Relay Therapeutics Discloses Three New Programs at New Program & Platform Event

June 6, 2024

3 new programs include 2 genetic disease programs – vascular malformations & Fabry disease – & 1 precision oncology program – NRAS-specific inhibitor

Cash guidance remains unchanged, and is expected to fund operations into second half of 2026

Relay Therapeutics to host webcast event today, June 6, at 8:00 a.m. ET

CAMBRIDGE, Mass., June 06, 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, will provide details on the company's portfolio during its New Program & Platform event today, June 6, 2024, from 8:00 to 10:00 a.m. ET. As part of the event, the company will disclose three new programs from its existing pre-clinical pipeline and will review how the Dynamo™ platform led to these discoveries. The new programs include two novel programs from its genetic disease portfolio and a potentially first-in-class NRAS-selective inhibitor. Both genetic disease programs have the potential to provide a unique approach to addressing clinically and commercially validated targets in vascular malformations and Fabry disease. The new programs announced today do not change cash guidance, which is expected to fund operations into the second half of 2026.

"Since Relay Therapeutics was founded eight years ago, our Dynamo platform has been very productive and we have made significant progress advancing our initial set of programs, including four that have entered the clinic. We have successfully created molecules for a variety of targets to-date, have shown clinical proof-of-concept for two of these programs and are aiming to start our first Phase 3 study next year with RLY-2608," said Sanjiv Patel, M.D., President and Chief Executive Officer of Relay Therapeutics. "Today, we are very excited to unveil the next set of innovative programs, which demonstrate the power of our Dynamo platform, and which we believe will drive the next wave of the company's growth. These new programs underscore the breadth of the platform's capabilities with expansion beyond precision oncology into genetic disease and beyond inhibitors to small molecule chaperones."

New Programs Potentially Addressing More Than 200,000 Patients in the United States

The New Program & Platform event presentation will highlight newly disclosed programs in vascular malformations, Fabry disease and NRAS.

Vascular Malformations

- Vascular malformations are a series of rare syndromes that occur due to atypical development of lymphatic and/or blood vessels, which enlarge or form tangles, pockets or shunting vessels that cause abnormal blood flow. They can occur in different parts of the body, vary in severity and may cause symptoms such as pain, swelling, skin discoloration, limb asymmetry and functional limits. The malformations typically grow over time, and, depending on what vessel(s) are involved, can become life-threatening.
- The primary vessel(s) involved determine the sub-type of malformation, which can include venous malformations, cerebral cavernous malformations, lymphatic malformations and PIK3CA-related overgrowth spectrum.
- PI3Kα is the most common driver mutation among these sub-types, causing an estimated 55 percent of these vascular malformations.
- In the U.S., an estimated 170,000 people have one of these sub-types driven by a PI3Kα mutation.
- A mutant selective PI3Kα inhibitor provides the opportunity for greater target coverage, leading to the potential for improved efficacy and better chronic tolerability.
- Relay Therapeutics plans to initiate clinical development of RLY-2608 in vascular malformations in the first quarter of 2025.

Fabry Disease

- In Fabry disease, a defective gene (*GLA*) prohibits the body from producing enough healthy versions of an enzyme called alpha-galactosidase A (αGal), which is responsible for breaking down Gb3 (globotriaosylceramide), a fat-like substance. As a result, harmful levels of Gb3 accumulate in blood cells and tissues throughout the body, which can lead to a range of symptoms, including potentially life-threatening ones such as kidney failure, heart failure and stroke.
- In the U.S., approximately 8,000 people are estimated to have this rare, progressive genetic disorder.

- Relay Therapeutics has created the first investigational non-inhibitory chaperone for Fabry disease, which is designed to stabilize the αGal protein without inhibiting its activity, thus enabling greater Gb3 clearance across organs.
- A non-inhibitory chaperone could potentially serve as a chronic treatment option for people with Fabry disease, either as a monotherapy or in combination with enzyme replacement therapy.
- The company expects its non-inhibitory chaperone to enter the clinic in the second half of 2025.

NRAS

- NRAS is a known oncogene driver that belongs to the RAS family of signaling proteins. It plays an important role in cell division, cell differentiation and programmed cell death. The NRAS protein is responsible for converting GTP to GDP and is turned “on” when it binds to GTP and “off” once the GTP is converted to GDP. When mutated, the NRAS gene creates NRAS proteins that are always “on”, which makes cells grow and divide uncontrollably and can lead to a number of cancers, including melanoma, colorectal and non-small-cell lung.
- In the U.S., an estimated 28,000 people are diagnosed each year with mutated NRAS solid tumors.
- Existing approved and in-development treatments either target all RAS proteins (pan-RAS) or target other downstream parts of the pathway such as RAF and MEK, which leads to significant off-target toxicity and limits efficacy.
- Relay Therapeutics has created the first NRAS-selective inhibitor, which has been designed to address the liabilities of current pan-RAS inhibitors by only binding to NRAS, while sparing KRAS and HRAS.
- The company expects to initiate clinical development of its NRAS-selective inhibitor in the second half of 2025.

Anticipated Milestones

- Breast Cancer
  - RLY-2608 + fulvestrant data update in the fourth quarter of 2024
  - RLY-2608 + fulvestrant + ribociclib initial safety data in the fourth quarter of 2024
  - RLY-2608 + fulvestrant + atirmociclib clinical trial initiation by the end of 2024
  - RLY-2608 + fulvestrant potential Phase 3 trial initiation in 2025
- Genetic Disease
  - Vascular malformations: RLY-2608 clinical trial initiation in the first quarter of 2025
  - Fabry disease: clinical start in the second half of 2025
- Precision Oncology
  - Lirafugratinib: tumor agnostic data and regulatory update in the second half of 2024
  - NRAS: clinical start in the second half of 2025

Platform Productivity

Since the founding of Relay Therapeutics in 2016, the company has built and grown its Dynamo drug discovery platform, which combines experimental and computational techniques, tools and team members. Over the last eight years, Dynamo has been very productive, resulting in eight drug candidates (DCs) and four Investigational New Drug Applications (INDs), including two programs that have demonstrated clinical proof-of-concept. By the end of 2025, Relay Therapeutics expects three new clinical starts from the additional novel programs announced today. Collectively, over the first decade of the company’s history, that would be 11 DCs, seven INDs and seven programs that have entered the clinic.

Cash Runway

The three new programs disclosed today are from Relay Therapeutics’ existing pre-clinical pipeline. The continued advancement of these programs has already been accounted for in the company’s existing cash runway guidance. As of March 31, 2024, cash, cash equivalents and investments totaled approximately $750 million and are expected to fund the current operating plan into the second half of 2026.

Event Information

Relay Therapeutics’ New Program & Platform event will begin at 8:00 a.m. ET and is expected to conclude at approximately 10:00 a.m. ET. The live webcast can be accessed here or on Relay Therapeutics’ website under Events in the News & Events section through the following link: https://ir.relaytx.com/news-events/events-presentations. An archived replay of the webcast will be available following the event. It is recommended that participants register at least 15 minutes in advance of the event.

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 updates on the clinical development of the programs across Relay Therapeutics' portfolio, including the expected therapeutic benefits of its programs, and potential efficacy and tolerability, and the timing and success of interactions with and approval of regulatory authorities; the timing of clinical data updates across Relay Therapeutics' pipeline, including the progress of doublet and triplet combinations for RLY-2608, the timing of clinical updates for RLY-2608, and the timing of a clinical data and regulatory update for lirafugratinib; the timing of clinical initiation of Relay Therapeutics' various programs, including a potential pivotal trial for RLY-2608, clinical development in vascular malformations, clinical development of Relay Therapeutics' non-inhibitory chaperone, and clinical development of its NRAS-selective inhibitor; the potential of Relay Therapeutics' product candidates to address a major unmet medical need; the cash runway projection; the competitive landscape and potential market opportunities for Relay Therapeutics' product candidates; the expected strategic benefits under Relay Therapeutics' collaborations; the capabilities and development of the Dynamo platform, including its role in identifying product candidates; Relay Therapeutics' ability to successfully establish or maintain collaborations or strategic relationships for its product candidates; expectations regarding current and future interactions with the U.S. Food and Drug Administration (FDA); Relay Therapeutics' ability to manufacture its product candidates in conformity with the FDA's requirements; plans to develop, manufacture and commercialize the current product candidates and any future product candidates; and the implementation of Relay Therapeutics' business model and strategic plans for its business, current product candidates and any future product candidates. 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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