

Immunoscore® is now available in Rectal Cancer for expert clinical centers through an Innovation Access Program

- Immunoscore® heads up to become the standard precision tool for the “Watch and Wait” strategy in locally advanced rectal cancer
 - Expert clinical centers already involved worldwide in this new *Innovation Access Program*

Marseille, France, May 11, 2021 - HaliDx SAS, the immuno-oncology diagnostics company pioneering the immunological diagnosis of cancers, announced today that Immunoscore® is now available through an *Innovation Access Program* for the management of locally advanced rectal cancer (LARC). In this new indication, Immunoscore® has a strong prognostic value and could support the clear-cut transition in therapeutic strategy: organ preservation in patients with locally advanced rectal cancer with a good prognosis.

In rectal cancer, where no standardized biomarker is available to personalize treatment, Immunoscore® is an independent parameter that is more informative than pre- and post-neoadjuvant treatment imaging for predicting disease-free survival.

[El Sissy et al. recently published a study in Clinical Cancer Research](#) where researchers assessed whether Immunoscore® could predict response to neoadjuvant treatment in different LARC patient cohorts and a validation "Watch and Wait" cohort. The researchers found that combining Immunoscore® with imaging post-neoadjuvant treatment can identify patients with a complete clinical response who could benefit from the organ preservation strategy. Strikingly, in the "Watch and Wait" cohort, nearly 100% of patients with a high Immunoscore achieved a good response to therapy, and all avoided relapse.

Dr. John Low Seng Hooi, MBBS, MRCP, FRCR, FRCP, FAMS, AM, Clinical Oncologist at Pantai Hospital Kuala Lumpur, Malaysia, added: *“To complete clinical assessment, Immunoscore® could rapidly become the precision tool we need for supporting our clinical decisions. We are delighted to implement Immunoscore® in our practice through this Innovation Access Program with HaliDx.”*

Dato’ Dr. Meheshinder Singh, founder of the Colorectal Cancer Survivorship Society Malaysia, and past President of the Malaysian Society of Colorectal Surgeons, Colorectal surgeon at Pantai Hospital Kuala Lumpur, Malaysia, commented: *“Colorectal Cancer is the most common cancer in men and number two cancer in women in Malaysia. At PHKL, we are deeply committed to improving quality of care in locally advanced rectal cancer patients.”*

Vincent FERT, CEO of HaliDx, concluded: *“We are very pleased to partner with oncologists, surgeons and pathologists committed to advance locally advanced rectal cancer patient management. Our Innovation Access Program leverages our Immunoscore® technology platform, already in the ESMO guidelines for colon cancer, that measure the host immune response at the tumor site in a spatially resolved manner enabling informed medical decisions.”*

To get further information on Immunoscore® **Innovation Access Program in LARC**, please contact us at infos@haliodx.com.

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 (^{1 2 3}).

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 assessing 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 and www.immunoscore-colon.com, and follow the company on [Twitter](#), [Linkedin](#) and [Youtube](#).

¹ [Pagès F et al. Lancet. 2018; 391 \(10135\)](#)

² [Sinicropo FA et al JNCI Cancer Spectrum 2020](#)

³ [Pagès F et al. Ann Oncol, 2020](#)

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