UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 09, 2024

RELAY THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39385**	**47-3923475**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

399 Binney Street **Cambridge, Massachusetts**	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 370-8837

399 Binney Street
Cambridge, Massachusetts 02139
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	RLAY	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 9, 2024, Relay Therapeutics, Inc. (the "Company") issued a press release announcing interim clinical data for RLY-2608, the first known allosteric, pan-mutant and isoform-selective inhibitor of phosphoinostide 3 kinase alpha ("PI3Kα"), a copy of which is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K. The Company intends to host a conference call and live webcast to discuss the interim clinical data on September 9, 2024 at 8:00 a.m. E.T. The Company has made available a slide presentation to accompany the call, a copy of which is being furnished as Exhibit 99.2 to this Current Report on Form 8-K. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

The information in this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 attached hereto, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

RLY-2608

On September 9, 2024, the Company announced interim clinical data for RLY-2608. RLY-2608 is currently being evaluated in the Company's ReDiscover Trial, an ongoing first-in-human study, which was designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of RLY-2608 alone, in combination with fulvestrant, and in combination with fulvestrant and ribociclib or atirmociclib.

The interim clinical data were based on an August 12, 2024 interim data cut-off date. As of such date, the RLY-2608 and fulvestrant combination arm of the study had enrolled 118 patients with PI3Kα-mutated, HR+, HER2– locally advanced or metastatic breast cancer across all doses in both the dose escalation and dose expansion portions of the study, including 64 patients at the Company's recommended Phase 2 dose ("RP2D") of 600mg twice daily (17 in dose escalation and 47 in dose expansion). Among these 64 patients, 31 had a kinase mutation and 33 had a non-kinase mutation. Twelve patients also had a PTEN or AKT co-mutation and were therefore excluded from the efficacy analysis, consistent with the currently proposed pivotal population.

All patients across doses had received a significant level of prior therapy in the advanced setting, including at least one prior endocrine therapy and at least one prior CDK4/6 inhibitor. Among the 64 patients who received the RP2D:

- 45% of patients (n=29) had received two or more prior lines of therapy;
- 52% of patients (n=33) had received a prior selective estrogen-receptor degrader ("SERD"), such as fulvestrant or a novel SERD;
- 25% of patients (n=16) had received chemotherapy or an ADC;
- 59% percent of patients (n=38) had visceral metastases; and
- 34% of patients (n=22) had a BMI of at least 30 and/or HbA1c of at least 5.7%.

Among the 52 patients who received the RP2D and did not have a PTEN or AKT co-mutation:

- Median progression free survival was 9.2 months across all mutations and 10.3 months among patients with kinase mutations;
- Clinical benefit rate ("CBR") was 57% across all patients (20 of 35 CBR-evaluable patients; CBR defined as the proportion of patients with complete response, partial response or stable disease for at least 24 weeks);
- Among the 30 patients with measurable disease, one third achieved a partial response ("PR") (33% objective response rate ("ORR"); n=10; 8 confirmed, 1 confirmed post data cut-off date, 1 unconfirmed in an ongoing patient);
    - Nearly three quarters of patients experienced tumor reductions (73%; n=22);
- Among the 15 patients with measurable disease who had a kinase mutation, more than half achieved a PR (53% ORR; n=8; 7 confirmed, 1 confirmed post data cut-off date); and
- Median follow-up was 7.5 months.

RLY-2608 in combination with fulvestrant was generally well tolerated in the 118 patients treated across all doses as of the data cut-off date. The overall tolerability profile consisted of mostly low-grade treatment-related adverse events ("TRAEs") that were manageable and reversible. Safety outcomes were generally as expected across dose levels based on exposure and consistent with mutant-selective PI3Kα inhibition. Among the 64 patients who received the RP2D:

- The low rate of TRAE-related dose modifications allowed for 95% median dose intensity;
- Only two patients discontinued treatment due to TRAEs (Grade 1 pruritis; Grade 1 nausea, loss of appetite);
- The majority of hyperglycemia was Grade 1; only one patient experienced Grade 3 hyperglycemia; no Grade 4-5 hyperglycemia; and
- Only 25% of patients experienced a Grade 3 TRAE; no Grade 4-5 TRAEs.

The Company also continues to progress two front-line triplet regimens with RLY-2608 and fulvestrant- one with the existing CDK4/6 standard-of-care, ribociclib, and one with Pfizer Inc.'s investigative selective-CDK4 inhibitor atirmociclib.

Lirafugratinib (RLY-4008)

On September 9, 2024, the Company also announced that it met with the FDA regarding the lirafugratinib regulatory path. The FDA suggested that the Company first file a new drug application ("NDA") in cholangiocarcinoma, followed by a tumor agnostic supplemental NDA for FGFR2 fusions with data from more patients and more follow up. Updated FGFR2 fusion tumor agnostic data, which have generally stayed consistent with the data disclosed by the Company in October 2023, will be presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place October 23-25, 2024. The Company plans to seek a global commercialization partner for lirafugratinib in order to maintain focus on the remainder of the portfolio.

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K and certain materials furnished or filed herewith contain 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 the Company's strategy, business plans and focus; the progress and timing of the clinical development of the programs across the Company's portfolio; 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, including lirafugratinib as well as the clinical data for RLY-2608; the interactions with regulatory authorities and any related approvals; the potential market opportunity for RLY-2608; the expected strategic benefits under the Company's clinical trial collaboration with Pfizer; the cash runway projection and the expectations regarding the Company's use of capital and expenses. 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, or the negative thereof, 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 and conflicts, or public health epidemics or outbreaks of an infectious disease on countries or regions in which the Company 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 or pause of any current or planned clinical trials or the development of the Company's drug candidates; the risk that the preliminary or interim 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 and that interim and early clinical data may change as more patient data become available and are subject to audit and verification procedures; the Company's 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 the Company's 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 the Company's views only as of today and should not be relied upon as representing its views as of any subsequent date. The Company 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.

Item 9.01 Financial Statements and Exhibits.

99.1	Press release issued by Relay Therapeutics, Inc. on September 9, 2024, furnished herewith.
99.2	Corporate presentation, dated September 9, 2024, furnished herewith.
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

RELAY THERAPEUTICS, INC.

Date: September 9, 2024

By: /s/ Brian Adams
Brian Adams
Chief Legal Officer

Relay Therapeutics Announces Positive Interim Data for RLY-2608 Demonstrating Clinically Meaningful Progression Free Survival

9.2-month median PFS in heavily pre-treated patients with PI3Kα-mutated, HR+/HER2- metastatic breast cancer at RP2D

33% ORR across all patients & 53% ORR in patients with kinase mutations at RP2D

Favorable overall tolerability profile; at RP2D, only 2 patients discontinued treatment due to adverse events & only 1 patient experienced Grade 3 hyperglycemia

Data support planned initiation of 2L pivotal study in 2025

Triplet combination with ribociclib expected to move into dose expansion in 1H 2025 & triplet combination with atirmociclib (CDK4) remains on track to start before year-end

Relay Therapeutics to host a conference call today, September 9, at 8:00 a.m. ET

Cambridge, Mass. – September 9, 2024 – 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 positive interim data for RLY-2608, the first known investigational allosteric, pan-mutant and isoform-selective inhibitor of PI3Kα. The data showed that despite heavy pre-treatment, patients with PI3Kα-mutated, HR+, HER2- locally advanced or metastatic breast cancer who received RLY-2608 600mg BID + fulvestrant demonstrated clinically meaningful progression free survival (PFS).

“These interim data suggest that by selectively targeting mutant PI3Kα, RLY-2608 has the potential to offer a level of benefit to patients that has not previously been possible with existing non-selective medicines, while also having significantly less toxicity,” said Don Bergstrom, M.D., Ph.D., President of R&D at Relay Therapeutics. “We are very encouraged to see that RLY-2608 + fulvestrant led to clinically meaningful progression free survival in heavily pre-treated patients with PI3Kα-mutated, HR+, HER2- metastatic breast cancer. We will move quickly to share these data with regulators and align on the design of a pivotal study, which we anticipate starting in 2025.”

ReDiscover – RLY-2608 First-in-Human Study

RLY-2608 is currently being evaluated in ReDiscover, an ongoing first-in-human study, which was designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary antitumor activity of RLY-2608 alone, in combination with fulvestrant, and in combination with fulvestrant and ribociclib or atirmociclib (Pfizer’s selective CDK4 inhibitor). As of the August 12, 2024 interim data cut-off, the RLY-2608 + fulvestrant arm of the study had enrolled 118 patients with PI3Kα-mutated, HR+, HER2- locally advanced or metastatic breast cancer across all doses in both the dose escalation and dose expansion portions of the study, including 64 patients at the company’s recommended Phase 2 dose (RP2D) of 600mg BID (17 in dose escalation and 47 in dose expansion). Among these 64 patients, 31 had a kinase mutation and 33 had a non-kinase mutation. Twelve patients also had a PTEN or AKT co-mutation and were therefore excluded from the efficacy analysis, consistent

with the currently proposed pivotal population. An abstract has been submitted for presentation at the San Antonio Breast Cancer Symposium, taking place December 10-13, 2024.

Patients were Heavily Pre-Treated

All patients across doses had received a significant level of prior therapy in the advanced setting, including at least one prior endocrine therapy and at least one prior CDK4/6 inhibitor. Among the 64 patients who received the RP2D:

- 45% of patients (n=29) had received two or more prior lines of therapy
- 52% of patients (n=33) had received a prior selective estrogen-receptor degrader (SERD), such as fulvestrant or a novel SERD
- 25% of patients (n=16) had received chemotherapy or an ADC
- 59% percent of patients (n=38) had visceral metastases
- 34% of patients (n=22) had a BMI of at least 30 and/or HbA1c of at least 5.7%

Promising Efficacy Data in Proposed Pivotal Population

Among the 52 patients who received the RP2D and did not have a PTEN or AKT co-mutation:

- Median PFS was 9.2 months across all mutations and 10.3 months among patients with kinase mutations
- Clinical benefit rate (CBR) was 57% across all patients (20 of 35 CBR-evaluable patients; CBR defined as the proportion of patients with complete response, partial response or stable disease for at least 24 weeks)
- Among the 30 patients with measurable disease, one third achieved a partial response (PR) (33% objective response rate, ORR; n=10; 8 confirmed, 1 confirmed post data cut-off date, 1 unconfirmed in an ongoing patient)
    - Nearly three quarters of patients experienced tumor reductions (73%; n=22)
- Among the 15 patients with measurable disease who had a kinase mutation, more than half achieved a PR (53% ORR; n=8; 7 confirmed, 1 confirmed post data cut-off date)
- Median follow-up was 7.5 months

Maintained Meaningfully Differentiated Tolerability Profile

RLY-2608 + fulvestrant was generally well tolerated in the 118 patients treated across all doses as of the data cut-off date. The overall tolerability profile consisted of mostly low-grade treatment-related adverse events (TRAEs) that were manageable and reversible. Safety outcomes were generally as expected across dose levels based on exposure and consistent with mutant-selective PI3Kα inhibition. Among the 64 patients who received the RP2D:

- The low rate of TRAE-related dose modifications allowed for 95% median dose intensity
- Only two patients discontinued treatment due to TRAEs (Grade 1 pruritis; Grade 1 nausea, loss of appetite)
- The majority of hyperglycemia was Grade 1; only one patient experienced Grade 3 hyperglycemia; no Grade 4-5 hyperglycemia
- Only 25% of patients experienced a Grade 3 TRAE; no Grade 4-5 TRAEs

Continued Progression of Front-Line Breast Cancer Regimens

Two front-line triplet regimens are being progressed – one with the existing CDK4/6 standard-of-care ribociclib and one with Pfizer's investigative selective-CDK4 inhibitor atirmociclib.

- RLY-2608 + ribociclib + fulvestrant dose escalation portion of the ReDiscover study is currently testing biologically active doses of RLY-2608
  - On track to identify a dose of RLY-2608 that is combinable with full-dose ribociclib
  - Initial safety data expected in the fourth quarter of 2024
  - Expect to initiate dose expansion cohort(s) in first half of 2025
- RLY-2608 + atirmociclib + fulvestrant triplet on track for initiation by the end of 2024

Anticipated RLY-2608 Next Steps

- Doublet – Breast Cancer:
  - Initiate 2L pivotal study of RLY-2608 + fulvestrant in 2025, pending regulatory discussions
- Triplets – Breast Cancer:
  - Report initial safety data for RLY-2608 + ribociclib + fulvestrant in the fourth quarter of 2024
  - Initiate RLY-2608 + ribociclib + fulvestrant triplet dose expansion cohort(s) in the first half of 2025
  - Initiate RLY-2608 + atirmociclib (CDK4) + fulvestrant triplet by the end of 2024
- Monotherapy – Solid Tumors:
  - Initiate RLY-2608 monotherapy solid tumor dose expansion cohort(s) by the end of 2024
- Monotherapy – Vascular Malformations:
  - Initiate vascular malformations study in the first quarter of 2025

Lirafugratinib Update

- Updated FGFR2 fusion tumor agnostic data, which have generally stayed consistent with the October 2023 disclosure, will be presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, taking place October 23-25, 2024
- The company met with the FDA regarding the lirafugratinib regulatory path. The FDA suggested that the company first file a new drug application (NDA) in cholangiocarcinoma, followed by a tumor agnostic supplemental NDA for FGFR2 fusions with data from more patients and more follow up
- The company plans to seek a global commercialization partner for lirafugratinib in order to maintain focus on the remainder of the portfolio

Portfolio Prioritization is a Continued Focus

- The company continues to advance high-value next-generation programs:
  - Fabry disease: clinical start anticipated in the second half of 2025
  - NRAS: clinical start anticipated in the second half of 2025
- Ongoing streamlining of the research organization

Wholly-Owned Portfolio Provides Strategic Flexibility for Cash Runway

As of the end of the second quarter of 2024, cash, cash equivalents and investments were approximately $688 million, which the company expects to be sufficient to fund its current operating plan into the second half of 2026, assuming all current programs remain wholly owned and are fully prosecuted.

Conference Call Information

Relay Therapeutics will host a conference call and live webcast today, Monday, September 9, 2024, at 8:00 a.m. ET. Registration and dial-in for the conference call may be accessed 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.

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 300,000 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.

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Exhibit 99.2

RELAY®
THERAPEUTICS

RLY-2608 Data

September 9, 2024

Disclaimer

This presentation 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; 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, including lirafugratinib as well as the clinical data for RLY-2608; the interactions with and approval of regulatory authorities and any related approvals; the potential market opportunity for RLY-2608; and the expected strategic benefits under Relay Therapeutics' clinical trial collaboration with Pfizer; the cash runway projection and the expectations regarding Relay Therapeutics' use of capital and expenses. 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, or the negative thereof, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this presentation 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 presentation, including, without limitation, risks associated with: the impact of global economic uncertainty, geopolitical instability and conflicts, or public health epidemics or outbreaks of an infectious disease 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, future operations and profitability; the delay or pause of any current or planned clinical trials or the development of our drug candidates; the risk that the preliminary or interim results of our preclinical or clinical trials may not be predictive of future or final results in connection with future clinical trials of our product candidates and that interim and early clinical data may change as more patient data become available and are subject to audit and verification procedures; our ability to successfully demonstrate the safety and efficacy of our 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, uncertainties and important factors are described in the section entitled "Risk Factors" in our 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. Any forward-looking statements represent our views only as of the date of this presentation and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, the occurrence of certain events or otherwise. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party studies, publications, surveys and other data to be reliable as of the date of this presentation, we have not independently verified, and make no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, no independent source has evaluated the reasonableness or accuracy of our internal estimates or research and no reliance should be made on any information or statements made in this presentation relating to or based on such internal estimates and research.

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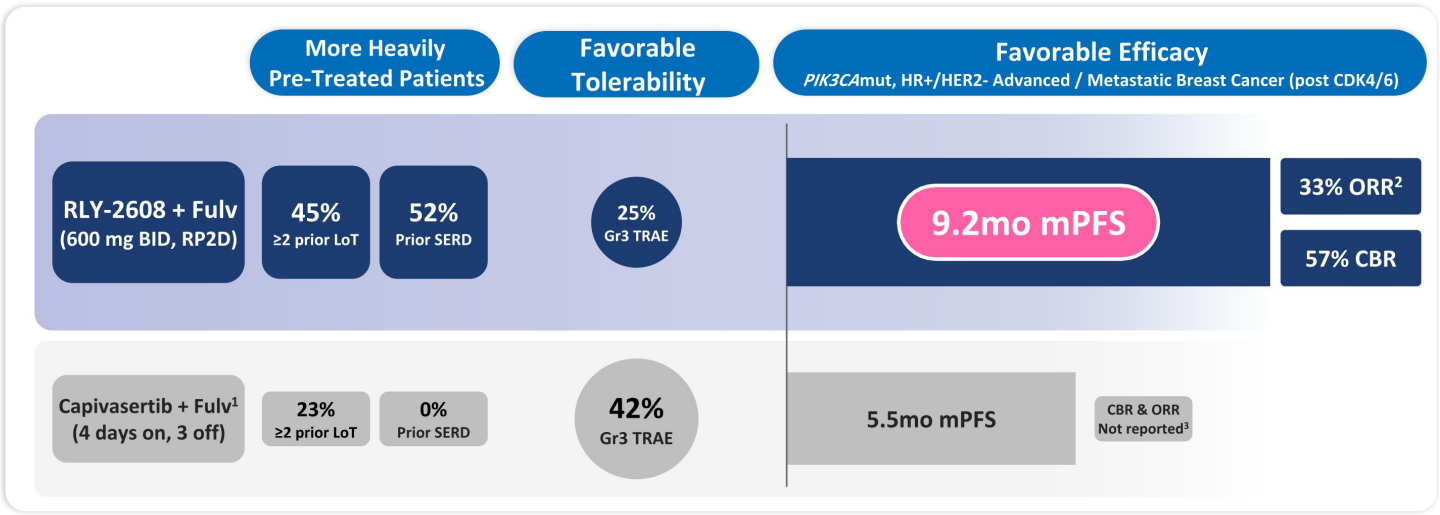
Today's Update

1. ReDiscover Trial Update – RLY-2608 + Fulvestrant Doublet Data
2. RLY-2608 – Next steps

RLY-2608 abstract submitted to San Antonio Breast Cancer Symposium

RLY-2608 – Interim Clinical Data Show Clinically Meaningful PFS



Interim RLY-2608 safety and efficacy data supportive of pivotal trial in 2L Breast Cancer against capivasertib

1. CAPItello-291: Turner N Engl J Med 2023; 388:2058-2070; 2. ORR includes 2 ongoing unconfirmed partial response as of the data cut-off. After the data cut-off, one uPR patient has confirmed and the other uPR patient remains on treatment; Additionally, one stable disease patient has converted to an unconfirmed partial response, remains on treatment and is not included in the ORR; 3. In CAPItello-291, CBR and ORR not reported for CDK4/6-experienced patient population; ORR = objective response rate, mPFS = median progression free survival, LoT = line of therapy (metastatic setting), SoC = Standard of Care, TRAE = treatment related adverse effects, RP2D = recommended Phase 2 dose, CBR = clinical benefit rate, SERD = selective estrogen receptor degrader; Note: data shown are not from head-to-head studies, and no head-to-head studies have been conducted.

ReDiscover preliminary data as of 08/12/2024

PI3Kα Mutations Represent a Large Commercial Opportunity

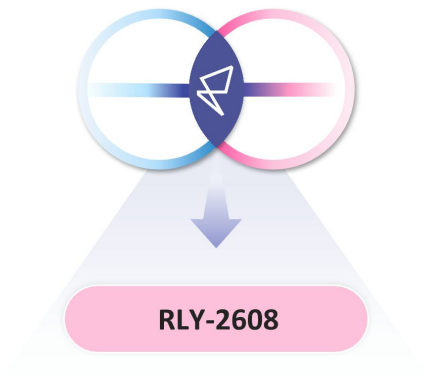
PI3Kα mutations represent a large commercial opportunity

- Breast Cancer — ~150k pts (prevalence[1])
- Vascular Malformations — ~170k pts (prevalence[2])
- Non-Breast Cancer Solid Tumors — ~160k pts (incidence[3])

Non-selective PI3Kα targeting has significant limitations

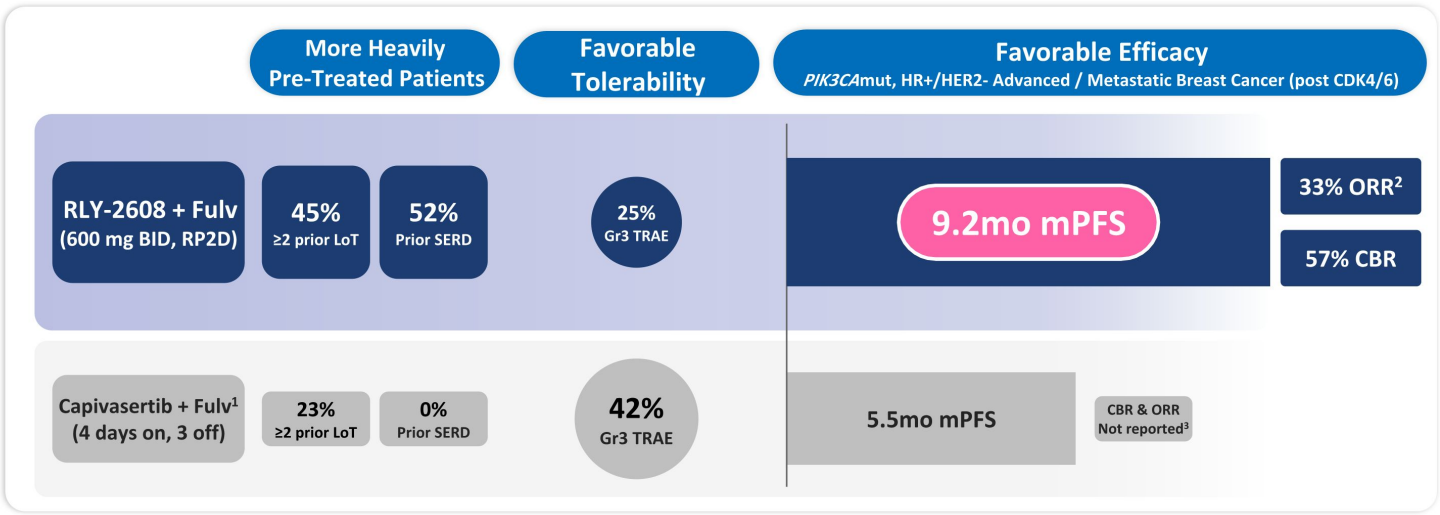
- Challenging Tolerability
- Limited Efficacy
- Limited Combinability

Relay Tx's Dynamo® Platform created mutant selective molecule



1. Prevalent US patient population with a PIK3CA mutation in each line of therapy (Global Data HR+/HER2- Breast Cancer Global Forecast, November 2023; 3rd party source for alteration rate); 2. Prevalent US patient population of vascular malformation patients with a PIK3CA mutation (multiple sources); 3. Incident US patient population solid tumors annually with a PIK3CA mutation (SEER; 3rd party source for alteration rate, May 2024)

RLY-2608 – Interim Clinical Data Show Clinically Meaningful PFS

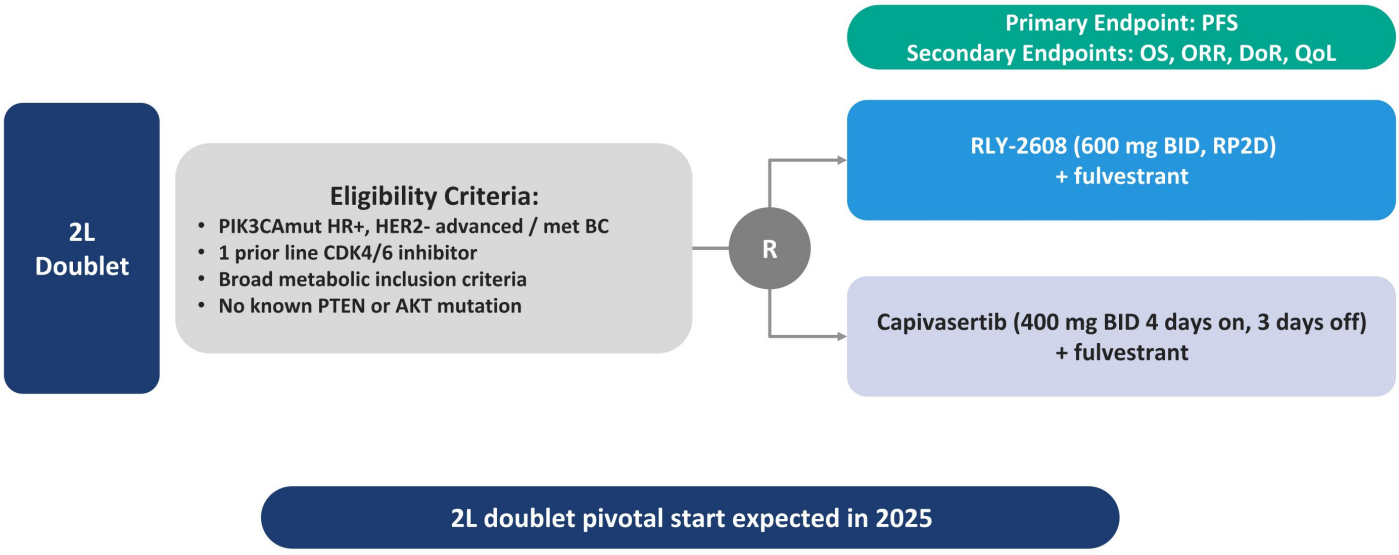


Interim RLY-2608 safety and efficacy data supportive of pivotal trial in 2L Breast Cancer against capivasertib

1. CAPItello-291: Turner N Engl J Med 2023; 388:2058-2070; 2. ORR includes 2 ongoing unconfirmed partial response as of the data cut-off. After the data cut-off, one uPR patient has confirmed and the other uPR patient remains on treatment; Additionally, one stable disease patient has converted to an unconfirmed partial response, remains on treatment and is not included in the ORR; 3. In CAPItello-291, CBR and ORR not reported for CDK4/6-experienced patient population; ORR = objective response rate, mPFS = median progression free survival, LoT = line of therapy (metastatic setting), SoC = Standard of Care, TRAE = treatment related adverse effects, RP2D = recommended Phase 2 dose, CBR = clinical benefit rate, SERD = selective estrogen receptor degrader; Note: data shown are not from head-to-head studies, and no head-to-head studies have been conducted.

ReDiscover preliminary data as of 08/12/2024

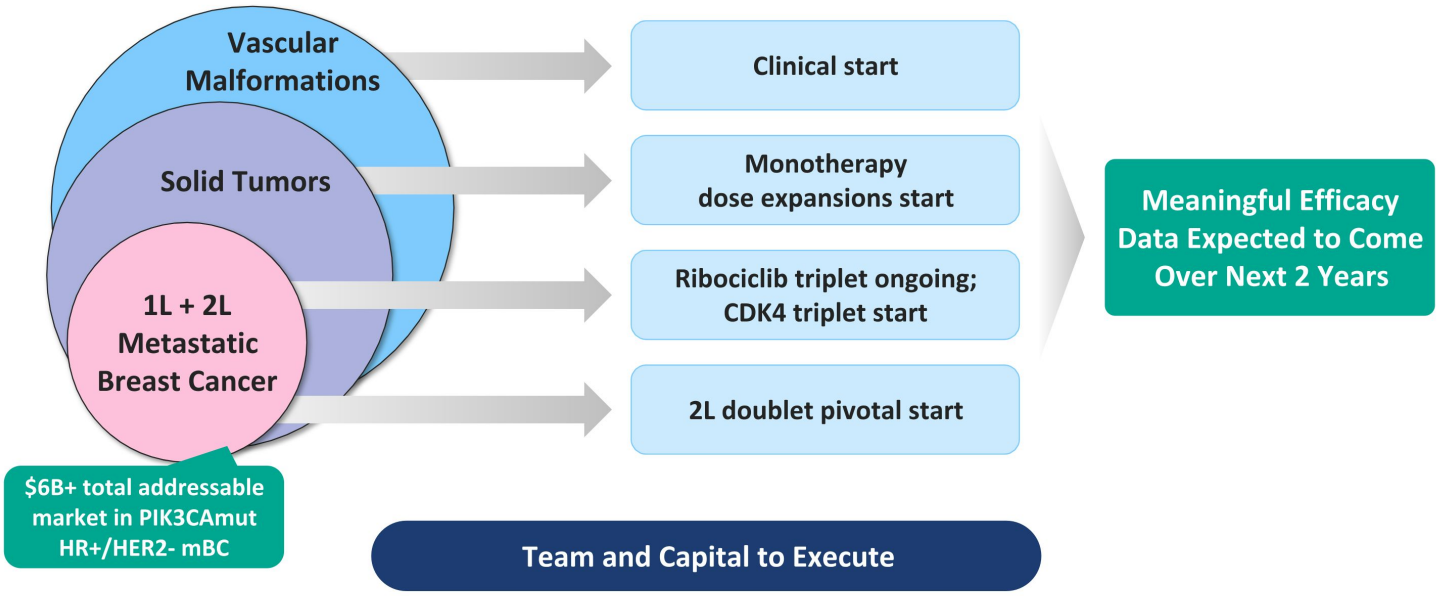
RLY-2608 – Initial Pivotal Trial Planned for 2L Doublet in 2025*



2L doublet pivotal start expected in 2025

*Subject to discussions with regulators; eligibility criteria, endpoints, RP2D, and other aspects of trial design have not yet been finalized; OS = overall survival, DoR = duration of response, QoL = quality of life, met BC = metastatic Breast Cancer; 2L = 2nd line

PI3Kα Franchise - Opportunity for Multiple Value-Creating Datasets Over Next 2 Yrs



Relay Tx – Broad Precision Medicine Pipeline

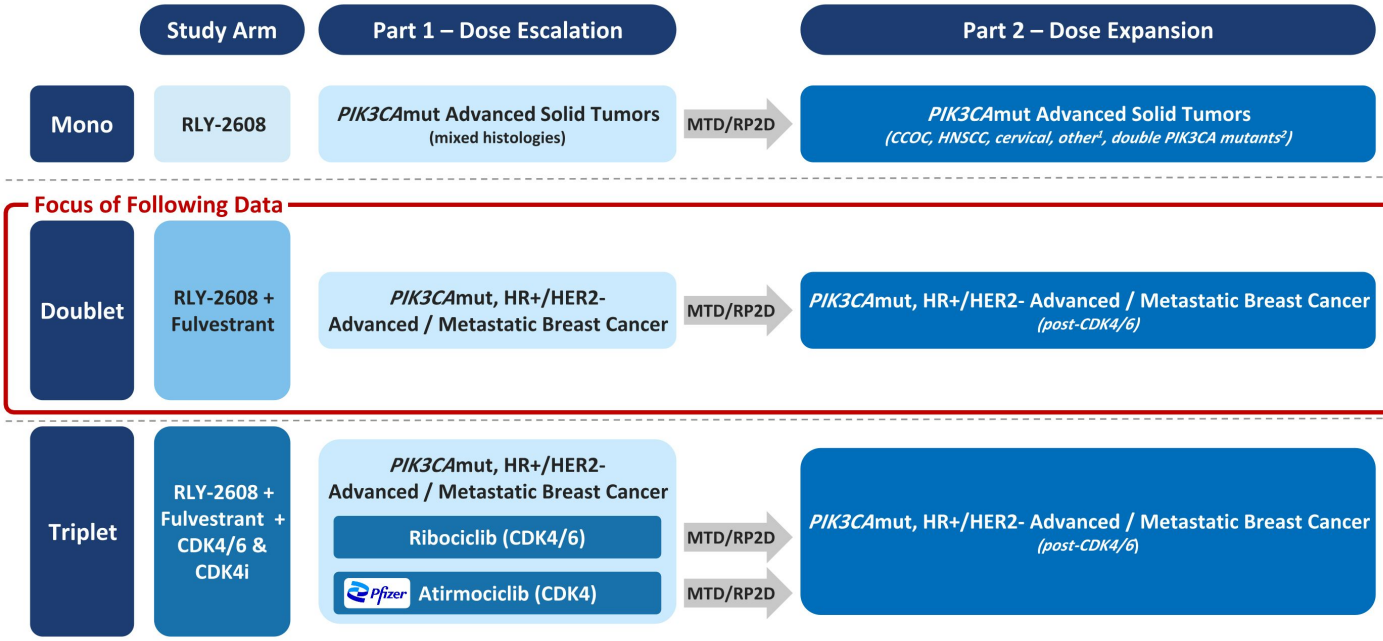
	Target	Program		Preclinical	Early Clinical	Late Clinical
BREAST CANCER	PI3Kα	RLY-2608 (PI3Kα^{PAN})	Endocrine Tx (ET) doublet			
			Ribociclib + ET triplet			
			CDK4i + ET triplet			
			Other Novel Combinations			
	CDK2	RLY-2139		Paused; IND ready		
	ERα	RLY-1013 (Degrader)		Advance to IND-ready		
GENETIC DISEASE	Fabry Disease	αGal Chaperone				
	Vascular Malformations	RLY-2608 (PI3Kα^{PAN})				
		Other PI3Kα^{PAN}				
SOLID TUMORS	NRAS	NRAS-selective Inhibitor				
	PI3Kα	RLY-2608 Monotherapy				
	FGFR2	Lirafugratinib (RLY-4008)		Seeking global commercialization partner		

DYNAMO® PLATFORM | 5+ unnamed research programs

~$688M cash as of end 2Q 2024
Expected to fund current operating plan into 2H 2026

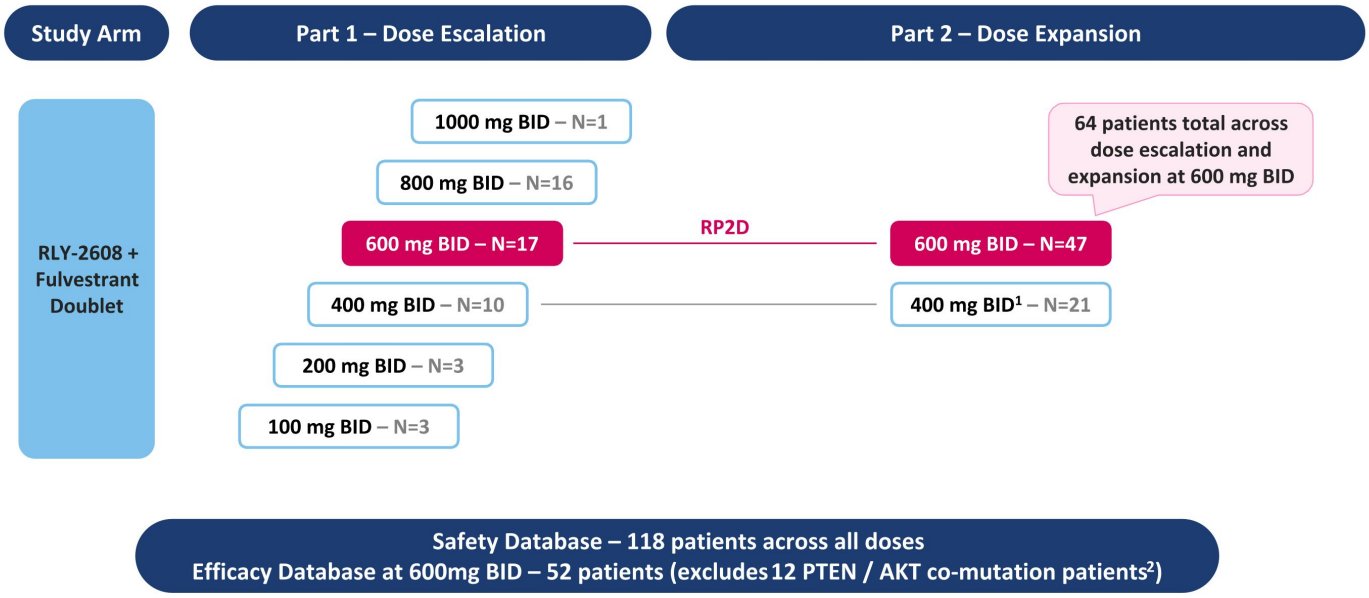
Note: IND = Investigational New Drug Application (FDA)

RLY-2608 – ReDiscoverTrial Overview



1. Excludes PIK3CAmut clear cell OvCA, HNSCC, Cervical cancer, and colorectal patients; 2. Double mutation defined as one major PIK3CA mutation (E542X, E545X, H1047X) + ≥1 additional PIK3CA mutation per local assessment; CCOC = clear cell ovarian cancer

RLY-2608 – ReDiscoverTrial Enrollment



Safety Database – 118 patients across all doses
Efficacy Database at 600mg BID – 52 patients (excludes 12 PTEN / AKT co-mutation patients[2])

1. 400mg cohort is not yet mature for efficacy analysis. Full Phase I results, including 400mg cohort, will be disclosed at a later date; 2. As defined by central ctDNA

ReDiscover preliminary data as of 08/12/2024

RLY-2608 – ReDiscover Trial Baseline Demographics

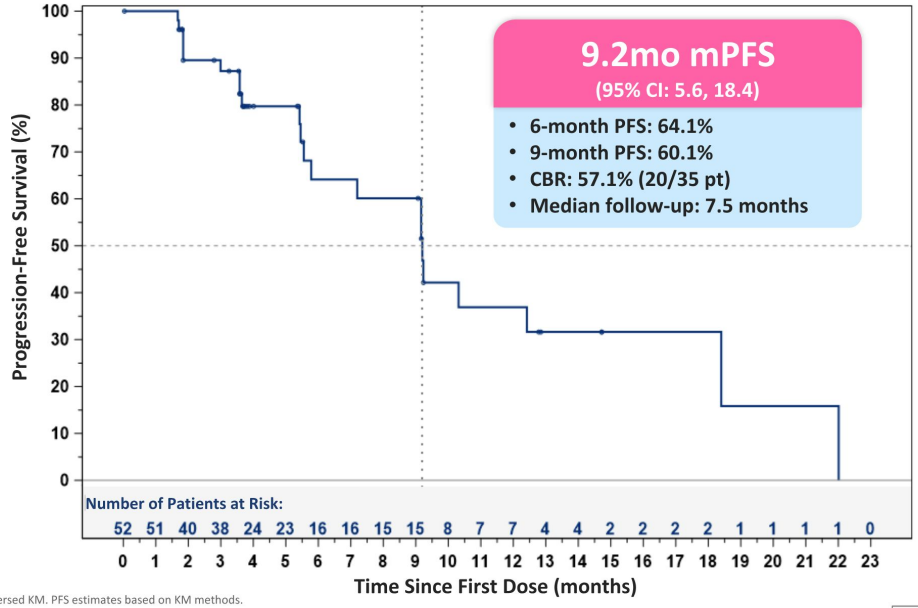
	RLY-2608 + Fulvestrant	
	All Patients (N=118)	600 mg BID (RP2D, N=64)
Age, Median (Range), Years	59.0 (34, 85)	59.0 (34, 80)
ECOG, 0 / 1, n (%)	69 (58.5) / 49 (41.5)	38 (59.4) / 26 (40.6)
Local PIK3CA Baseline Results		
Kinase Mutation, n (%)	56 (47.5)	31 (48.4)
Non-Kinase Mutations, n (%)	62 (52.5)	33 (51.6)
BMI ≥30 and/or HbA1c ≥5.7%, n (%)	44 (37.3)	22 (34.4)
Measurable Disease, n (%)	83 (70.3)	42 (65.6)
Patients with Visceral Metastases, n (%)[1]	75 (63.6)	38 (59.4)
Prior Lines of Therapy in Advanced Setting		
1, n (%)	59 (50.0)	35 (54.7)
2+, n (%)	59 (50.0)	29 (45.3)
Prior Therapies in Advanced Setting		
CDK4/6, n (%)[2]	118 (100.0)	64 (100.0)
Fulvestrant or Novel SERD, n (%)	66 (55.9)	33 (51.6)
Chemo / ADC, n (%)	30 (25.4)	16 (25.0)
ESR1 Mutation (Central Read)[3], n (%)	40 (36.0)	18 (29.5)

1. Visceral metastatic sites include lung, liver, brain, pleural, peritoneal involvement; 2. Two patients received prior CDK4/6 in the adjuvant setting which is allowed per protocol; 3. Percentage was based on pts with evaluable ctDNA data at baseline;
ECOG = Eastern Cooperative Oncology Group performance status

ReDiscover preliminary data as of 08/12/2024

RLY-2608 – Efficacy: Median PFS 9.2 Months

RLY-2608 600 mg BID (RP2D) + Fulvestrant
Excluding PTEN / AKT Co-Mutations (N=52)



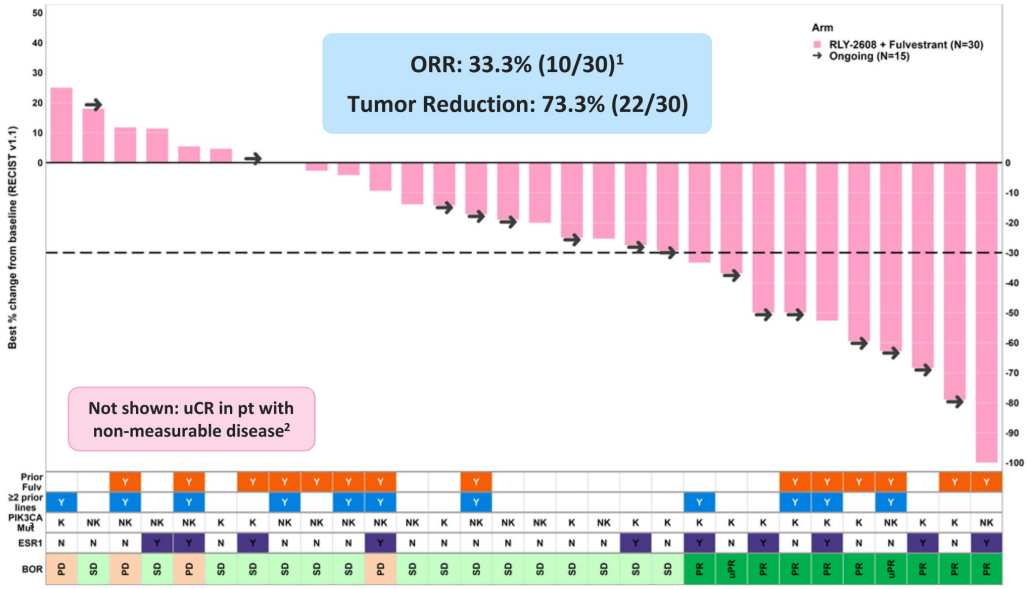
Note: Follow-up estimated based on reversed KM. PFS estimates based on KM methods.

ReDiscover preliminary data as of 08/12/2024

RLY-2608 – Efficacy: ORR 33%

RLY-2608 600 mg BID (RP2D) + Fulvestrant

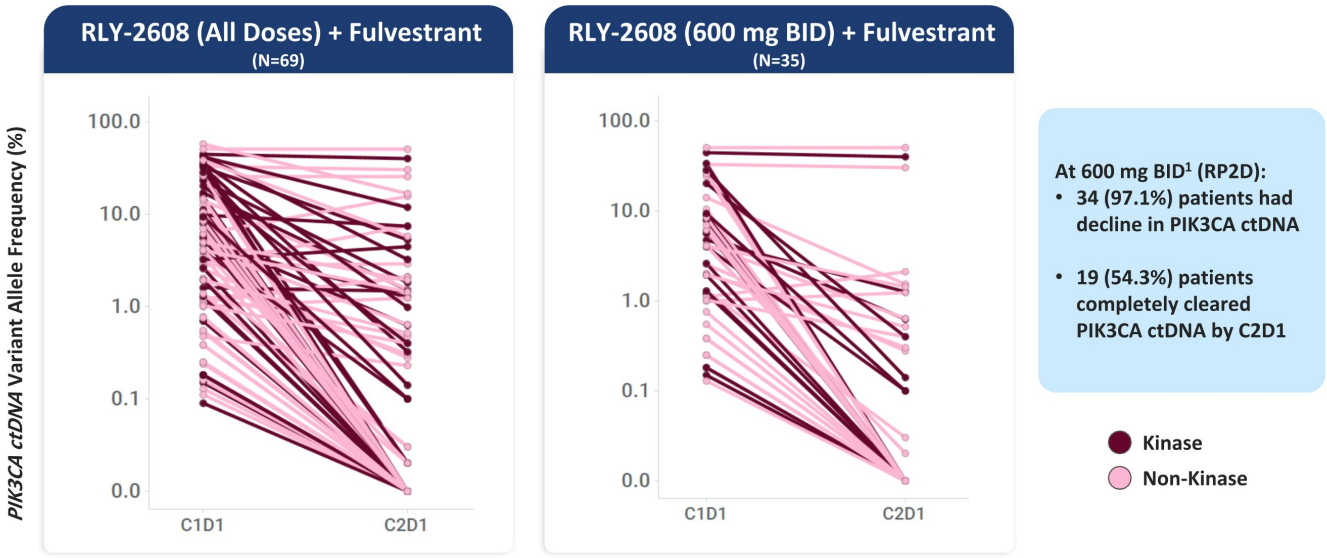
Excluding PTEN / AKT Co-Mutations – Measurable Disease (N=30)



1. ORR includes 2 ongoing unconfirmed partial response as of the data cut-off. After the data cut-off, one uPR patient has confirmed and the other uPR patient remains on treatment; Additionally, one stable disease patient has converted to an unconfirmed partial response, remains on treatment and is not included in the ORR; 2. Patient confirmed post data cut off and is not included in the ORR; 3. PIK3CA mutation: "K" = Kinase domain mutation, "NK" = Non-Kinase domain mutation; uCR = unconfirmed complete response

ReDiscover preliminary data as of 08/12/2024

RLY-2608 – Efficacy: ctDNA Clearance

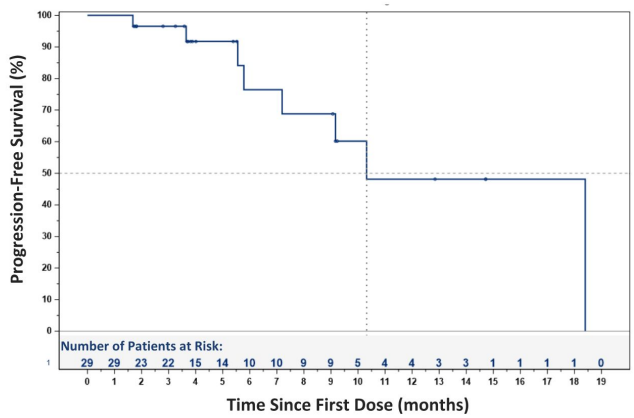


1. N=35 patients without PTEN/AKT co-alterations who have detectable PIK3CA at baseline and a paired C1D1-C2D1 ctDNA result are presented

ReDiscover preliminary data as of 08/12/2024

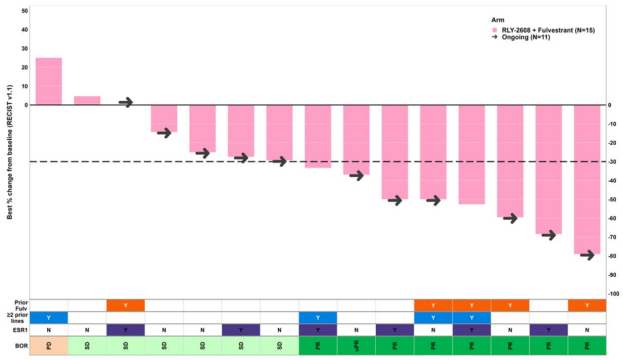
RLY-2608 – Efficacy: Kinase Mutations mPFS 10.3 Months, ORR 53%

RLY-2608 600 mg BID (RP2D) + Fulvestrant
PIK3CA Kinase mutations, excluding PTEN / AKT co-mutations (N=29)



10.3mo mPFS
(95% CI: 5.8, NR)

RLY-2608 600 mg BID (RP2D) + Fulvestrant
PIK3CA Kinase mutations, excluding PTEN / AKT co-mutations (N=15)

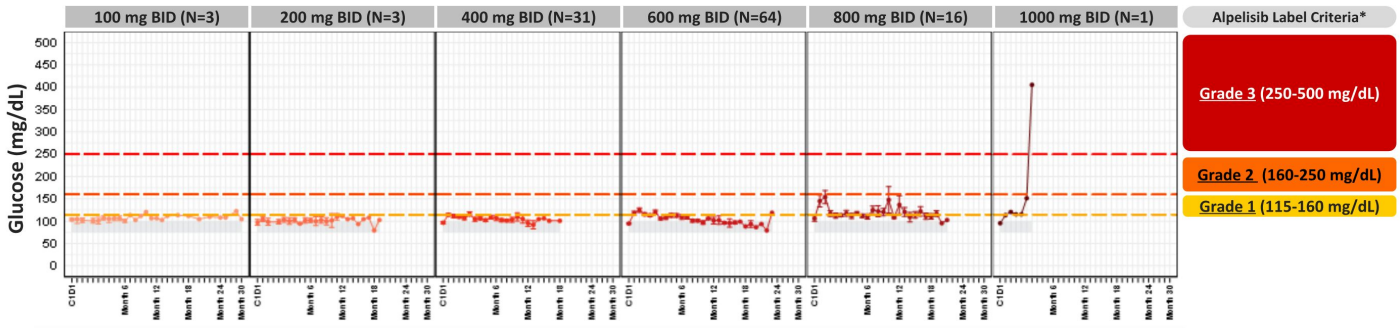


53.3% ORR
(8/15 pt)[1]

1. ORR includes 1 ongoing unconfirmed partial response as of the data cut-off. After the data cut-off, this 1 uPR patient has confirmed and remains on treatment; Additionally, one stable disease patient has converted to an unconfirmed partial response, remains on treatment and is not included in the ORR

RLY-2608 – Tolerability: Limited Observed Impact on Glucose Homeostasis

RLY-2608 + Fulvestrant



Note: *Based on CTCAE version 4 criteria; Data represent mean per cohort +/- standard deviation; Source: Central lab analysis

ReDiscover preliminary data as of 08/12/2024

RLY-2608 – Tolerability: TRAEs

		All Patients (N=118)		600mg BID (RP2D, N=64)	
		All Gr	Gr3	All Gr	Gr3
Any TRAE		91.5%	20.3%	93.8%	25.0%
TRAEs ≥15% of 600 mg BID	Hyperglycemia[1]	42.4%	1.7%	46.9%	1.6%
	Nausea	39.8%	0.8%	48.4%	1.6%
	Creatinine Increased[2]	33.9%	0%	32.8%	0%
	Fatigue[1]	38.1%	7.6%	32.8%	7.8%
	Diarrhea	29.7%	1.7%	34.4%	3.1%
	Decreased Appetite	16.1%	0%	18.8%	0%
	Hypokalemia[1]	15.3%	1.7%	17.2%	1.6%
Other select TRAEs	Rash[1]	11.9%	0.8%	10.9%	1.6%
	Stomatitis	3.4%	0.8%	4.7%	0%

30% Gr1 hyperglycemia (no intervention required)

No Gr4-5 TRAEs

1: Hyperglycemia includes the MedDRA v26.0 Preferred Terms (PTs): Hyperglycemia, Blood Glucose Increased, Glucose Tolerance Impaired; Fatigue includes the PTs: Fatigue and Asthenia; Hypokalemia includes the PTs: Hypokalemia and blood potassium decreased; Rash includes the PTs: Rash, Rash Macular, Rash Maculo-Papular; 2. No acute kidney injury reported

ReDiscover preliminary data as of 08/12/2024

RLY-2608 – Tolerability: Dose Intensity and Modifications

		All Patients (N=118)	600mg BID (RP2D, N=64)
Dose Intensity	Relative Dose Intensity (%), Median	97.54	95.16
Dose Modifications Due to TRAE	Dose Reduction, n (%)	36 (30.5)	23 (35.9)
	Dose Interruption, n (%)	49 (41.5)	27 (42.2)
	Dose Discontinuation, n (%)	7 (5.9)	2 (3.1)
TRAEs Leading to Dose Reduction	Fatigue*	11 (9.3)	5 (7.8)
	Blood Creatinine Increased	8 (6.8)	3 (4.7)
	Diarrhea	6 (5.1)	3 (4.7)

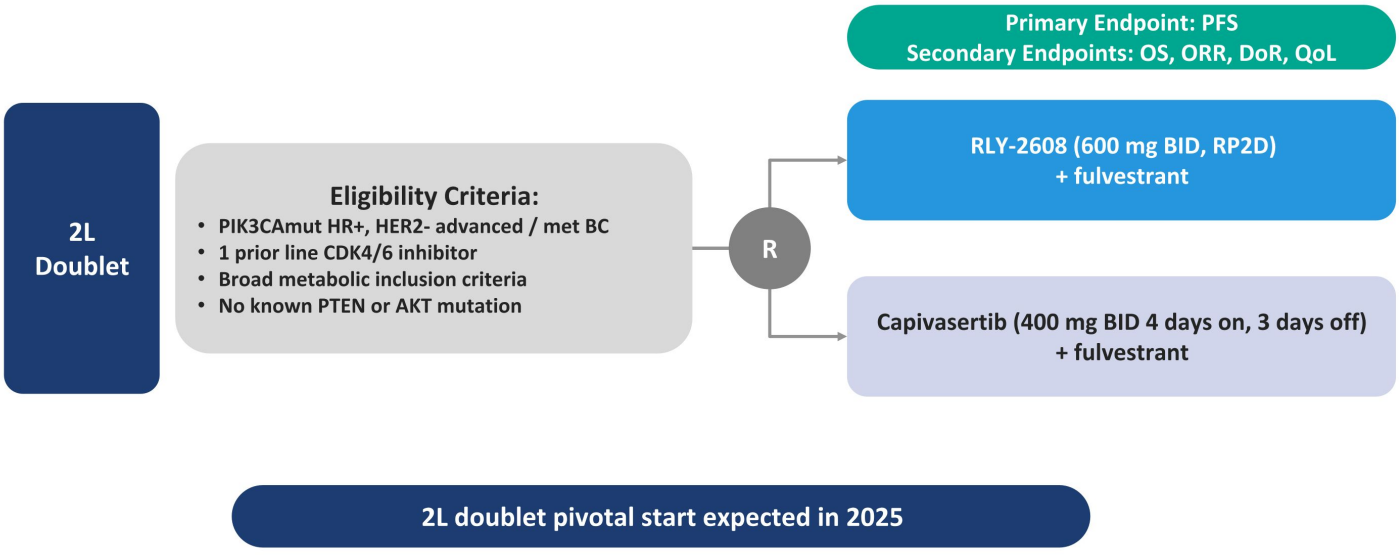
Grade 1 pruritis; Grade 1 nausea and loss of appetite

Maintained 95% dose intensity with very low TRAE discontinuations at 600mg BID

Note: * Fatigue includes the Preferred Terms: Fatigue and Asthenia; TRAEs leading to Dose Reduction in more than 2 patients within 600 mg BID are presented.

ReDiscover preliminary data as of 08/12/2024

RLY-2608 – Initial Pivotal Trial Planned for 2L Doublet in 2025*



2L doublet pivotal start expected in 2025

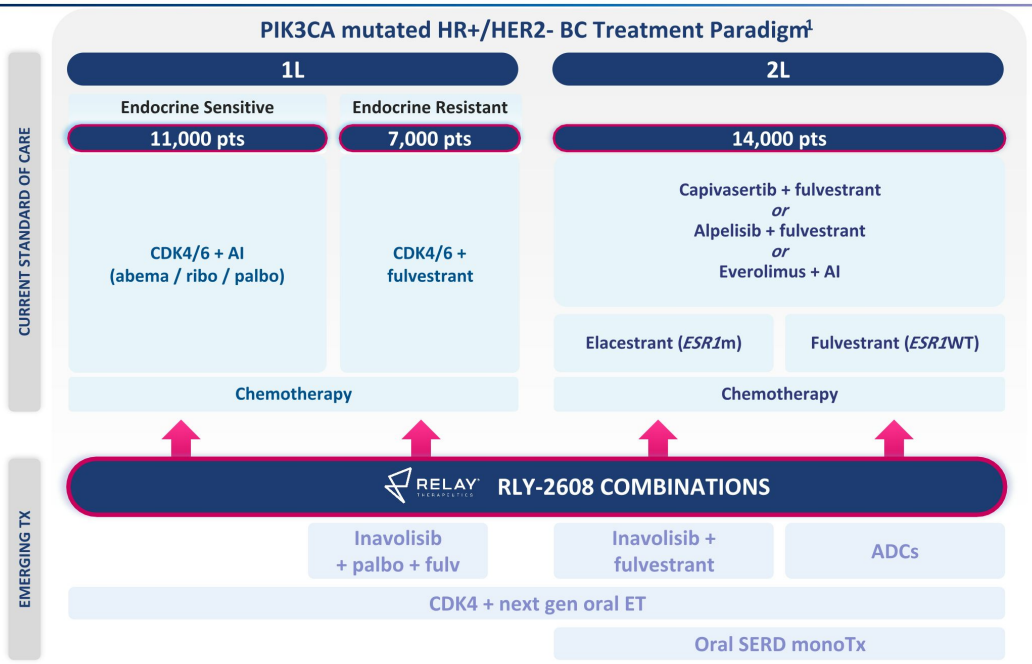
*Subject to discussions with regulators; eligibility criteria, endpoints, RP2D, and other aspects of trial design have not yet been finalized; OS = overall survival, DoR = duration of response, QoL = quality of life, met BC = metastatic Breast Cancer; 2L = 2nd line

RLY-2608 – On Track to Realize 1L Potential with Triplet Combinations

Triplets			Dose Escalation	Plan to Identify Dose and Move into Expansion Cohorts
RLY-2608 + Fulvestrant	+	Ribociclib (CDK4/6, commercial SoC)	Currently dosing at biologically active doses of RLY-2608	On track to identify dose by late 2024/early 2025
RLY-2608 + Fulvestrant	+	Atirmociclib (CDK4, Pfizer)	On track for end of year initiation	On track to identify dose in 2025

Phase 1 Aim for Triplets: Demonstrate safety, tolerability and preliminary efficacy with both current generation CDK4/6 and next-gen CDK4 to enable pivotal development potential in both

Breast Cancer – Large Market in Current and Emerging Standards of Care



$6B+

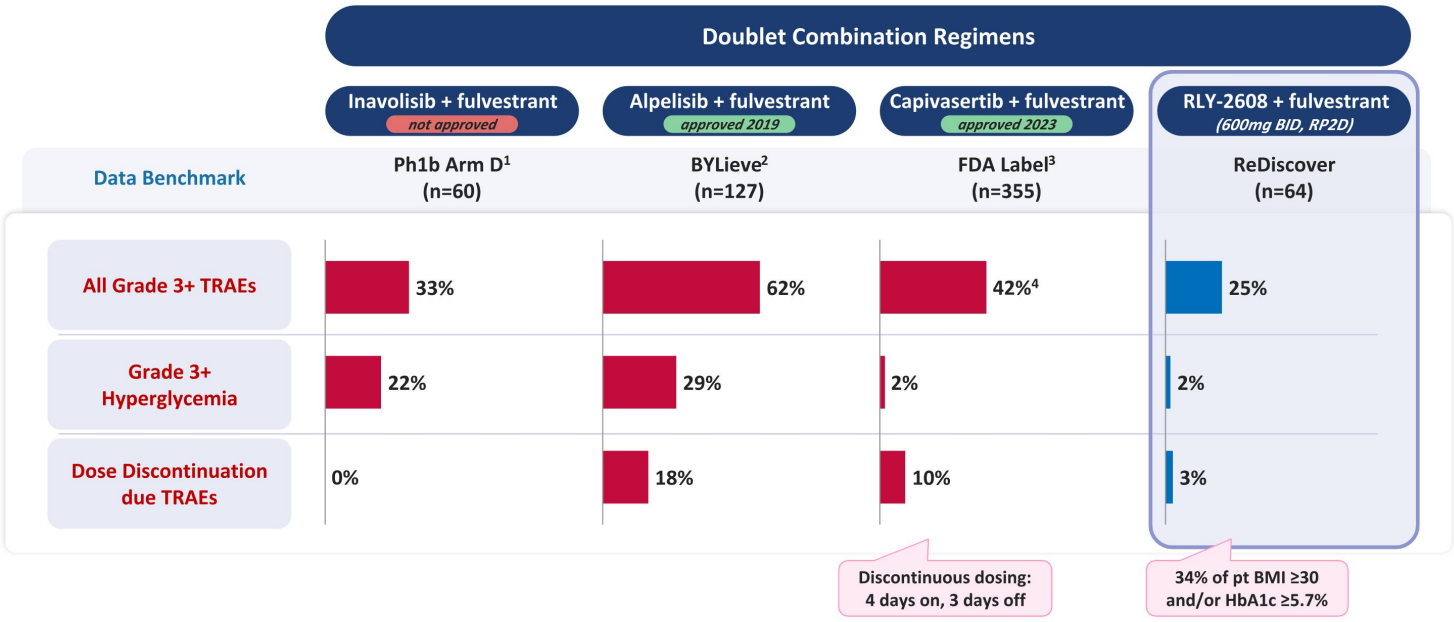
Current PI3Kα Pathway Total Addressable Market[2]

(Metastatic HR+/HER2- Breast Cancer)

1. Prevalent US patient population with a PIK3CA mutation in each line of therapy (Global Data HR+/HER2- Breast Cancer Global Forecast, November 2023; 3rd party source for alteration rate); 2. Relay Tx PIK3CA internal market forecast (patient-based – US, EU5, Japan). Forecast includes estimates for genetic testing, class share, market access, compliance, duration of therapy and assumes current PIK3CA therapy net price (primary sources: SEER; GloboCan; Global Data; Evaluate Pharma; DRG Market Forecast; PIK3CAi PIs)

PI3Kα Inhibitors – Tolerability Profiles

Data below are not from head-to-head studies. Cross-trial data interpretation should be considered with caution as it is limited by differences in study population, design and many other factors.



1. SABCS 2021 #PS-17-05; 2. Rugo 2021 Lancet Oncol 22:489; 3. FDA Prescribing Information Document; 4. CAPItello-291: Turner N Engl J Med 2023; 388:2058-2070;

Note: These data are derived from different clinical trials at different points in time, with differences in molecule composition, trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

ReDiscover preliminary data as of 08/12/2024

PI3Kα Inhibitors – Tolerability Profiles

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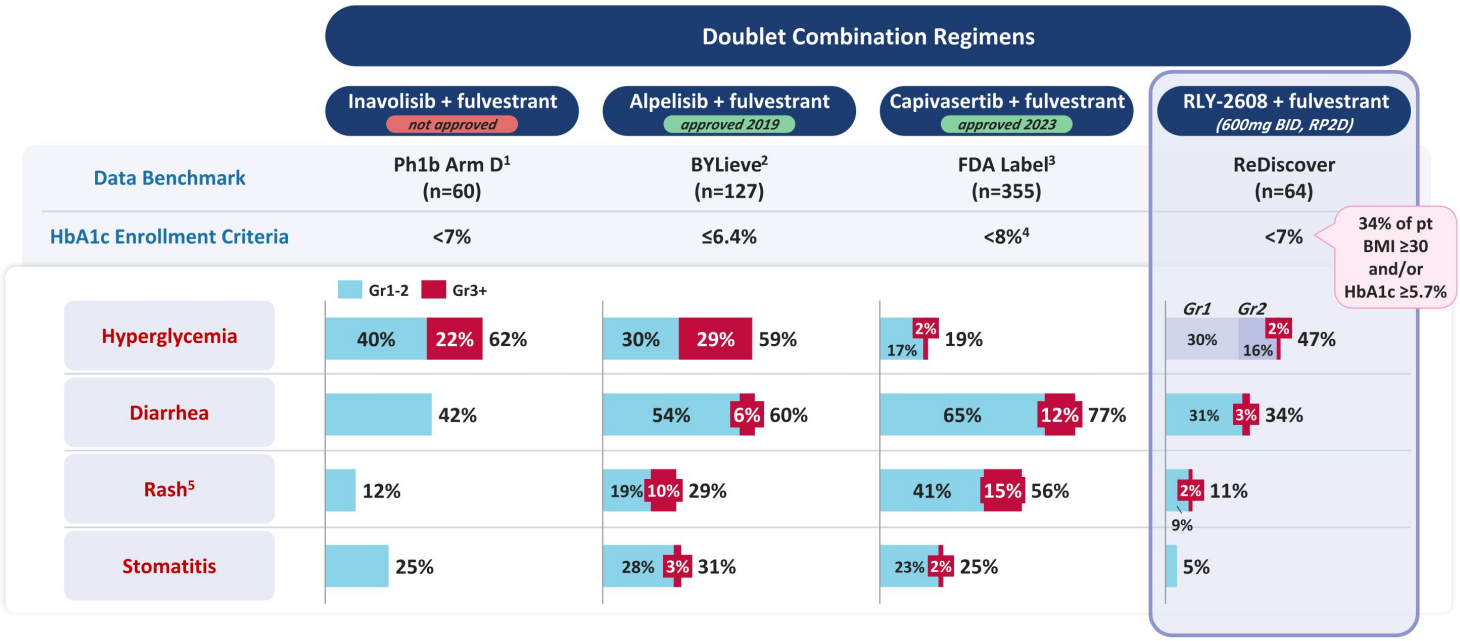


1. SABCS 2021 #P5-17-05; 2. Rugo 2021 Lancet Oncol 22:489; 3. FDA Prescribing Information Document; 4. per CAPItello-291 enrollment criteria; 5. Rash for capivasertib references Cutaneous Adverse Reactions grouped term includes a number of preferred terms listed in FDA prescribing information
Note: These data are derived from different clinical trials at different points in time, with differences in molecule composition, trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

ReDiscover preliminary data as of 08/12/2024

PI3Kα Inhibitors – Efficacy Profiles

Data below are not from head-to-head studies. Cross-trial data interpretation should be considered with caution as it is limited by differences in study population, design and many other factors.

Doublet Combination Regimens

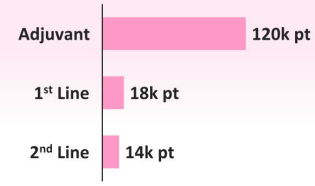
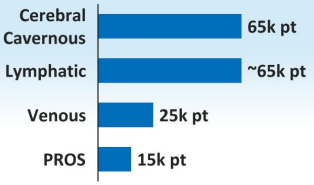
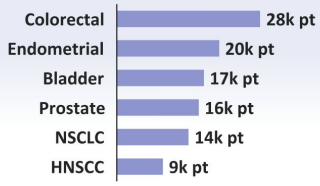
Data Benchmark	Inavolisib + fulvestrant *not approved* — Ph1b Arm D[1] (N=60)	Alpelisib + fulvestrant *approved 2019* — BYLieve Cohort C[2] (N=126)	Capivasertib + fulvestrant *approved 2023* — CAPItello-291[3,6] (N=355)	RLY-2608 + fulvestrant *(600mg BID, RP2D)* — ReDiscover (N=52)
% pt with >=2 prior LoT	57%	63%	23%	44%
% prior SERD[5]	47%	33%	0%	52%
mPFS	7.1mo	5.6mo	5.5mo[4]	9.2mo
CBR	48%	37%	56%	57%
ORR	19%	24%	26%[6]	33%[7]

Capi ORR & CBR include 30% of pts who are CDK4/6-naïve

1. SABCS 2021 #P5-17-05 (n=60); 2. SABCS 2021 #PD-13-05; 3. Turner N Engl J Med 2023; 388:2058-2070 (n=355); 4. 5.5mo mPFS reported in CDK4/6-experienced patient sub-population of CAPItello-291; 5. Prior SERD includes fulvestrant and next-generation SERDs; 6. ORR as reported in FDA Label (from CAPItello-291); 7. ORR includes 2 ongoing unconfirmed partial response as of the data cut-off. After the data cut-off, one uPR patient has confirmed and the other uPR patient remains on treatment; Additionally, one stable disease patient has converted to an unconfirmed partial response, remains on treatment and is not included in the ORR; Note: These data are derived from different clinical trials at different points in time, with differences in molecule composition, trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

ReDiscover preliminary data as of 08/12/2024

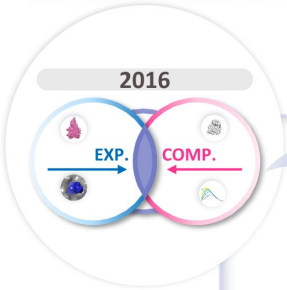
Relay Tx's PI3Kα Franchise – Large Opportunities Across 3 Pillars

	PIK3CA mutant HR+/HER2- Breast Cancer	*PIK3CA* mutant Vascular Malformations	*PIK3CA* mutant Other Solid Tumors
	~150k Patients (US prevalence)[1]	**~170k Patients** (US prevalence)[2]	**~160k Patients** (US incidence)[3]
	RLY-2608	Potential for initial POC with RLY-2608, then distinct molecule for pivotal	RLY-2608
			
Anticipated Next Steps	CDK4/6 triplet data – 2024 CDK4 triplet clinical start – 2024 CDK4/6 triplet expansion start – 1H25 2L doublet pivotal start – 2025	Clinical start – Q1 2025	Open monotherapy dose expansion – YE 2024

1. Prevalent US patient population with a PIK3CA mutation in each line of therapy (Global Data HR+/HER2- Breast Cancer Global Forecast, November 2023; 3rd party source for alteration rate); 2. Prevalent US patient population of vascular malformation patients with a PIK3CA mutation (multiple sources); 3. Incident US patient population solid tumors annually with a PIK3CA mutation (SEER; 3rd party source for alteration rate, May 2024); POC = proof of concept; PROS = PIK3CA Related Overgrowth Spectrum, NSCLC = non-small cell lung cancer, HNSCC = hand and neck squamous cell carcinoma

ReDiscover preliminary data as of 08/12/2024

Relay Tx's Dynamo® – Productive Computationally Enabled Platform



2024 Dynamo® Platform

EXPERIMENTATION

- NMR
- Mechanistic enzymology
- HDX-MS
- Cryo-EM
- X-ray fragment screening
- REL-DEL
- Structure ensembles
- Integrated pharmacology
- Protein design and engineering
- Automated Ligand ID System (ALIS)
- Ambient temp. X-Ray crystallography
- High throughput automated chemistry

PEOPLE

COMPUTATION

- Free energy calculations
- Long time-scale MD
- Giga-scale virtual screening
- Differential dynamics
- Digitally encoded libraries
- ML-DEL + AI models for DEL
- ADME/PK models
- Active learning
- Generative design
- Automated Chemical Design
- Computational fragment merging

Relay Tx – Additional Near-Term Clinical Programs

	GENETIC DISEASE	SOLID TUMORS
	Fabry Disease 	NRAS-Driven Solid tumors 
Program Updates	1st non-inhibitory αGal chaperone	1st NRAS-selective inhibitor
Large US Opportunity	~8,000 pts[1] *(chronic treatment)* $2B current market[3]	~28,000 pts[2]
Anticipated Milestones	Clinical start in 2H 2025	Clinical start in 2H 2025

1. Prevalence of Fabry patients (National Fabry Disease Foundation, Jan 2024); 2. Newly diagnosed (incident) solid tumors with an NRAS mutation, excluding melanoma stages 0-II (SEER, 3rd party source for alteration rate, Jan 2024);
3. Fabry disease forecasted 2024 market size per EvaluatePharma, includes Galafold® and ERTs (May 2024)

Lirafugratinib (RLY-4008) – Updated Data and Next Steps

Scope of Commercial Opportunity[1]

CCA: FGFR2 Fusions

~650 US pts/yr	~1,400 Global pts/yr

All Solid Tumors: FGFR2 Fusions

~4,000 US pts/yr	~13,000 Global pts/yr

Updated Tumor Agnostic data

Tumor Agnostic FGFR2 Fusions *(non-CCA)*

N=47; preliminary data as of 06/26/24

- 37% ORR
- 7.3mo mDoR

Data to be presented at ENA 2024

Regulatory Feedback

Per recent meeting with FDA:

1. Suggest to file NDA in CCA
2. Suggest to generate additional data for subsequent sNDA in Tumor Agnostic

Next Step: Seek global commercialization partner for lirafugratinib

1. Based on annual number of patient deaths due to expected later-line use. Global figure includes U.S., EU5, Japan.; Sources: SEER 2023, Global Cancer Observatory 2022

Relay Tx – Broad Precision Medicine Pipeline

	Target	Program		Preclinical	Early Clinical	Late Clinical
BREAST CANCER	PI3Kα	RLY-2608 (PI3Kα^{PAN})	Endocrine Tx (ET) doublet			
			Ribociclib + ET triplet			
			CDK4i + ET triplet			
			Other Novel Combinations			
	CDK2	RLY-2139		Paused; IND ready		
	ERα	RLY-1013 (Degrader)		Advance to IND-ready		
GENETIC DISEASE	Fabry Disease	αGal Chaperone				
	Vascular Malformations	RLY-2608 (PI3Kα^{PAN})				
		Other PI3Kα^{PAN}				
SOLID TUMORS	NRAS	NRAS-selective Inhibitor				
	PI3Kα	RLY-2608 Monotherapy				
	FGFR2	Lirafugratinib (RLY-4008)		Seeking global commercialization partner		

DYNAMO® PLATFORM | 5+ unnamed research programs

Relay Tx – Anticipated Milestones 2024-25

BREAST CANCER PORTFOLIO MILESTONES

PI3Kα *RLY-2608*	Doublet 2L pivotal trial start – 2025
	Ribociclib triplet data – 2024
	Ribociclib triplet expansion start – 1H25
	CDK4i triplet clinical start – 2024

GENETIC DISEASE PORTFOLIO MILESTONES

Vascular Malformations *RLY-2608*	Clinical start – 1Q 2025
Fabry Disease *Pre-clinical*	Clinical start – 2H 2025

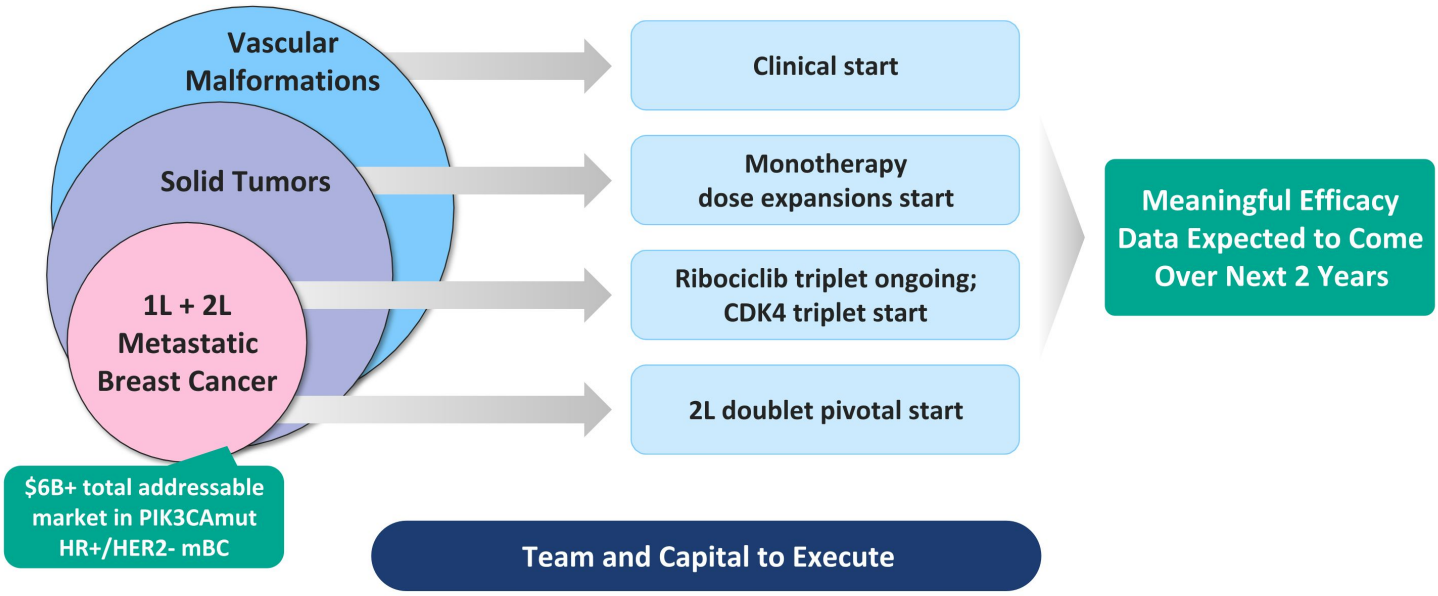
SOLID TUMORS PORTFOLIO MILESTONES

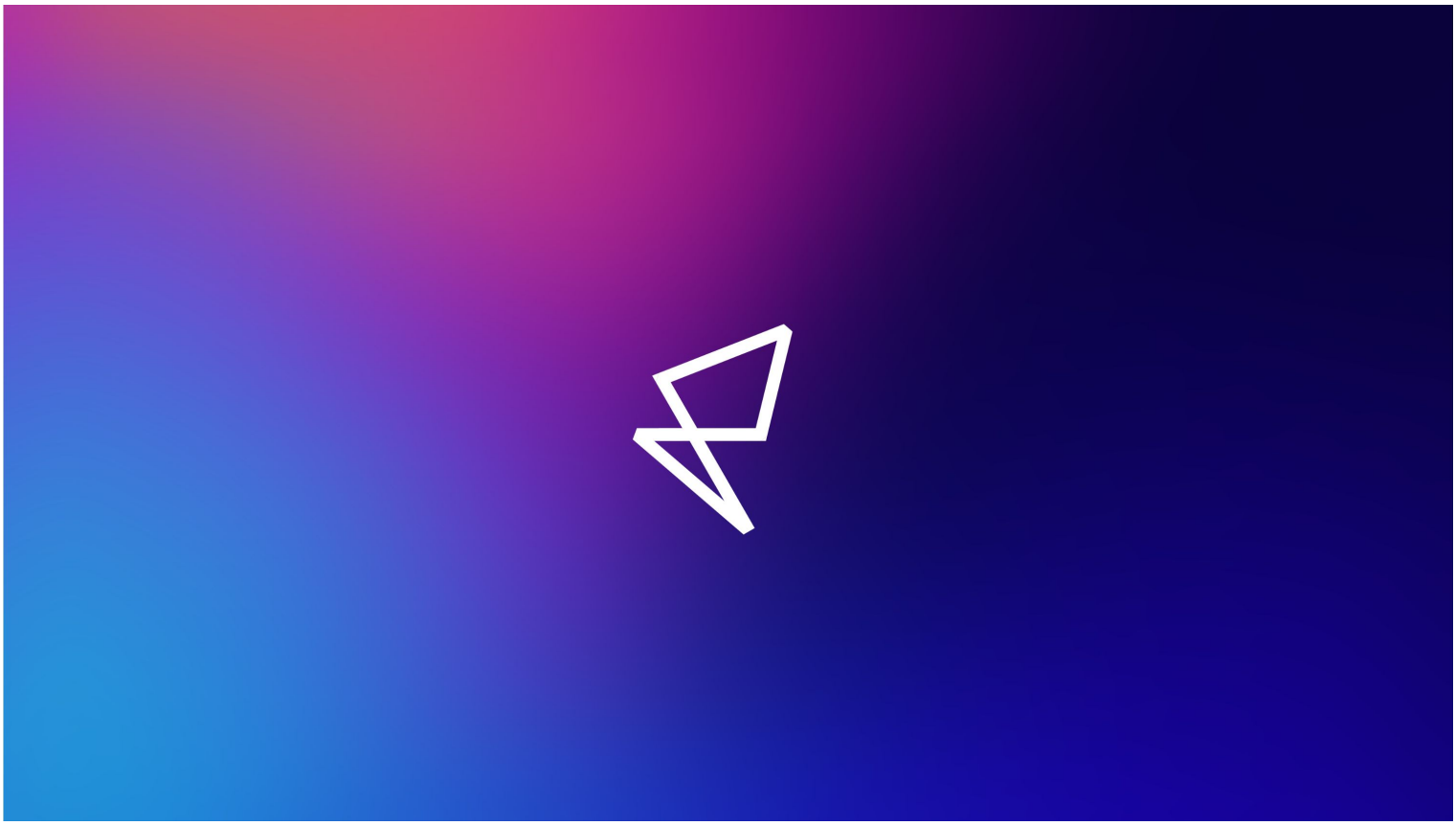
PI3Kα *RLY-2608*	Open monotherapy dose expansion – YE24
NRAS *Pre-clinical*	Clinical start – 2H 2025

DYNAMO® PLATFORM | 5+ unnamed research programs

~$688M cash as of end 2Q 2024
Expected to fund current operating plan into 2H 2026

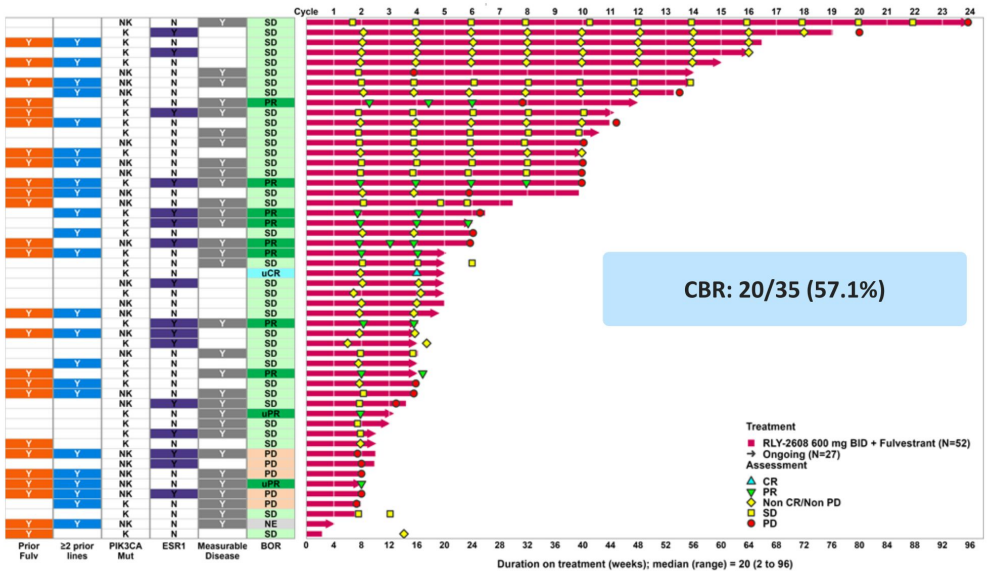
PI3Kα Franchise - Opportunity for Multiple Value-Creating Datasets Over Next 2 Yrs





RLY-2608 – Efficacy: 57.1% CBR

RLY-2608 600 mg BID (RP2D) + Fulvestrant
Excluding PTEN / AKT Co-Mutations (N=52)



CBR: Clinical Benefit defined as all patients with confirmed complete response or partial response or stable disease ≥24 weeks; evaluable patients started treatment ≥24 weeks prior to the data cutoff

ReDiscover preliminary data as of 08/12/2024