisting of samples taken from retrospective series (pre-existing samples) and multi-centric prospective ancillary studies (studies conducted in parallel with clinical trials currently being included), gathering around fifty specialized sites.

"Identification of this combination of eight microRNAs predicting patient response to chemoradiotherapy represents a major advance in the development of our theranostic test. To date, no individual biomarker has been validated in this situation", added Dr. Evelyne Crapez, Ph.D., Pharm.D. Head of ICM's Translational Research unit.

¹ Neoadjuvant therapy: pre-operative treatment that consists, in this instance, in radiotherapy and concomitant chemotherapy to enhance local control of the disease.

² See press release dated March 24, 2014: [Theradiag awarded the Worldwide Innovation Challenge \(CMI\) prize](#)



A poster of these results will be presented by Dr. Evelyne Crapez at the JFHOD (French-language hepato-gastroenterology and digestive oncology) congress. The event is taking place at the Palais des Congrès in Paris from March 17 to 20.

A summary of the poster is available in the program for the JFHOD event:

<http://www.jfhod.com/Data/PDF/Livre-resumes-2016-V2.pdf>

About rectal cancer

Rectal cancer is the fifth most common cancer in France. Currently, more than 17,000 cases of rectal cancer are diagnosed each year in this country, and this figure is expected to rise to 45,000 new cases annually by 2020. Rectal cancer is also prevalent in Western Europe (United Kingdom, Italy, Spain, Germany), the United States and, more recently, Japan. Indeed, on these 7 major markets, more than 175,000 new cases of rectal cancer were diagnosed in 2013, 102,000 of them locally advanced cases (stages II and III). Taking into account every stage of the pathology, the 5-year survival rate for patients suffering from rectal cancer is approximately 65% (sources: Guide infection de longue durée: Cancer colorectal adénocarcinome, INCa/HAS, 2012 and DataMonitor).

About ICM

Created in 1923, the Regional Cancer Institute of Montpellier (ICM) is now recognized as one of the leading national centers for cancer patient care, as well as the benchmark regional center for cancer patients in the Languedoc Roussillon area (31,000 patients treated per year). The ICM is one of the 20 Cancer Centers (CLCC) of the UNICANCER group, the first hospital group fully dedicated to cancerology with over 970 employees including 113 doctors, over 70 people dedicated to clinical and translational research and 16 research teams. The ICM is one of 8 research centers in France to have received the Integrated Research Center of Cancer (SIRIC) mark, as well as one of France's leading CLCCs in terms of clinical, fundamental and translational research.

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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