

HalioDx announces clinical collaboration with PRODIGE to evaluate Immunoscore® in IDEA¹ stage III colon cancer study

- Objective: Evaluate Immunoscore® as a key risk-factor to optimally adapt chemotherapy prescription in stage III CC patients
- Immunoscore® will be performed on the 1450 French IDEA patients

Marseille, France, September 8, 2017 – HalioDx SAS, an immuno-oncology diagnostic company, announced a collaboration with PRODIGE, a digestive oncology intergroup gathering the GERCOR, the FFCD and UNICANCER organizations, to further validate Immunoscore® clinical value in stage III Colon Cancer (CC). The study will focus on investigating Immunoscore® performance to guide oncologist decision for chemotherapy (CT) prescription in stage III CC patients.

Immunoscore® will be performed on 1450 patients' samples collected during the French IDEA trial (2010 patients included). The IDEA France results presented at the ASCO 2017 meeting showed that in patients with stage III colon cancer, with 90% of patients treated with mFOLFOX6 regimen, a 6-month adjuvant chemotherapy course was superior to a 3-month course, especially in the T4 and N2 high-risk subgroups. These results should be considered alongside the international IDEA collaboration and the SCOT² and TOSCA³ results (respectively the UK and Italian studies). The IDEA France study and the international IDEA collaboration showed significant reduced rates of peripheral neuropathy toxicity with the shorter regimen. The IDEA International collaboration showed that the 3-month course was most appropriate for low-risk patients, especially with the CAPOX regimen. Thus, a risk-based approach is now recommended by the IDEA collaboration to guide adjuvant CT prescription.

Immunoscore® has been validated as a strong prognostic factor in 600 stage III CC patients treated with FOLFOX alone from the randomized Phase III adjuvant trial NCCTG N0147 where accurate identification of high-risk patients was confirmed ([F. Sinicrope et al. J Clin Oncol 2017 ; 35 \(suppl; abstr 3579\)](#)). The IDEA trial provides now a unique opportunity to evaluate Immunoscore® as an additional and objective criterion to refine treatment adaptation through improved risk classification, and thus provide better care for patients and reduce treatment costs for National Health Systems.

Testing will take place in the HalioDx laboratory. Analysis of results will be done by Q4 2018.

Vincent FERT, CEO of HalioDx comments: *"We are proud to collaborate with the PRODIGE consortium, an organization developing large programs of national and international clinical trials, aimed at improving colon cancer patient management. This collaboration has been set up based on the previous results on Immunoscore® demonstrating its unique potential to play a role as a major risk-factor in localized Colon Cancer."*

Meet our team at ESMO 2017 to further discuss Immunoscore® results & perspectives:

Visit us at booth #30 in ESMO Society Village & Technology Exhibition,

08 -12 Sep, 2017 - Madrid, Spain

About HalioDx

The Immune Response to Cancer Diagnostics

HalioDx is an immuno-oncology diagnostic company providing oncologists with first-in-class Immune-based diagnostic products and services to guide cancer care and contribute to precision medicine in the era of immuno-oncology and combination therapies.

Immunoscore® proprietary technology, pioneered by Jérôme Galon at the Cordeliers Research Center, Paris, France, integrates immunohistochemistry combined with advanced imaging analysis enabling extraction of spatially-organized tissue molecular information. Immunoscore® is a platform for many cancers, as immune response to tumor is a key hallmark of disease progression. HalioDx collaborates with renowned international clinical groups to support clinical utility and ensure rigorous performance validation of its assays in selected cancer indications. HalioDx develops also assays such as Halioseek™ and Immunosign® to help stratifying patients for immunotherapies.

HalioDx has an experienced team of more than 120 employees, a CLIA-certified laboratory and compliant facilities to develop, manufacture, register and market *in vitro* diagnostic (IVD) products. HalioDx executes biomarker studies and companion diagnostic assay development in conformity with regulations and in partnership with biopharmaceutical companies. The company co-founded the European immunology cluster Marseille Immunopôle (MI).

For more information, please visit our websites www.halioldx.com, www.immunoscore-colon.com and www.halioseek.com and follow the company on Twitter [@HalioDx](https://twitter.com/HalioDx).

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¹ IDEA: International Duration Evaluation of Adjuvant Chemotherapy.

² SCOT: Short Course Oncology Treatment trial.

³ TOSCA: Three or Six Colon Adjuvant trial.