Press release

New data on Halioseek™ PD-L1/CD8 presented at AACR 2017

- HalioDx has developed an assay based on the dual staining of PD-L1 + and CD8+ cells enabled by advanced image analysis tool
- The assay shows excellent concordance with approved PD-L1 methods
- Combined analysis of PD-L1+ cells and CD8+ cells is expected to improve predictive performance to identify immune checkpoint inhibitors resistant NSCLC patients
- Data presented support the potential benefit of using of Halioseek™ PD-L1/CD8 in routine practice and development of a CE-IVD version is ongoing

Marseille, France, March 31, 2017 – HalioDx SAS, an immuno-oncology diagnostic company, will present a new set of data confirming the good performance of Halioseek™ PD-L1/CD8 at the American Association for Cancer Research (AACR) Annual Meeting 2017 in Washington D.C., USA, on Sunday, April 2, 2017 (1:00 - 5:00 PM EST).

PD1/PD-L1 pathway blockade results in a durable clinical response in a fraction of the non-small cell lung cancer (NSCLC) patients. Today, the expression of PD-L1, detected by immunohistochemistry (IHC) at the surface of tumor or tumor-infiltrating immune cells, is used to select patients that may respond to immune checkpoint inhibitors (ICI). However the predictive value of PD-L1 biomarker alone is questioned. In order to better stratify NSCLC patients, HalioDx has developed Halioseek™ PD-L1/CD8*, a new dual-staining IHC assay of PD-L1+ and CD8+ cells (TILs) present in the tumor microenvironment on a single slide prepared from FFPE tissue.

The Halioseek™ assay, powered by advanced image analysis tool, extracts a full set of information such as CD8+ cell density (cells/mm²), proximity between CD8+ and PD-L1+ cells and finally cluster indexes for CD8+ cells and PD-L1+ cells. Cell-to-cell distances were validated with an independent Digital Pathology (DP) tool. Variability and accuracy were assessed for all parameters using adjacent dual-stained slides on complete tissue sections. The concordance with main IVD approved PD-L1 methods was established on a representative set of 55 NSCLC tumors.

Vincent FERT, CEO of HalioDx comments*: "Because it measures the two key components of the immune microenvironment with respect to the known ICI mechanism of action, Halioseek™ PD-L1/CD8 has the potential to become the reference assay for precision Immunotherapy. The assay has proven today its accuracy and concordance with main IVD approved PD-L1 methods."* **He adds:** *"This assay is already available to provide our pharmaceutical partners a unique solution for companion diagnostic development and registration. A CE-IVD version is under development to assist clinicians in defining immunotherapy treatment strategy for NSCLC patients in combination with other tumor and patient biological and clinical features."*

Poster details:

Session Title: Checkpoints 1
Session Date and Time: Sunday, April 2, 2017 1:00 - 5:00 PM EST
Location: Poster Section 25 / Poster Board Number: 24
The poster will be downloadable on HalioDx website when the session will start.

* For Research Use Only. Not for Use in Diagnostic Procedures.

About HalioDx

The Immune Response to Cancer Diagnostics

HalioDx is an immuno-oncology diagnostic company providing oncologists 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.

HalioDx Immunoscore® technology integrates immunohistochemistry combined with advanced imaging analysis enabling extraction of spatially-organized tissue molecular information.

Immunoscore® is a platform for many cancers, as immune response to tumor is a key hallmark of disease progression.

Pioneered by Jérôme Galon at the Cordeliers Research Center, Paris, France, Immunoscore® Colon is the flagship assay of HalioDx, positioned to be a future diagnostic standard for delivering prognostic and predictive information. HalioDx develops also assays such as Halioseek™ and Immunosign® to help stratifying patients for immunotherapies.

HalioDx collaborates with an increasing number of renowned international clinical groups and biopharmaceutical companies to support clinical utility and ensure rigorous performance validation of its assays in a large number of cancer indications.

HalioDx has an experienced team of more than 100 employees, a CLIA-certified laboratory (H1 2017) and compliant facilities to develop, manufacture, register and market *in vitro* diagnostic (IVD) products.

HalioDx executes biomarker studies and companion diagnostic assay development in conformity with regulations and in partnership with biopharmaceutical companies.

The company co-founded the European immunology cluster Marseille Immunopole (MI).

For more information, please visit our website www.haliodx.com and follow the company on Twitter @HalioDx.

Contacts

HalioDx SAS
Vincent Fert
President and CEO
+ 33 (0)4 91 29 30 90
vincent.fert@haliodx.com

ATCG Press
Marie Puvieux (France)
Mob: +33 (0)6 10 54 36 72
Jean-Mehdi Grangeon (ROW)
Mob: +33 (0)6 62 22 00 24
haliodx@atcg-partners.com