

HalioDx launches Halioseek™ CR (PD-L1/CD8), a new assay toward precision immunotherapy

- Analyzing both adaptive immunity (CD8+ T cells) and PD-L1 expression status should allow clinicians to improve Immune Checkpoint Inhibitors (ICI) prescription & patients' stratification.
- Halioseek™ is already available as a Clinical Research (CR) service for biopharmaceutical companies and academic centers evaluating PD1/PD-L1 pathway blockade.

Marseille - France, November 7, 2016 – HalioDx SAS, an independent immuno-oncology diagnostic company, today announced that its assay Halioseek™ CR (PD-L1/CD8) is available as a clinical research service for biopharmaceutical companies and academic centers. Halioseek™ CR has been optimized for Non-Small Cell Lung Cancer (NSCLC). The assay can be used to evaluate other tumor types.

PD1/PD-L1 pathway blockade has elicited durable clinical responses in a fraction of cancer patients but clinicians are still waiting for a robust predictive biomarker of response. Today, we know that PD-L1 expression is more an indicator of the likelihood of response than a predictor of response, this is why the solution must include the other key parameter of the game: the intra-tumor immune response. Today, HalioDx provides clinicians and biopharmaceutical developers the very first standardized assay that will allow them to analyze these two biomarkers simultaneously.

The Halioseek™ CR (PD-L1/CD8) assay measures both the expression of PD-L1 on tumor and immune cells and the density CD8+ (cytotoxic) T cells in a multiplexed IHC assay on a unique slide using two different dyes (colors). It is a standardized full service solution, optimized for utilizing minimal amount of FFPE tissue, where interpretation is combining high-resolution image analysis system with a proprietary bioinformatics pipeline.

The assay can provide tumor microenvironments classification in 4 types, type I (adaptive immune resistance), type II (immunological ignorance), type III (intrinsic induction), and type IV (tolerance), based on the presence of TILs and PD-L1 expression (Teng et al. Cancer Res. 2015), to guide Immunotherapeutic strategies. In addition, thanks to advanced image analysis, distances between these cell populations can be utilized together with clinico-pathologic parameters to improve further microenvironment's classification. A significant correlation between the proximity of the PD1 and PD-L1(+) cells and pre-existing CD8(+) T cells at the invasive tumor margin with the response to ICI treatment has been demonstrated in melanoma (Tumeh et al. Nature 2014 ; Taube JM, Sc Trans Med. 2012; Sznol M, Clin Cancer Res. 2013; Teng et al. Cancer Res. 2015).

HalioDx is about to launch an independent study to establish the concordance between Halioseek™ and the existing PD-L1 tests currently under investigation in NSCLC. A CE marked Halioseek™ test is under development.

Vincent FERT, CEO of HalioDx comments: *“because it measures the two strongest components of the immune microenvironment with respect to the known ICI mechanism of action, Halioseek™ CR (PD-L1/CD8) has the potential to become the reference assay for precision Immunotherapy”*. He adds: *“A decentralized version of the assay is under development to provide our pharmaceutical partners a unique solution for PD-1/PD-L1 ICI development and registration.”*

HalioDx at SITC congress, Nov. 9 -13, 2016, National Harbor, Maryland, USA

New performance data for Immunoscore® Colon will be presented in the following oral presentations:

- **Immunoscore® Colon Analytical Performance** presented by Dr Fabienne Hermitte, VP, R&D – Reg & Medical Affairs – HalioDx | Concurrent Session II: Promoting and Measuring Antitumor Immunity
Friday, November 11th, 5:50 – 6:05 p.m, Maryland A.
A poster will also be presented the same day (**Poster# 341**)
- **Immunoscore as a Prognostic Marker in Stage I-III Colon Cancer: Results of a SITC-Led Global Validation Study** presented by Dr Jérôme Galon – Cordeliers Research Center – Paris, France
Update Session: Society Initiatives
Saturday, November 12th, 7:40 – 7:55 a.m, Maryland Ballroom
- **Combination in Patient Selection** presented by Dr Jérôme Galon – Cordeliers Research Center – Paris, France | Beyond Single-Agents: The Future of Combination Immunotherapy
Saturday, November 12th, 9:35 – 10:00 a.m, Maryland Ballroom

HalioDx Booth #212

Don't miss the opportunity to meet and discuss with HalioDx's team at SITC congress.

About HalioDx

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® and Halioseek™ technologies) 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 more than 100 employees and compliant facilities to develop, manufacture, deliver and market *in vitro* diagnostic products and services in immuno-oncology. Based, in Marseille, France, HalioDx® is co-founder of the European immunology cluster Marseille Immunopole (MI).

More information: www.haliodx.com

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