

Immunoscore® demonstrates clinical utility in stage III colon cancer

- Positive results on Immunoscore® in stage III colon cancer patients treated with oxaliplatin in the prospective IDEA France cohort study have been presented at ASCO 2019.

Chicago, IL, USA, June 3, 2019, 12:15 PM (CDT): HalioDx SAS, an immuno-oncology company pioneering the immunological diagnosis of cancers, today announced results demonstrating Immunoscore® strong ability to identify stage III colon cancer patients at high risk of relapse, and predictive value for the benefit of 6 months versus 3 months of mFOLFOX6 adjuvant chemotherapy.

This study¹, conducted by HalioDx in collaboration with clinicians and researchers from PRODIGE, a digestive oncology intergroup gathering the GERCOR, the FFCD and UNICANCER organizations, was presented at the 2019 ASCO Annual meeting. Objective of the study was to 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.

Immunoscore® was successfully analyzed on 1062 patients' samples collected during the French IDEA trial conducted by GERCOR (Phase III randomized study of stage III colon cancer patients as part of the IDEA international collaboration²).

The study met its primary objective of validating that Immunoscore® Low (e.g. poor immune response) identifies patients with higher risk of relapse or death. Immunoscore® -reported in given categories and as a continuous variable- is confirmed as a strong prognostic factor for Disease Free Survival (DFS) in stage III colon cancer patients ($p < 0.001$).

Furthermore, only patients with a good immune response at the tumor site, measured by Immunoscore®, did benefit from 6 months of mFOLFOX6 treatment compared with 3 months, both in low (T1-3, N1) and high (T4 and/or N2) clinical risk groups (significant interaction).

Thierry ANDRE, MD, Hôpital Saint Antoine, principal investigator of the French IDEA study comments: *"Immunoscore® significantly predicts different efficacy between 3 and 6 months of mFOLFOX6 treatment. Noteworthy, patients with low Immunoscore® and thus with a low lymphocytic infiltration did not benefit from the 6-month mFOLFOX6. These results need to be confirmed on another patients' population included in the IDEA international study, to evaluate the IS impact on the efficacy of 3 vs 6 months of CAPOX treatment, and to validate its use to guide the choice of oxaliplatin-based adjuvant chemotherapy duration in stage III colon cancer."*

Vincent FERT, CEO of HalioDx comments: *"Assessment of the anti-tumor immune response measured by immunoscore® significantly improve the prognostic accuracy for Stage III colon cancer patients. These positive findings should improve individual risk-assessment in order to guide oncologists' decisions for oxaliplatin-based adjuvant chemotherapy duration in stage III CC patients."*

¹ The study design is registered on ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT03422601>

² Grothey A et al. NEJM 2018

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 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 135 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.haliodx.com and www.immunoscore-colon.com and follow the company on Twitter [@HalioDx](https://twitter.com/HalioDx).

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