

## Creation of HalioDx

A management buy-out by the QIAGEN Marseille Executive team

The ambition to become the reference diagnostic company in immuno-oncology

A business model combining immune companion diagnostics with biopharma  
and standalone developments

Marseille, France, March 23, 2015 – HalioDx, created from a management buy-out of QIAGEN Marseille, today announces its inception. HalioDx ambition is to become the reference company in immuno-oncology diagnostics, moving personalized medicine forward.

To achieve its ambition, HalioDx will from Day 1 combine three assets:

- An experienced and complementary management team, cofounders of HalioDx. The team has a proven track record in all components of IVD oncology assays development and commercialization
- Worldwide licences on a broad portfolio of patents on immuno-oncology biomarkers created by Inserm Transfert on behalf of Inserm, AP-HP and Paris-Descartes University. The inventions, developed by Jérôme Galon, Research Director at Inserm (cofounder of HalioDx and Chairman of the Scientific Board) and his team (Inserm UMRS1138) at Cordeliers Research Center, Paris, France, comprise the Immunoscore® and several immune gene expression signatures. The Immunoscore® is an innovative combination of immunohistochemistry (with specific T lymphocytes markers) and digital pathology-based scoring<sup>1</sup>. It has been shown to significantly improve prognostication of colon cancer – a challenge for clinicians –, and is currently validated in a large international study<sup>2</sup>. The Immunoscore®, as well as gene expression signatures assessing multiple immune-related biomarkers currently under investigation, are promising candidates for predicting patient response to immuno-oncology treatments in several solid tumors
- Fully operational R&D and manufacturing teams, and facilities and quality system

HalioDx will operate in the field of immuno-oncology, the most active today in oncology. Over the last 5 years, three immuno-oncology drugs – one anti-CTLA-4 and two anti-PD-1 molecules – have been approved in the US or in EU, for advanced melanoma and lung cancer, despite the absence of robust predictive biomarkers; many new molecules are in development by various biopharma companies. The IVD industry will play an essential role in accelerating the development of immunotherapies and their adoption in routine practice. Jérôme Galon and his team have been at the forefront of the development of immune-related assays and the concept of immune contexture. Nature, topography and intensity of the patient's immune reaction around his tumor are altogether key drivers of prognosis and of the potential to respond to immuno-oncology drugs. Work from other scientific groups supports this approach<sup>3</sup>.

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<sup>1</sup> Galon et al, Science 2006, Mlecnik et al, JCO 2011

<sup>2</sup> Galon et al, J Pathol 2014

<sup>3</sup> Tumeh et al, Nature 2014, Llosa et al, Cancer Discov 2015

HalioDx has raised 7.5 million euros in a Round A of financing combining the founders and three leading capital venture funds, MI Care, Sham Innovation Santé advised by Turenne Capital and Sofipaca. The first partner of HalioDx is today QIAGEN via manufacturing and R&D contracts. The company will leverage this relationship and others to come, to develop its proprietary offering in immuno-oncology diagnostics with the aim to classify tumors and guide individual treatment decisions.

HalioDx business model is based on 2 pillars:

- Development of standalone assays, with the objective to obtain CE marking for the Immunoscore® in colon cancer within 18 months
- Collaboration agreements with key biopharma players to develop and register immune companion diagnostics based on its portfolio of licenses.

*"Inserm Transfert quickly realised that the technology Immunoscore® developed by Dr. J. Galon and his team had an outstanding potential in helping physicians to stratify cancer patients and support anti-cancer therapeutic approaches. Then we built the appropriate strategy (maturation, protection, commercialisation included) to allow its industrial transfer within the best possible conditions, all along in a trustful relationship with the academic team. We are very pleased to sign this licensing agreement with HalioDx, and delighted to contribute to its development and, in this regard, to the national ecosystem of innovation in human health."* said Pascale Augé, CEO of Inserm Transfert.

*"HalioDx is an ambitious entrepreneurial project"* added Vincent Fert, President and Chief Executive Officer of HalioDx. *"With our team of 75 people, we have the resources and collective expertise to drive diagnostic innovation in immuno-oncology, the most active field in oncology today. Considering the strength and scientific value of our worldwide license portfolio, and the need for powerful prognostic and predictive biomarkers in immuno-oncology, we are confident we will rapidly bring the Immunoscore® into routine clinical practice for colon cancer, and validate innovative predictive immune companion diagnostics for solid tumors. With these immune-related assays, we will contribute to a new dimension of personalized medicine in oncology, and support clinicians and patients to identify the optimal anti-cancer treatment strategy."*

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#### About MICare

MICare is an investment holding specialized in health care. It follows Matignon Technologies 1 and 2, two funds which have supported for 11 years the current HalioDx leadership team in their previous responsibility as Ipsogen management team.

### About Sham Innovation Santé

Founded in May 2014, Sham Innovation Santé is an innovation capital vehicle controlled and held by Sham, a mutual insurer specialized in risk management for health care, social welfare and community health organizations. Advised by Turenne Capital, Sham Innovation Santé's mission is to support innovative businesses in the health care sector through the growth and development phases of their life cycle.

### About Sofipaca

Sofipaca is the private equity branch of Crédit Agricole Alpes-Provence and Provence Côte d'Azur. Since its creation in 1984, Sofipaca supports Provence-Alpes-Côte d'Azur based businesses in their capital development and capital transmission projects. A long-term investor and minority shareholder, Sofipaca can support companies with different development profiles, and provides strategic input without interfering with operational management.

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