Foundation Medicine Announces Collaboration with Pierre Fabre Laboratories to Develop Companion Diagnostics in Non-Small Cell Lung Cancer

Cambridge, Mass., & Castres, France – November 15, 2023- Foundation Medicine, Inc., and Pierre Fabre Laboratories today announced a collaboration to develop Foundation Medicine's high-quality genomic tests, FoundationOne®CDx and FoundationOne®Liquid CDx, as companion diagnostics for new targeted therapies to treat patients with non-small cell lung cancer (NSCLC). The companies will work collaboratively to seek the regulatory approval for Foundation Medicine assays which detect mutations including $BRAF^{V600E}$ to identify patients for potential treatment with Pierre Fabre Laboratories's BRAF/MEK inhibitor combination regimen, BRAFTOVI® (encorafenib) and MEKTOVI® (binimetinib), in the European Union. This combination therapy is currently under evaluation by the European Medicines Agency for patients with $BRAF^{V600}$-mutant advanced NSCLC and was evaluated in a clinical trial sponsored by Pfizer and supported by Pierre Fabre.

Lung cancer – the number one cause of cancer deaths worldwide – remains an area of high unmet need notably for those people living with $BRAF^{V600E}$ mutations, which occur in approximately 2% of all non-small cell lung cancer.[1] FoundationOne CDx and FoundationOne Liquid CDx are U.S. Food and Drug Administration (FDA) approved in-vitro diagnostics used to identify potentially targetable mutations, including BRAF, in blood- and tissue-based solid tumor samples.

"Today, as the number of indications and approvals in oncology grow rapidly, companion diagnostics provide information that is critical for the safe and effective use of targeted therapies. And that's why we are excited to work with Foundation Medicine" said Núria Perez-Cullell, Head of Medical and Patient Consumer Department, Pierre Fabre Laboratories. "Thanks to those companion diagnostics, physicians will have comprehensive, reliable information about what is driving a patient's cancer, such as $BRAF^{V600E}$ mutations, so they can make personalized treatment decisions".

Foundation Medicine has the only FDA-approved portfolio of comprehensive genomic profiling tests offering physicians both blood- and tissue-based testing options for detecting genomic alterations like $BRAF^{V600E}$ to help guide personalized treatment decisions. Foundation Medicine has demonstrated initial success in navigating the new In Vitro Diagnostics Regulation (IVDR) in Europe through activation of dozens of global clinical studies or using patient samples from over 20 European Union member states in compliance with IVDR Authorization and Notification pathways.[2]

"High-quality companion diagnostics play a crucial role in helping physicians match their patients with targeted treatment options," said Troy Schurr, Chief Biopharma Business Officer

at Foundation Medicine. “We are excited to support Pierre Fabre Laboratories in offering more treatment options for cancer patients, and to increase access to precision therapies in the European Union.”

Foundation Medicine® and FoundationOne® are registered trademarks of Foundation Medicine, Inc.

About Foundation Medicine: Your Essential Partner in Cancer Care
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 FoundationOne®CDx
FoundationOne CDx is a next-generation sequencing based in vitro diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations (CNAs) in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) using DNA isolated from formalin-fixed, paraffin-embedded (FFPE) tumor tissue specimens. FoundationOne CDx is for prescription use only and is intended as a companion diagnostic to identify patients who may benefit from treatment with certain targeted therapies in accordance with their approved therapeutic product labeling. Additionally, FoundationOne CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. 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. Some patients may require a biopsy. For a full list of targeted therapies for which FoundationOne CDx is indicated as a companion diagnostic, please visit www.F1CDxLabel.com.

About FoundationOne®Liquid CDx
FoundationOne Liquid CDx is a qualitative next generation sequencing based in vitro diagnostic test for prescription use only that uses targeted high throughput hybridization-based capture technology to analyze 324 genes utilizing circulating cell-free DNA (cfDNA) isolated from plasma derived from anti-coagulated peripheral whole blood of advanced cancer patients. The test is FDA-approved to report short variants in over 300 genes and is 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 labeling. Additional

genomic findings may be reported and are not prescriptive or conclusive for labeled 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. Patients who are negative for companion diagnostic mutations should be reflexed to tumor tissue testing and genomic alteration status confirmed using an FDA-approved tumor tissue test, if feasible. For the complete label, including companion diagnostic indications and complete risk information, please visit www.F1LCDxLabel.com.

About Pierre Fabre Laboratories

Pierre Fabre Laboratories is a leading French medical and beauty care company with 4 decades of experience in innovation, development, manufacturing, and commercialization in oncology. The company dedicated about 80% of its R&D spendings to oncology in 2022 and has recently declared targeted therapies as its main R&D priority. Its current commercial portfolio in oncology covers colorectal, breast and lung cancers, melanoma, hematology, and pre-cancerous skin conditions like actinic keratosis.

In 2022, Pierre Fabre Laboratories posted 2.7 billion euros in revenues, 69% of which came from international sales in 120 countries. Established in the South-West of France since its creation in 1962, the Group manufactures over 90% of its products in France and employs some 9,600 people worldwide. The company is 86%-owned by the Pierre Fabre Foundation, a government-recognized public-interest foundation, and secondarily by its own employees through an international employee stock ownership plan. Pierre Fabre Laboratories 's sustainability policy has been assessed by the independent AFNOR Certification body at the "Exemplary" level of its CSR label (ISO 26 000 standard for sustainable development). Further information about Pierre Fabre Laboratories can be found at www.pierre-fabre.com, @PierreFabre.

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[1] American Cancer Society. What is Non-Small Cell Lung Cancer? https://www.cancer.org/cancer/non-small-cell-lung-cancer/about/what-is-non-small-cell-lung-cancer.html

[2] Data on file.