

New data reinforces Immunoscore clinical utility in localized Colon Cancer

- Changes in patterns of oncology care with the incorporation of immune response in a study of Stage II colon cancer presented at ASCO Quality Care Symposium, and
- Evaluation of 763 stage III patients published in the Journal of Clinical Oncology

Marseille, France, October 20, 2020 HalioDx SAS, an immuno-oncology diagnostic company, announced the results of a study led by Dr Afsaneh Barzi, MD, PhD, from City of Hope, a comprehensive cancer center based in Southern California. Dr. Barzi presented the Impact of Immune Assessment with Immunoscore[®] on Patterns of Care In Stage II Colon Cancer at the ASCO Quality Care Symposium on October 9-10, 2020 (<u>https://meetinglibrary.asco.org/record/192936/abstract</u>). The Company also announced publication of a study which provides additional evidence of Immunoscore[®] clinical value in stage III colon cancer, by identifying which patients will recur and who is likely to benefit from adjuvant chemotherapy (<u>B. Mlecnik et al.</u>, Journal of Clinical Oncology 2020).

In an abstract presented on October 9, 2020 at the ASCO Quality Care Symposium, incorporation of the Immunoscore[®] classification data into the risk assessment process resulted in changes to the post-surgical management strategy for stage II colon cancer patients 55% of the time. The study design involved a panel of 25 gastrointestinal oncologists from different cancer centers in the US that evaluated several clinical cases (real-life, de-identified stage II cases submitted for clinical Immunoscore[®] testing).

"As City of Hope and other health care institutions embark on fulfilling the potential of precision oncology, diagnostic tests such as Immunoscore offer an evidence-based way to refine adjuvant chemotherapy prescription for stage II colon cancer patients," **commented Afsaneh Barzi, MD, PhD, City of Hope, CA, US.** Passionate about improving her patients' quality of life, Dr. Barzi believes in not just leading-edge treatment but also compassionate patient care. "This is why I am exploring strategies to improve patient outcomes," she said.

In parallel, the new publication in the *Journal of Clinical Oncology* published earlier in September, explored the subgroup of stage III patients (n=763) from the large SITC study (<u>F. Pagès et al., Lancet 2018</u>). The population of this cohort fits real-world practice settings as it includes both untreated (mostly elderly) and treated stage III patients receiving heterogeneous treatments (5-FU or FOLFOX or XELOX or FOLFIRI).

"This study shows that a high Immunoscore is significantly associated with prolonged survival in stage III colon cancer. Our findings suggest that patients with a high Immunoscore will benefit the most from chemotherapy in terms of recurrence risk." said Bernhard Mlecnik, PhD, Inserm UMRS1138 at Cordeliers Research Center, Paris, France.

About Immunoscore®

Immunoscore[®] is an *in vitro* diagnostic test which measures the host immune response at the tumor site. It provides a robust, quantitative and standardized assessment of lymphocytic infiltration and has been shown to predict patient outcome and response to therapies in several indications. 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.

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Subsequently, Immunoscore[®] was included in the 2020 European Society of Medical Oncology (ESMO) Clinical Practice Guidelines for Diagnosis, Treatment and Follow-up for Localised Colon Cancer. 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[®] 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 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 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 <u>www.haliodx.com</u> and <u>www.immunoscore-</u> <u>colon.com</u> and follow the company on <u>Twitter</u>, <u>Linkedin</u> and <u>Youtube</u>.

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