

New evidence from 2 pivotal studies reinforces clinical value of Immunoscore® In Colon Cancer

- Two large Immunoscore® studies from Phase III trials published in JNCI Cancer Spectrum & Annals of Oncology
- Consistent prognostic performance established on 1600+ colon cancer patients strengthen Immunoscore® Level of Evidence
- Immunoscore® unique predictive performance demonstrated for FOLFOX adjuvant chemotherapy duration

Marseille, France, May 26, 2020 HalioDx SAS, the immuno-oncology diagnostic company, today announced the publication of two major Immunoscore clinical studies in Stage III colon cancer patients validating the clinical value of Immunoscore® to refine patients stratification and predict which patients benefit most from 6 months adjuvant chemotherapy.

Published in JNCI Cancer Spectrum¹, the Immunoscore-N0147 study was conducted in collaboration with clinicians and researchers from the Mayo Clinic. The Immunoscore-IDEA France study, published in Annals of Oncology² was conducted in collaboration with PRODIGE, a digestive oncology intergroup gathering the GERCOR, the FFCD and UNICANCER organizations. Objectives of these retrospective studies in prospectively conducted trials were to examine and validate the ability of Immunoscore® to identify patients at high-risk of relapse and investigate survival differences according to Immunoscore® in predefined subgroups, including Tumor/Node Stage and treatment duration.

The two studies were performed on independent large Phase III randomized clinical trials cohorts, and included 559 patient samples from the FOLFOX alone arm of the NCCTG N0147 trial³, and 1062 patient samples from both arms (3 versus 6 months) of the IDEA France trial⁴ (as part of the IDEA international collaboration⁵). Consistent prognostic performance were obtained, and Immunoscore® predictive performance was demonstrated for FOLFOX therapy duration.

These results strengthen Immunoscore® Level of Evidence and position Immunoscore® as an essential diagnostic tool to enable a personalized management of stage III colon cancer patients.

Frank A. Sinicrope, MD, Mayo clinic, Rochester, Minnesota, principal investigator of the study utilizing NCCTG N0147 tumors comments : *“Those two large-scale studies confirm that use of Immunoscore® in combination with established prognostic factors allows one to more accurately assess prognosis, highlighting the clinical utility of Immunoscore®.”*

¹ [Sinicrope FA et al JNCI Cancer Spectrum 2020](#)

² [Pagès F et al Annals of Oncology 2020](#)

³ [Alberts SR JAMA 2012](#)

⁴ [André T et al JCO 2018](#)

⁵ [Grothey A et al NEJM 2018](#)

Pr Franck Pagès, MD, HEGP, AP-HP, Paris: *“The Immunoscore-IDEA study shows that a good quality of the immune system, particularly at the tumor site, is essential to achieve a maximum benefit from chemotherapy.”*

Vincent FERT, CEO of HalioDx comments: *“The results of these two studies confirm Immunoscore® as an essential diagnostic tool for GI oncologists managing localized colon cancer. HalioDx is now actively working to facilitate market access for enabling oncologists and institutions to use Immunoscore® in their routine practice.”*

About Immunoscore®

Immunity Assessed, Personalized Treatment

Evaluated as an essential and desirable diagnostic criteria by the WHO, immune response assessment is becoming now the necessary complement to the traditional cancer staging system and Immunoscore® is the diagnostic standard to perform this evaluation.

Today, Immunoscore® includes a unique family of immune-based assays, ranging from diagnostic tests such as Immunoscore® Colon (CE-marked In Vitro Diagnostic and CLIA compliant) and Immunoscore® family assays for clinical research. At the forefront of Multiplex Spatial Tissue Analysis, these assays combine proprietary multiplexed immunohistochemistry, advanced image analysis and computerized algorithms.

By precisely quantifying immune cell infiltration in and around the tumor, Immunoscore® has already proven its superior prognostic value than the usual tumor risk parameters, notably in localized colon cancer. Today, Immunoscore® is investigated in a broad number of clinical studies and cancer indications for establishing its performances as a prognostic factor as well as a predictive factor for response to drugs, notably chemotherapies and immunotherapies.

Immunoscore® is commercially available in more than 20 countries.

About HalioDx

The Immune Response to Cancer Diagnostics

HalioDx is an immuno-oncology diagnostic company providing oncologists and Biopharma 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 sophisticated algorithm and 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 has an experienced team of more than 165 employees, CLIA-certified laboratories and compliant facilities in Europe and in the US 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 and www.immunoscore-colon.com and follow

the company on Twitter [@HalioDx](https://twitter.com/HalioDx) and LinkedIn <https://www.linkedin.com/company/halioldx/>.

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