Relay Therapeutics Announces Dosing of First Patient in First-in-Human Clinical Trial of RLY-4008, a Highly Selective FGFR2 Inhibitor

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CAMBRIDGE, Mass., Sept. 03, 2020 (GLOBE NEWSWIRE) -- Relay Therapeutics, Inc. (Nasdaq: RLAY), a clinical-stage precision medicine company transforming the drug discovery process by leveraging unparalleled insights into protein motion, today announced the first patient has been dosed in a first-in-human clinical trial of RLY-4008 enriched for patients with intrahepatic cholangiocarcinoma (ICC) and other advanced solid tumors harboring a fibroblast growth factor receptor 2 (FGFR2) alteration. RLY-4008 is the only selective small molecule inhibitor of FGFR2 in clinical development.

“We are excited to bring RLY-4008, our second targeted therapeutic, into clinical development,” said Don Bergstrom, M.D., Ph.D., executive vice president of R&D of Relay Therapeutics. “FGFR2 altered tumors are known to respond clinically to pan-FGFR inhibitors but with limited benefit to patients. RLY-4008 is an exquisitely selective and purpose-built medicine, discovered with our Dynamo platform, designed to dramatically alter the course of disease for patients with FGFR2 altered cancers.”

The first-in-human trial is designed to evaluate the safety and tolerability of RLY-4008 in patients with advanced or metastatic solid tumors. The trial will predominantly enroll patients with molecularly identified FGFR2 fusions, mutations and amplifications during the dose escalation phase. Given RLY-4008’s strong preclinical activity against both primary oncogenic alterations and acquired pan-FGFR inhibitor resistance mutations, the trial is enrolling patients who are naïve to pan-FGFR inhibitors as well as those who have been exposed to prior therapy with pan-FGFR inhibitors. In the expansion part of the trial, five cohorts are planned to evaluate genetically defined populations: 1) ICC patients with a FGFR2 fusion previously treated with a pan-FGFR inhibitor; 2) ICC patients with a FGFR2 fusion not previously treated with a pan-FGFR inhibitor; 3) patients with an FGFR2 fusion and solid tumor other than ICC; 4) advanced, unresectable solid tumor patients with focal FGFR2 amplification; 5) advanced, unresectable solid tumor patients with an oncogenic FGFR2 mutation. Trial objectives include evaluating safety, tolerability, pharmacokinetics and anti-tumor efficacy. The trial is designed to enroll up to 125 patients.

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, while showing minimal inhibition of other targets, including other members of the FGFR family. RLY-4008 is currently being evaluated in a first-in-human trial designed to treat patients with advanced or metastatic FGFR2-altered solid tumors. To learn more about the first-in-human 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 with the goal of bringing life-changing therapies to patients. Built on unparalleled insights into protein motion and how this dynamic behavior relates to protein function, Relay Therapeutics aims to effectively drug protein targets that have previously been intractable, with an initial focus on enhancing small molecule therapeutic discovery in targeted oncology. The Company’s Dynamo platform integrates an array of leading-edge experimental and computational approaches to provide a differentiated understanding of protein structure and motion to drug these targets. For more information, please visit www.relaytx.com or follow us on Twitter.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding plans and timelines for the clinical development of RLY-4008, including plans and timelines for pursuing development in five additional cohorts to evaluate genetically defined patient populations, the therapeutic potential and clinical benefits thereof; expectations regarding current and future interactions with the U.S. Food and Drug Administration (FDA); and Relay Therapeutics' strategy, business plans and focus. The words "may," “might,” "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," “expect,” "estimate," “seek,” "predict," “future,” "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: the impact of COVID-19 on countries or regions in which we have operations or do business, as well as on the timing and anticipated results of our clinical trials, strategy and future operations; the delay of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates, including, but not limited to, RLY-1971 and RLY-4008; the risk that the results of our clinical trials may not be predictive of future results in connection with future clinical trials; Relay Therapeutics' ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of our planned interactions with regulatory authorities; and obtaining, maintaining and protecting our intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Relay Therapeutics’ Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Relay Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. Relay Therapeutics explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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