Relay Therapeutics Announces Clinical Trial Collaboration with Pfizer to Evaluate Atirmociclib in Combination with RLY-2608

June 5, 2024

Initial triplet combination of RLY-2608 + atirmociclib + fulvestrant to be evaluated in patients with PI3Kα-mutated HR+/HER2- metastatic breast cancer; initiation planned by end of 2024

CAMBRIDGE, Mass., June 05, 2024 (GLOBE NEWSWIRE) -- Relay Therapeutics, Inc. (Nasdaq: RLAY), a clinical-stage precision medicine company transforming the drug discovery process by combining leading-edge computational and experimental technologies, today announced a clinical trial collaboration with Pfizer Inc. (NYSE: PFE) to evaluate atirmociclib, Pfizer's investigative selective-CDK4 inhibitor, in combination with RLY-2608 and fulvestrant in patients with PI3Kα-mutated, HR+, HER2- metastatic breast cancer.

"We are very enthusiastic to evaluate Pfizer's novel investigative selective-CDK4 inhibitor atirmociclib in combination with RLY-2608, the first mutant selective PI3Kα inhibitor," said Don Bergstrom, M.D., Ph.D., President of R&D at Relay Therapeutics. "We believe that combining these two selective agents – atirmociclib and RLY-2608 – will avoid key off-target toxicity that comes from hitting CDK6 and wild-type PI3Kα, which has historically significantly limited use of non-selective agents. The breast cancer treatment landscape continues to evolve quickly, and we are pleased that the safety profile RLY-2608 has demonstrated to-date makes it well-positioned to be part of the next generation of therapies."

Under the terms of the agreement, Pfizer will provide atirmociclib for use in the study and Relay will be responsible for conducting the study. The RLY-2608 + atirmociclib + fulvestrant triplet combination is planned to begin by the end of 2024.

About RLY-2608

RLY-2608 is the lead program in Relay Therapeutics' efforts to discover and develop mutant selective inhibitors of PI3Kα, the most frequently mutated kinase in all cancers, with oncogenic mutations detected in about 14% of patients with solid tumors. RLY-2608 has the potential, if approved, to address more than 250,000 patients per year in the United States, one of the largest patient populations for a precision oncology medicine.

Traditionally, the development of PI3Kα inhibitors has focused on the active, or orthosteric, site. The therapeutic index of orthosteric inhibitors is limited by the lack of clinically meaningful selectivity for mutant versus wild-type (WT) PI3Kα and off-isoform activity. Toxicity related to inhibition of WT PI3Kα and other PI3K isoforms results in sub-optimal inhibition of mutant PI3Kα with reductions in dose intensity and frequent discontinuation. The Dynamo™ platform enabled the discovery of RLY-2608, the first known allosteric, pan-mutant, and isoform-selective PI3Kα inhibitor, designed to overcome these limitations. Relay Therapeutics solved the full-length cryo-EM structure of PI3Kα, performed computational long time-scale molecular dynamic simulations to elucidate conformational differences between WT and mutant PI3Kα, and leveraged these insights to support the design of RLY-2608. RLY-2608 is currently being evaluated in a first-in-human trial designed to treat patients with advanced solid tumors with a PIK3CA (PI3Kα) mutation. For more information on RLY-2608, please visit here.

About Relay Therapeutics

Relay Therapeutics is a clinical-stage precision medicine 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 complementary techniques and 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 or inadequately addressed. 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.

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 Relay Therapeutics' strategy, business plans and focus; the progress and timing of the clinical development of the programs across Relay Therapeutics' portfolio, including the timing of clinical initiation of the RLY-2608 + atirmociclib + fulvestrant triplet combination; the expected therapeutic benefits and potential efficacy and tolerability of RLY-2608, both as a monotherapy and in combination with other agents, and its other programs; the potential market opportunity for RLY-2608; and the expected strategic benefits under Relay Therapeutics' clinical trial collaboration with Pfizer. The words "may," "might," "will," "could," "would," "should," "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 global economic uncertainty, geopolitical instability, or public health epidemics or outbreaks of an infectious disease on countries or regions in which Relay Therapeutics has operations or does business, as well as on the timing and anticipated results of its clinical trials, strategy, future operations and profitability; the delay of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates; the risk that the preliminary results of its preclinical or clinical trials may not be predictive of future or final results in connection with future clinical trials of its product candidates; Relay Therapeutics' ability

to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of its planned interactions with regulatory authorities; and obtaining, maintaining and protecting its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled “Risk Factors” in Relay Therapeutics’ most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, 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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