

## HalioDx performed development work for *ipsogen*<sup>®</sup> JAK2 510(k) clearance by QIAGEN

- HalioDx has successfully performed critical development phases for *Ipsogen*<sup>®</sup> JAK2 510(k) in close collaboration with QIAGEN and a panel of international clinical centers
- QIAGEN has received 510(k) clearance from the U.S. Food and Drug Administration to market *ipsogen*<sup>®</sup> JAK2 RGQ PCR kit
- HalioDx intend to further apply its development expertise in immuno-oncology projects

Marseille, France, March 30, 2017 – HalioDx SAS, an immuno-oncology diagnostic company, today announced that its R&D collaboration with QIAGEN N.V., a leading global provider of Sample to Insight solutions, has resulted in a U.S. Food and Drug Administration (FDA) 510(k) clearance for QIAGEN's *ipsogen*<sup>®</sup> JAK2 RGQ PCR test.

The *ipsogen*<sup>®</sup> JAK2 RGQ PCR test is a qualitative *in vitro* diagnostic test for the detection of the JAK2 V617F/G1849T allele in genomic DNA extracted from EDTA whole blood. It is a real time PCR test performed on the QIAGEN Rotor-Gene Q MDx instrument. The test is intended for use as an adjunct to evaluation of suspected Polycythemia Vera, in conjunction with other clinicopathological factors and will be marketed by QIAGEN as part of their Personalized Healthcare assays portfolio.

HalioDx performed feasibility & development phases including clinical validation on behalf of QIAGEN. Design, verification & validation phases were led by HalioDx on the basis of IDE & pre-IDE approvals. The clinical performance of the *ipsogen* JAK2 RGQ PCR Kit was evaluated during a multicenter, international, prospective, interventional study conducted by HalioDx. The study had successful patient enrollment at 7 sites in the United States, 12 sites in France, and 5 sites in Italy.

**Vincent FERT, CEO of HalioDx comments:** *“By successfully achieving this project on behalf of QIAGEN we have demonstrated our expertise and capabilities to drive IVD projects through complex US IVD regulatory path. The commitment of our team and the excellent collaboration framework with our partner QIAGEN and international clinical centres exemplify how we want to drive HalioDx company value in the near future. We intend to leverage this expertise with QIAGEN but also with our growing biopharma partners in immuno-oncology”.*

## 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.haliordx.com](http://www.haliordx.com) and follow the company on Twitter [@HalioDx](https://twitter.com/HalioDx).

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