Inivata and Gustave Roussy Publish Positive Results from Prospective Clinical Study in use of ctDNA Liquid Biopsy to Guide Cancer Treatment

Publication in Annals of Oncology Shows Benefit of Osimertinib in EGFR-mutant Non-Small Cell Lung Cancer Patients with T790M-Mutation Detected by InVision™ ctDNA liquid biopsy platform

First Reported Study of Clinical Outcomes in Patients Whose Treatment was Based on ctDNA Profiling

Research Triangle Park, NC and Cambridge, UK, and Villejuif, France, March 30, 2017 -- Inivata, a global clinical cancer genomics company employing a revolutionary approach to circulating tumor DNA (ctDNA) analysis to improve personalized healthcare in oncology, and Gustave Roussy, a premier European Cancer Centre, today announce the publication in the journal *Annals of Oncology* of positive results from a study using the InVision™ liquid biopsy platform to guide cancer treatment[i].

The study by a world-leading team of investigators led by Benjamin Besse, Chairman of the Thoracic Unit, Medical Oncologist at Gustave Roussy is the first to be published on the prospective testing of the efficacy of a cancer treatment based on ctDNA results in a real-world setting.

In this study, 48 patients with advanced non-small cell lung cancer (NSCLC), who had been shown to have a common epidermal growth factor receptor *EGFR* mutation at an initial biopsy, and had developed tyrosine kinase inhibitor (TKI) resistance, were tested using Inivita's InVision™ ctDNA liquid biopsy platform for the presence of *T790* mutations. The *T790* mutation is a known mechanism of acquired resistance to the first and second TKIs used in the treatment of this patient cohort. Importantly, the patients in the study were not able to have a new tissue biopsy at the time of disease progression for reasons including lack of available tissue or the localisation of the tumour. The ctDNA *T790M* mutational status was detected in 50% of NSCLC patients, which is consistent with detection rates seen in tissue biopsies.

Benjamin Besse, Chairman of the Thoracic Unit, Medical Oncologist at Gustave Roussy said: "This Inivata test allowed us to rescue patients unable to undergo a biopsy. The latter situation is frequent in EGFR-mutated NSCLC patients. Indeed, recurrences during first line TKIs may be too small or in a site inadequate for molecular testing, such as bone metastases. Liquid biopsies are easy to manage in a real-life setting, and can be performed potentially in any centre. They are meant to become the upfront test, keeping tissue biopsy as a second line test. I foresee a future where liquid biopsy will not only be used as a diagnostic tool, but also as a dynamic test to prospectively monitor NSCLC evolution."

The *T790M* positive NSCLC patients within the study were treated with osimertinib (marketed as TAGRISSO™), a third generation TKI recently approved by both the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) for patients with acquired EGFR *T790M* mutations. Among evaluable patients, osimertinib gave a partial response rate of 62.5% and a stable disease rate of 37.5%. All responses were confirmed responses. These results are comparable to the efficacy reported with osimertinib in patients with the *T790M* mutation detected in tumour tissue biopsy as seen in registration trials.

These results show, in a prospective clinical setting, that ctDNA from liquid biopsy can be used as a surrogate marker for *T790M* in tumour tissue and, more broadly, the potential for the technology to guide personalised cancer treatment.

Clive Morris, Chief Medical Officer at Inivata, said: "This study shows for the first time the clinical utility of our InVision™ ctDNA liquid biopsy platform in guiding treatment decisions and delivering better patient outcomes. While a relatively small study, the fact that these patients were able to receive targeted therapy despite the unavailability of a tissue biopsy and the close comparability of mutation detection and treatment outcomes to standard practice based on tissue profiling is extremely encouraging. We are proud to have worked closely with Gustave Roussy, a world-renowned cancer centre, on this study. We have an extensive, international clinical validation programme ongoing and look forward to presenting further results as we advance towards commercialisation of our InVision™ platform."

- Ends -

About Inivata

Inivata, a clinical cancer genomics company, is employing the precision of ctDNA analysis to improve personalized healthcare in oncology. Using a simple blood test, ctDNA analysis is a new tool for oncologists to detect cancer, stratify patients, and assess individual response to treatment. Inivata's proprietary technology is based on pioneering research from the Rosenfeld Lab at the Cancer Research UK Cambridge Institute (CRUK-CI), University of Cambridge. Inivata's InVision™ ctDNA assay provides a highly sensitive analysis of a highly-select gene panel to identify actionable mutations for oncologists to treat their patients optimally. In 2016, Inivata opened a CLIA lab in Research Triangle Park, NC and launched a large-scale, prospective clinical validation study of the Company's ctDNA analysis in lung cancer. For more information and a full listing of investors, please go to www.inivata.com. Follow us on Twitter @Inivata.

About Gustave Roussey

Gustave Roussy is the leading Cancer Centre in Europe. It is a centre where all the skills in cancer care are focused on the patient. It comprises 3,000 professional staff who are engaged in care, research and teaching. www.gustaveroussy.fr/en

Media Contacts:

Consilium Strategic Communications
Chris Gardner/Laura Thornton
Email: inivata@consilium-comms.com
Phone: +44 (0)20 3709 5700

Karen Chandler-Smith
Karen.chandler-smith@inivata.com
Phone: +44 (0) 7900 430235

[i] *Osimertinib benefit in EGFR-mutant NSCLC patients with T790M-mutation detected by circulating tumour DNA*. J. Remon *et al*. (Ann Oncol 2017; 28-4: 784-790)