

Immunoscore® Colon prognostic performance confirmed in data presented by Mayo Clinic at ASCO 2017

- Immunoscore® Colon is strongly prognostic in the N0147 600 patient cohorts
- Using pre-specified cut off in a retro-prospective design, these results provide a significant level of evidence
- Immunoscore® Colon is clinically useful and reliable to identify high risk stage III colon cancer patients

Marseille, France, June 3, 2017 – HalioDx SAS, an immuno-oncology diagnostic company, announced the presentation of data on Immunoscore® Colon providing a retro-prospective validation on a US clinical cohort (FOLFOX-treated resected stage III colon cancer patients) at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting.

In the study presented by Dr Sinicrope, Mayo Clinic, Rochester, MN (poster [abstract #3579](#)), the prognostic value of individual immune markers and of the standardized Immunoscore® Colon test was evaluated in stage III colon cancer (CC) patients treated with adjuvant FOLFOX. Six hundred (600) resected tumors of stage III CC patients from the FOLFOX arm of the prospective NCCTG N0147 clinical trial were analysed retrospectively for 3 individual immune markers (CD3, CD8 and CD20), and for Immunoscore® (IS 0 to IS 4). In this population, the study has demonstrated that risk classification based on immune markers density analysis in core tumor and invasive margin provides valuable prognostic information.

Immunoscore® Colon, based on a standardized method and validated pre-specified cutoffs, showed a strong association with relapse in this cohort. Immunoscore Low (IS 0-1) was associated with worse DFS* (HR=0.64, CI, 0.45-0.92, p=0.015); therefore, Immunoscore® Colon is clinically useful and reliable to identify high risk patients.

These results provide an additional clinical level of evidence and validate the strong prognostic value of the CE-IVD Immunoscore® Colon assay in a retro-prospective US clinical trial cohort.

Vincent FERT, CEO of HalioDx comments:

“The N0147 study results provide a second landmark achievement for Immunoscore® Colon. Combining SITC results communicated at ASCO last year and now the NO147 study results we reach a significant level of evidence for Immunoscore® Colon. We have several other large retro-prospective studies on-going that will further reinforce Immunoscore® Colon medical value to support the wide dissemination of this assay”

* Disease Free Survival.

Poster presentation:

- [Association of immune markers and Immunoscore with survival of stage III colon carcinoma \(CC\) patients \(pts\) treated with adjuvant FOLFOX: NCCTG N0147 \(Alliance\)](#)

Abstract #3579**Poster Session:** Gastrointestinal (Colorectal cancer)**Poster Board #202****Session Time/Location:** Saturday, June 3, 2017: 8:00-11:30 AM CDT, Hall A**Presenter:** Frank A. Sinicrope, MD, Mayo Clinic, Rochester, MN

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.

HalioDx Immunoscore® technology 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.

Pioneered by Jérôme Galon at the Cordeliers Research Center, Paris, France, Immunoscore® Colon is the flagship assay of HalioDx, positioned to be a future diagnostic standard for delivering prognostic and predictive information. HalioDx develops also assays such as Halioseek™ and Immunosign® to help stratifying patients for immunotherapies.

HalioDx collaborates with an increasing number of renowned international clinical groups and biopharmaceutical companies to support clinical utility and ensure rigorous performance validation of its assays in a large number of cancer indications.

HalioDx has an experienced team of more than 100 employees, a CLIA-certified laboratory (H1 2017) 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 Immunopole (MI).

For more information, please visit our website www.haliidx.com and follow the company on Twitter [@HalioDx](https://twitter.com/HalioDx).

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