Immunoscore® confirms its potential to become a major component of the colon cancer classification at ASCO 2016

- Dr. Jérôme GALON presented today positive results from the Immunoscore® study, an international initiative led by the SITC.

- Immunoscore® predicts Time To Recurrence (TTR), Disease Free Survival (DFS) and Overall Survival (OS) among stage I-III Colon Cancer patients.

- Immunoscore® classification identified a subgroup of high-risk stage II patients that could potentially benefit from adjuvant chemotherapy.

Marseille, France, June 05, 2016 – HalioDx SAS, an immuno-oncology diagnostic company, today announced key data assessing the performance of Immunoscore® in stage I/II/III colon cancer. These results are issued from a study conducted by the Immunoscore® worldwide consortium, led by the Society for Immunotherapy of Cancer (SITC) involving 23 pathology centers from 17 countries, where more than 3,800 patient samples were evaluated. Results have been presented at ASCO 2016 by Dr Jérôme GALON, Research Director at Inserm, Head of the laboratory of Integrative Cancer Immunology, Paris, France and principal investigator of the study.

Highlights of the presentation entitled "Validation of the Immunoscore® as a prognostic marker in stage I/II/III colon cancer" were:

- Primary endpoint of the worldwide Immunoscore® study has been reached, with significantly longer TTR for patients classified as Immunoscore-High.
- Immunoscore® was also able to predict DFS and OS among stage I-III colon cancer patients, and was significant in multivariate analysis. In addition, the Immunoscore® classification identified a subgroup of high-risk stage II patients, as TTR was also significantly longer in Immunoscore-High compared with Immunoscore-Low stage II colon cancer patients (n=1433) (HR (95% CI), .36 (.23-.56), p<.0001).

Jérôme GALON underlined: "*In the era of oncology, notably in immunotherapy, it is now essential to classify cancer patients based on immune parameters. The results of this study conducted by an international consortium has the potential to drive the implementation of the Immunoscore® as a new component for the classification of cancer, designated as TNM-I (TNM-Immune)*".

Vincent FERT, CEO of HalioDx added "*These outstanding results, thanks to the collective effort and leadership of the SITC organization, represent a crucial milestone in the paradigm shift to empower the immune system to fight cancers. The data demonstrate also that Immunoscore® is a highly robust and accurate assay that can be implemented in the routine settings of pathology laboratories. HalioDx is committed to develop Immunoscore® as a standardized, globally available, diagnostic assay for guiding therapeutic decisions in colon cancer.*"

- **See abstract**: http://abstract.asco.org/176/AbstView_176_168666.html
- **See SITC press release**: http://www.sitcancer.org/UserFiles/ImmunoscorePressRelease-Final.pdf

About Immunoscore® Colon

Immunoscore® Colon measures the density of two T lymphocyte populations in the center and at the periphery of the tumor: CD8+ and CD3+ T cells. The technology used is immuno-histochemistry coupled to advanced image analysis for a standardized tissue segmentation and immune cells quantification. Cell densities are then computed to provide the patient's Immunoscore®.

Dr. Jérôme GALON, Research Director at Inserm and Head of the Laboratory of Integrative Cancer Immunology, developed the concept of immune contexture consisting on analyzing the immune variables associating the type, density, location and functional orientation of immune cells within and around the tumor from which Immunoscore® was derived. The assay was developed to predict the ability of a person's immune system to fight tumor cells and its performance has been documented in a number of studies for its ability to predict recurrence in colon cancer.

Immunoscore® Colon is one of the first diagnostic test that will be used in routine by pathology labs leveraging advanced image analysis. The accuracy and robustness of the test relies on precise counting of positive immune cells in predefined regions and automatic calculation of Immunoscore® for each patient based on specific algorithm.

The Immunoscore® Colon assay will be available in 2016.

About HalioDx SAS

The Immune Response to Cancer Diagnostics

By precisely measuring the immune reaction in and around the tumor, HalioDx tests allow the clinician to determine the degree of severity of the patient's disease and predict the response to treatment, regardless of the cancer stage or the molecular class.

HalioDx designs and develops a unique range of immune scoring tests, whose first-in-class product is Immunoscore®. Considered a future diagnostic standard in Oncology, this biomarker has already demonstrated strong prognostic value in colorectal cancer. HalioDx was founded in 2014 by the former management team of Ipsogen (leader in the molecular diagnosis of leukemia), and a pioneer in integrative immunology and oncology, Dr. Jérôme Galon. HalioDx benefits of worldwide licenses on a broad portfolio of IP rights on immuno-oncology biomarkers (including the Immunoscore® technology) developed by Dr. Jérôme Galon, Research Director at Inserm, and his team (Inserm UMRS1138) at Cordeliers Research Center, Paris, France.

HalioDx has an experienced team of 87 employees and compliant facilities to develop, manufacture, deliver and market in vitro diagnostic products and services in immuno-oncology.

For more information, please visit: www.haliodx.com

HalioDx and Immunoscore are registered trademarks.

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