

Halioseek® PD-L1/CD8 now CE-IVD for clinical testing

- Halioseek® is now CE-IVD and can be used for % PD-L1 Tumor Cells assessment in Non-Small Cell Lung Cancer (NSCLC)
- Performance of the test have been established against main PD-L1 assays, SP263 and 22C3
- The dual detection of PD-L1 and CD8 + cells offered by Halioseek®PD-L1/CD8 has the potential to improve prediction of response to immune checkpoint inhibitors

Marseille, France, October 24, 2017 – HalioDx SAS, an immuno-oncology diagnostic company, announces the commercial launch of its Halioseek® PD-L1/CD8 CE-IVD assay and its proprietary image analysis solution that will be presented at SITC congress in November 8-12th 2017.

Anti-PD-1/PD-L1 are now established treatments for advanced NSCLC patients whose tumors express PD-L1 as assessed by immunohistochemistry. However, patients with PD-L1 negative tumors can still achieve clinical benefit. Therefore, although PD-L1 positivity enriches for populations with clinical benefit, the selection of patients can be further improved with additional markers; in particular the presence of tumor-infiltrating lymphocytes like CD8+ T cells which are known to play a crucial role in immune response to cancer ([Teng et al. Cancer Res. 2015](#)).

Performance of Halioseek® on PD-L1 quantification have been validated during the development of the CE-IVD assay. Tests on 162 samples demonstrated the high concordance between Halioseek® PD-L1 and both SP263 and 22C3 clones. The concordance is established for 1%, 5%, 10% and 50% thresholds, covering the major clinical cut offs for PD-L1 assays used in combination with anti-PD-1 ICI for patients stratification.

Halioseek® Analyzer allows the standardized computation of CD8+ and PD-L1+ cell densities as well as the PD-L1+ cell percentage on the same slide. Proximity index calculated between PD-L1+ and CD8+ cells is analyzed and may be indicative of T cells exhaustion within the tumor microenvironment. These outputs are computed within predefined regions of interest either automatically or manually selected (e.g. core tumor, invasive margin).

Vincent FERT, CEO of HalioDx comments: *“The availability of our CE-IVD version of Halioseek® PD-L1/CD8 is a great improvement in term of standardization and in assisting clinicians to define immunotherapy treatment strategy for NSCLC patients. By precisely measuring the two key components of the immune microenvironment involved in the known ICI mechanism of action, Halioseek® PD-L1/CD8 has the potential to become the reference assay for precision immunotherapy.”* **He adds:** *“This assay in clinical research is already available and used by our pharmaceutical and academic partners. We expect results of clinical studies involving Halioseek® PD-L1/CD8 to be shared in the coming months.”*

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.

Immunoscore® proprietary technology, pioneered by Jérôme Galon at the Cordeliers Research Center, Paris, France, 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. HalioDx collaborates with renowned international clinical groups to support clinical utility and ensure rigorous performance validation of its assays in selected cancer indications. HalioDx develops also assays such as Halioseek™ and Immunosign® to help stratifying patients for immunotherapies.

HalioDx has an experienced team of more than 130 employees, a CLIA laboratory and compliant facilities to develop, manufacture, register and market *in vitro* diagnostic (IVD) products and perform patient sample testing in a GCP/GCLP compliant environment. 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 Immunopôle (MI).

For more information, please visit our websites www.haliodx.com, www.immunoscore-colon.com and www.halioseek.com and follow the company on Twitter [@HalioDx](https://twitter.com/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