Roche France, Foundation Medicine and the Institute Gustave Roussy announce unique partnership to provide in-house liquid biopsy genomic testing to cancer patients in France

- **Roche France and Foundation Medicine will transfer FoundationOne® Liquid CDx technology to the Institute Gustave Roussy, with the potential to provide comprehensive genomic profiling (CGP) through liquid biopsy testing to all patients with advanced cancer in France**
- **Liquid biopsy testing, which is based on the analysis of circulating cell-free DNA, is an important option for patients with advanced cancer, allowing them to benefit from CGP when a tissue biopsy is not possible or recommended, and may yield results faster than tissue testing**
- **The partnership underscores Roche and Foundation Medicine's commitment to investing in personalised healthcare to advance precision medicine**

Roche France, Foundation Medicine, Inc. and the Institute Gustave Roussy, the leading cancer centre in Europe, announced today a unique partnership to establish in-house liquid biopsy testing at the Institute Gustave Roussy's facilities in France, by transferring technology from Foundation Medicine's FoundationOne®Liquid CDx, a blood-based comprehensive genomic profiling (CGP) test.

Using a simple blood sample, FoundationOne Liquid CDx analyses more than 300 cancer-related genes for genomic alterations that cause the cancer to grow. Identifying alterations in the cancer genome of a patient can help provide a diagnosis faster, and guide treatment strategies. CGP has transformed the traditional 'one-size fits-all' approach to cancer and is an important tool for identifying rare and hard to find mutations. FoundationOne Liquid CDx also reports tumour fraction, to provide prognostic, diagnostic and predictive insights that inform research or treatment decisions for individual patients across all solid tumours. Liquid biopsy allows more patients with advanced cancer to benefit from the targeted therapies informed by CGP, for example when a tissue biopsy is not possible or recommended, because the tumour is inaccessible, when there is insufficient tissue, when preferred because of patient convenience or when results are needed more quickly. Liquid biopsy is indicated in all guidelines for the management of patients living with cancer including ESMO, ASCO and NCCN. [1-4]

As part of this public-private partnership, the Institute Gustave Roussy will increase its biopathology capacity by creating an innovative laboratory for genomic testing in coordination with various leading precision medicine experts, centres and institutions in France. This will drive advancement for cancer patients being treated in France by making CGP available to more patients, enabling physicians to more efficiently diagnose their patients and identify potential treatments options, as well as accelerating the development of new clinical trials, providing comprehensive insights to support research and development, and contributing to the optimisation of treatment strategies and care pathways.

"This future platform for the strategic analysis of liquid biopsies together with the creation of clinico-genomic database will support the advancements already made possible by the France Médecine Génonique 2025 plan," said Professor Fabrice Barlesi, General Director of the Institute Gustave Roussy. "Genomic profiling is indicated for up to 200,000 patients every year in France, and this partnership could help provide access to cancer treatments tailored to the individual patient's actionable molecular alterations, as well as access more

clinical trials, particularly in early phases, enabling greater equity in access to precision medicine."

"Liquid biopsy is a diagnostic revolution that we expect will improve quality of life and outcomes for many people living with cancer," said Jean-François Brochard, President of Roche Pharma France. "The transfer of FoundationOne Liquide CDx technology to the Institute Gustave Roussy represents a major step forward in improving its availability to patients in Europe, and demonstrates Roche's commitment to investing in more personalised, tailored medicine to better meet their needs"

“Cancer is a disease of the genome and it’s critical that physicians have access to high-quality, well-validated genomic tests to inform treatment options for their patients,” said Brian Alexander, Chief Executive Officer, Foundation Medicine. “Our vision is to make comprehensive genomic profiling indispensable to cancer care and this partnership with the Institute Gustave Roussy is a critical step forward in realising that vision.”

This partnership, expected to become fully operational in 2024, underscores the commitment from Roche and Foundation Medicine to invest in personalised healthcare, combining pioneering science, data, analytics and technology to advance care and improve patients’ lives. This partnership also aims to strengthen the ecosystem of the Paris-Saclay Cancer Cluster, initiated following President Macron’s announcement in June 2021 as part of the Strategic Council of Health Industries.

About FoundationOne®Liquid CDx

FoundationOne®Liquid CDx is for prescription use only and is a qualitative next-generation sequencing based in vitro diagnostic test for advanced cancer patients with solid tumours. The test analyses 324 genes utilising circulating cell-free DNA and is FDA-approved to report short variants in 311 genes and as a companion diagnostic to identify patients who may benefit from treatment with specific therapies (listed in Table 1 of the Intended Use) in accordance with the approved therapeutic product labelling. Additional genomic findings may be reported and are not prescriptive or conclusive for labelled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. When considering eligibility for certain therapies for which FoundationOne Liquid CDx is a companion diagnostic, testing of plasma is only appropriate where tumour tissue is not available. Patients who are negative for other companion diagnostic mutations should be reflexed to tumour tissue testing and mutation status confirmed using an FDA-approved tumour tissue test, if feasible. For the complete label, including companion diagnostic indications and complete risk information, please visit www.F1LCDxLabel.com.

About the Institute Gustave Roussy

Ranked first in Europe and third worldwide, the Institute Gustave Roussy is a centre of global expertise entirely dedicated to cancer patients. The Institute is a founding pillar of the Paris-Saclay Cancer Cluster oncology biocluster. A source of therapeutic innovations and diagnostic advances, the Institute welcomes nearly 50,000 patients each year and develops an integrated approach between prevention, research, care and education. An expert in rare cancers and complex tumours, the Institute Gustave Roussy treats all cancers, at all stages of life. It offers its patients personalised care that combines innovation and humanity, where care is taken into account but also the physical, psychological and social quality of life. With 4,100 employees spread over two sites, Villejuif and Chevilly-Larue, the Institute Gustave

Roussy brings together the expertise essential for high-level cancer research; 40% of patients treated are included in clinical studies.

To find out more about the Institute Gustave Roussy and follow the Institute's news, please visit www.GustaveRoussy.fr, or follow us on Twitter, Facebook, LinkedIn and Instagram.

About Foundation Medicine

Foundation Medicine is a pioneer in molecular profiling for cancer, working to shape the future of clinical care and research. We collaborate with a broad range of partners across the cancer community and strive to set the standard for quality, scientific excellence, and regulatory leadership. Our deep understanding of cancer biology helps physicians make informed treatment decisions for their patients and empowers researchers to develop new medicines. Every day, we are driven to help our partners find answers and take action, enabling more people around the world to benefit from precision cancer care. For more information, please visit us on www.FoundationMedicine.com and follow us on Twitter and LinkedIn.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

References

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[4] NCCN Clinical Practice Guidelines in Oncology. Occult Primary (Cancer of Unknown Primary). NCCN. 2021;1.