Foundation Medicine and Relay Therapeutics Collaborate to Develop FoundationOne®CDx as a Companion Diagnostic for Relay's Investigational FGFR2 Inhibitor, RLY-4008

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CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Today Foundation Medicine, Inc., a pioneer in molecular profiling for cancer, and Relay Therapeutics (Nasdaq: RLAY), a clinical-stage precision medicine company transforming the drug discovery process by combining leading-edge computational and experimental technologies, announced a collaboration to develop FoundationOne®CDx as a companion diagnostic for RLY-4008, the company's investigational FGFR2 inhibitor.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20220912005297/en/

RLY-4008 is a selective oral small molecule inhibitor of FGFR2, which is currently being evaluated for use in patients with FGFR2-mutated cholangiocarcinoma (CCA), or bile duct cancer, and other solid tumors. FGFR2 is one of four members of the FGFR family, a set of closely related proteins with highly similar protein sequences and properties. If the therapy and companion diagnostic are approved, FoundationOne CDx would be used to identify patients with FGFR2 fusions and select rearrangements in CCA who may be appropriate for treatment with RLY-4008.

Yesterday, at the European Society of Medical Oncology (ESMO) 2022 Congress, Relay presented interim clinical data for RLY-4008 from this patient population in pan-FGFR inhibitor naïve patients demonstrating an 88% overall response rate and anticipates fully enrolling this pivotal cohort in the second half of 2023.

"FGFR2-mutated cholangiocarcinoma is an aggressive condition that's generally diagnosed in advanced stages when prognosis is poor and treatment options are limited," said Don Bergstrom, M.D., Ph.D., President of R&D at Relay Therapeutics. "We're proud to partner with the leader in companion diagnostic approvals as we work to advance this potentially life-changing therapy and create access to it once approved."

Foundation Medicine's portfolio of FDA-approved comprehensive genomic profiling tests offers physicians both blood- and tissue-based testing options for detecting genomic alterations that help guide personalized treatment decisions. As companion diagnostics, FoundationOne CDx and FoundationOne®Liquid CDx allow oncologists to identify patients who may be appropriate for FDA-approved targeted therapies.

"Relay Therapeutics is an innovator in precision therapy development who shares our commitment to bringing more effective treatment options to patients, as expeditiously as possible," said Sanket Agrawal, Chief Biopharma Business Officer at Foundation Medicine. "We're proud to join forces with them as they advance their novel approach to therapy development, and work to increase treatment options for patients living with cholangiocarcinoma."

The oral presentation from the ESMO Congress for RLY-4008 is available on the Relay Therapeutics website under Publications: https://relaytx.com/publications/.

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 http://www.foundationmedicine.com/genomic-testing/foundation-one-cdx.

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.

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

About RLY-4008

RLY-4008 is a potent, selective and oral small molecule inhibitor of FGFR2, a receptor tyrosine kinase that is frequently altered in certain cancers. FGFR2 is one of four members of the FGFR family, a set of closely related proteins with highly similar protein sequences and properties. Preclinically, RLY-4008 demonstrated FGFR2-dependent killing in cancer cell lines and induced regression in in vivo models, while minimal inhibition of other targets was observed, including other members of the FGFR family. In addition, RLY-4008 demonstrated strong activity against known clinical on-target resistance mutations in cellular and in vivo preclinical models. RLY-4008 is currently being evaluated in a clinical trial in patients with advanced or metastatic FGFR2-altered solid tumors with a single arm, potentially registration-enabling cohort for pan-FGFR ("FGFRi") treatment-naïve FGFR2-fusion CCA. To learn more about the clinical trial of RLY-4008, please visit here.

About Relay Therapeutics

Relay Therapeutics (Nasdaq: RLAY) is a clinical-stage precision medicines company transforming the drug discovery process by combining leading-edge computational and experimental technologies with the goal of bringing life-changing therapies to patients. As the first of a new breed of biotech created at the intersection of disparate technologies, Relay Therapeutics aims to push the boundaries of what's possible in drug discovery. Its Dynamo™ platform integrates an array of leading-edge computational and experimental approaches designed to drug protein targets that have previously been intractable. Relay Therapeutics' initial focus is on enhancing small molecule therapeutic discovery in targeted oncology and genetic disease indications. For more information, please visit www.relaytx.com or follow us on Twitter.

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