

## Expanding Immunoscore® clinical utility on 3000+ stage III colon cancer patients

Marseille, France, December 03, 2020 HalioDx SAS, the immuno-oncology diagnostic company pioneering the immunological diagnosis of cancers, today announced that Immunoscore® is evaluated in a new study with two cohorts from the prospective randomized IDEA<sup>1</sup> international trial in Stage III Colorectal Cancer<sup>2</sup>: the SCOT<sup>3</sup> cohort in the UK<sup>4</sup> and the HORG<sup>5</sup> cohort in Greece<sup>6</sup>.

The objectives of the new Immunoscore® study announced today are to consolidate results obtained in the Immunoscore-IDEA France<sup>7</sup> study for its predictive and prognostic performance in additional independent series. Moreover, the study will investigate Immunoscore® performance in CAPOX treated patients, in order to assist oncologists to select optimal adjuvant chemotherapy regimen for individual patients. The study will be conducted in 3000 patients receiving either FOLFOX or CAPOX chemotherapy.

Updated results from the parent IDEA collaboration showed that Overall Survival and 5 years Disease Free Survival results continue to support the use of 3 months versus 6 months adjuvant chemotherapy for the vast majority of stage III colon cancer patients, but conclusion underlined oncologists' needs for more accurate risk profiling beyond Tumor/Node stage classification, such as Immune status scoring (i.e. Immunoscore®), to help define the best adjuvant therapy in Stage III colon cancer.

**Pr John Souglakos, MD, PhD, University of Heraklion, Crete, commented:** *"This study will provide additional data on the consistency of evaluating immune response at the tumor site to adjust for optimal treatment duration in stage III colon cancer and more specifically data on a CAPOX cohort will be generated. We are very happy to bring a complementary cornerstone of evidence participating in this randomized clinical study in a multicentric framework".*

**Vincent FERT, CEO of HalioDx mentioned:** *'We are delighted to work with experts in GI oncology from UK and Greece and access to FOLFOX and CAPOX patients from IDEA study will strengthen Immunoscore® Level of Evidence in stage III colon cancer.'* **He added** *"One of our priority is to provide oncologists with best in class precision medicine tools and this study addresses precisely this objective".*

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<sup>1</sup> IDEA: International Duration Evaluation of Adjuvant Chemotherapy

<sup>2</sup> [Grothey A et al. NEJM, 2018](#)

<sup>3</sup> SCOT: Short Course Oncology Treatment trial

<sup>4</sup> [Iveson TJ et al. Lancet Oncol, 2018](#)

<sup>5</sup> HORG: Hellenic Oncology Research Group

<sup>6</sup> [Souglakos J et al. Ann Oncol, 2019](#)

<sup>7</sup> [Pagès F et al. Ann Oncol, 2020](#)

### About Immunoscore®

Immunoscore® is an *in vitro* diagnostic test measuring the host immune response at the tumor site. It provides a robust, precise, quantitative, and consensus assessment of lymphocytic infiltration and has been shown to predict patient outcome and response to therapies in several indications (<sup>8 9 10</sup>).

In 2020, the World Health Organization (WHO), in its latest edition of the Digestive System Tumours, introduced immune response as an essential and desirable diagnostic criterion for colorectal cancer, in addition to traditional histological parameters.

Subsequently, Immunoscore® was included in the 2020 European Society of Medical Oncology (ESMO) Clinical Practice Guidelines for Diagnosis, Treatment and Follow-up for Localized Colon Cancer.

Immunoscore® Colon is the first IVD diagnostic test of our Immunoscore® portfolio for which a comprehensive corpus of clinical data demonstrating its clinical utility associated with TNM scoring in the management of localized colon cancer has been published. Additional immune-based assays in the same portfolio are used as clinical trial assays to support translational research and clinical development. Those assays enable Multiplex Spatial Tissue Analysis and combine proprietary multiplexed immunohistochemistry, advanced image analysis and computerized algorithms.

Immunoscore® is currently being investigated in a broad number of clinical studies and cancer indications for establishing its performance 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

HalioDx is an immuno-oncology diagnostic company providing oncologists and drug development organizations 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.

Leveraging the pioneering work of Dr Jérôme Galon, HalioDx provides a unique range of immune scoring solutions including its flagship Immunoscore® assay for the assessment of the immune contexture of a tumor, as a key determinant of patients' outcomes and response to cancer treatments.

HalioDx has developed a unique Biopharma partnering ecosystem for the identification of clinically relevant biomarker signatures, the demonstration of their clinical utility in trials and the development and commercialization of resulting diagnostic or companion diagnostic tests. Our programs draw on our expertise and focus on immuno-oncology, a complete suite of genomic and proteomic biomarker profiling services, a world-class data analysis and biostatistics platform, and CLIA-certified laboratories with compliant facilities in Europe and in the US to develop, manufacture, register and market *in vitro* diagnostic (IVD) products. HalioDx has rapidly become the preferred partner of Biopharma developing therapeutic antibodies, vaccines, chemotherapies, oncolytic peptides, and CAR-T cell therapies.

**For more information, please visit our websites [www.halioldx.com](http://www.halioldx.com) and [www.immunoscore-colon.com](http://www.immunoscore-colon.com) and follow the company on [Twitter](#), [Linkedin](#) and [Youtube](#).**

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<sup>8</sup> [Pagès F et al. Lancet. 2018; 391 \(10135\)](#)

<sup>9</sup> [Sinicrope FA et al JNCI Cancer Spectrum 2020](#)

<sup>10</sup> [Pagès F et al. Ann Oncol, 2020](#)

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