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): October 12, 2023

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**	**02139**
(Address of Principal Executive Offices)	**(Zip Code)**

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

(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 October 12, 2023, Relay Therapeutics, Inc. (the "Company") issued a press release announcing initial clinical data for RLY-4008 (lirafugratinib), a potent, selective and oral small molecule inhibitor of fibroblast growth factor receptor 2 ("FGFR2") in patients with FGFR2-altered solid tumors, a copy of which is being furnished as Exhibit 99.1 to this Current Report on Form 8-K. The Company intends to host a conference call and live webcast on October 12, 2023 at 5:30 p.m. E.T. to discuss this data for RLY-4008 (lirafugratinib). 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 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-4008 (lirafugratinib)

On October 12, 2023, the Company announced initial clinical data for RLY-4008 (lirafugratinib) in patients with FGFR2-altered solid tumors that was presented at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.

RLY-4008 (lirafugratinib) is currently being evaluated in the two-part global Phase 1/2 ReFocus trial in patients with FGFR2-altered tumors. The first part of the trial, or the dose escalation, is complete, and the second part of the trial, or the dose expansion, is ongoing at the 70mg once daily recommended Phase 2 dose. The dose expansion part of the trial includes four cholangiocarcinoma ("CCA") arms and three tumor agnostic (non-CCA) arms (such tumor agnostic arms being: (1) FGFR2 fusions, (2) FGFR2 amplifications and (3) FGFR2 mutations). As of the August 23, 2023 data cut-off date, the three tumor agnostic arms of the trial had enrolled 84 FGFR inhibitor-naïve patients who were efficacy evaluable across 18 tumor types, including 26 patients with FGFR2 fusions, 34 patients with FGFR2 amplifications and 24 patients with FGFR2 mutations. Across these arms of the trial, enrolled patients had received a median of approximately three prior lines of therapy, with the vast majority (94%) having received prior chemotherapy/ADC and nearly half (45%) having received prior targeted therapies.

In patients with FGFR2 fusions, there was consistent activity across a range of tumor types.

- Nine of 26 patients experienced a partial response ("PR") (35% overall response rate ("ORR")).
- Sixty-three percent of confirmed responders experienced a duration of response of at least six months as of the August 23, 2023 data cut-off date.
- There were 11 tumor types represented amongst enrolled patients with FGFR2 fusions, including pancreatic (n=6), ovarian (n=3), gastric (n=3), non-small-cell lung ("NSCLC") (n=2), and breast (n=2).

The trial enrolled 14 patients with breast cancer across all FGFR2 alterations, 10 of whom had HR+/HER2- breast cancer.

- Four of the 10 HR+/HER2- patients achieved PRs (40% ORR).
  - Three of the four responders remain on treatment, with the longest duration of response 72 weeks and ongoing, as of the August 23, 2023 data cut-off date.
- All responders had a duration of response of at least 6 months.
- All 14 patients were very heavily pre-treated, with a median of six prior lines of therapy.
  - All patients had received prior targeted therapies.
  - Nearly all patients had received prior chemotherapy/ADC (93%).
  - The vast majority of patients had received prior endocrine therapy (79%) and prior cyclin dependent kinase 4/6 ("CDK 4/6") (71%).

There were signals of activity in patients with a range of FGFR2-amplified tumor types.

- Eight of 34 patients experienced a PR (24% ORR).
  - PRs were seen across tumor types, including gastric, breast, colorectal, and esophageal.
- Six patients remain on treatment as of the August 23, 2023 data cut-off date, including four responders, one patient with stable disease and one patient who continued treatment beyond disease progression.
- Forty-three percent of confirmed responders experienced a duration of response of at least six months.

Early, promising efficacy signals were seen in patients with FGFR2-fusions and amplifications across eight tumor types, including gastric, breast, pancreatic, NSCLC, ovarian, colorectal, esophageal, and carcinoma of unknown primary origin. In addition, three of the 24 patients with FGFR2 mutations achieved a PR (breast, gastric and ameloblastic tumors).

The safety analysis from the tumor agnostic cohorts, as of the August 23, 2023 data cut-off date, was generally consistent with the analysis reported by the Company at the European Society for Medical Oncology Congress 2022.

- Most treatment-related adverse events were expected FGFR2 on-target, low-grade, monitorable, generally manageable and largely reversible.
- There were no observed Grade 4 or 5 adverse events.
- Off-target toxicities of hyperphosphatemia and diarrhea continued to be clinically insignificant.

Enrollment is complete in the pivotal expansion cohort in patients with FGFR2-fusion CCA who have not previously received an FGFR inhibitor.

Other Updates

On October 12, 2023, the Company announced additional pipeline updates, including the Company's plans to initiate a triplet combination with RLY-2608, fulvestrant and CDK4/6, and the Company's decision to pause further development efforts on RLY-2139, its CDK2 inhibitor. Taking into account the updates across the Company's portfolio, the Company expects its cash, cash equivalents and investments will be sufficient to fund its current operating plan into the second half of 2026.

Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K and certain of the 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 updates on the clinical development of the programs across the Company's portfolio, including RLY-4008; expected therapeutic benefits of its programs; and the Company's expected cash runway into the second half of 2026. 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 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 Current Report on Form 8-K or the materials furnished or filed herewith, including, without limitation, risks associated with: the impact of global economic uncertainty, geopolitical instability, or public health epidemics or outbreaks of an infectious disease, such as COVID-19, 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 of any current or planned clinical trials or the development of the Company's 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; 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 October 12, 2023, furnished herewith.
99.2	Corporate presentation, dated October 2023, 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: October 12, 2023

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

Relay Therapeutics Announces Initial RLY-4008 (lirafugratinib) Data Demonstrating Durable Responses Across Multiple FGFR2-Altered Solid Tumors

35% ORR in patients with FGFR2 fusions (excluding CCA) & 40% ORR in patients with FGFR2-altered HR+/HER2- breast cancer

RLY-4008 commercialization plans to focus on broader tumor agnostic opportunities

Clinical focus on PI3Kα mutant selective programs, with plans to initiate RLY-2608 triplet combinations in HR+/HER2- breast cancer by YE 2023

Pipeline updates extend cash runway by 1 year into 2H2026

Relay Therapeutics to host a conference call today, October 12, at 5:30 p.m. ET

Boston – October 12, 2023 – 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 initial clinical data for RLY-4008 (lirafugratinib) in patients with FGFR2-altered solid tumors. The data demonstrate activity across several sub-groups, including patients with FGFR2-fusion tumors and patients with FGFR2-altered HR+/HER2- breast cancer. These data are being presented today at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics.

“These data provide important early evidence that RLY-4008, or lirafugratinib, has the potential to help both patients with FGFR2-fusion cholangiocarcinoma as previously reported, as well as those with multiple other types of FGFR2-altered tumors,” said Don Bergstrom, M.D., Ph.D., President of R&D at Relay Therapeutics. “We are excited by the potential for lirafugratinib to help many more patients and are focused on advancing this opportunity as well as our PI3Kα programs, with the initiation of a RLY-2608 triplet combination trial this year.”

ReFocus Trial

Lirafugratinib is currently being evaluated in the two-part global Phase 1/2 ReFocus trial in patients with FGFR2-altered tumors. The first part of the study (dose escalation) is complete, and the second part of the study (dose expansion) is ongoing at the 70mg QD recommended Phase 2 dose. The dose expansion portion of the study includes four cholangiocarcinoma (CCA) arms and three (non-CCA) tumor agnostic arms (1: FGFR2 fusions, 2: FGFR2 amplifications and 3: FGFR2 mutations).

As of the August 23, 2023 cut-off date, the three tumor agnostic arms of the study had enrolled 84 FGFR inhibitor-naïve patients who were efficacy evaluable across 18 tumor types, including 26 patients with FGFR2 fusions, 34 patients with FGFR2 amplifications and 24 patients with FGFR2 mutations. Across these arms of the study, enrolled patients had received a median of approximately three prior lines of therapy, with the vast majority (94%) having received prior chemotherapy/ADC and nearly half (45%) having received prior targeted therapies.

Encouraging Initial FGFR2-Fusion Tumor-Agnostic Signal with Promising Durability

In patients with FGFR2 fusions, there was consistent activity across a range of tumor types.

- Nine of 26 patients experienced a partial response (PR) (35% overall response rate (ORR))
- Sixty-three percent of confirmed responders experienced a duration of response of at least 6 months as of the data cut-off date
- There were 11 tumor types represented amongst enrolled patients with FGFR2 fusions, including pancreatic (n=6), ovarian (n=3), gastric (n=3), non-small-cell lung (NSCLC, n=2), and breast (n=2)

Compelling Response Rate with Multiple Long-Term Responses in Heavily Pre-Treated Patients with HR+/HER2- Breast Cancer

The study enrolled 14 patients with breast cancer across all FGFR2 alterations, 10 of whom had HR+/HER2- breast cancer.

- Four of the 10 HR+/HER2- patients achieved PRs (40% ORR)
    - Three of the four responders remain on treatment, with the longest duration of response 72 weeks and ongoing as of the data cut-off date
    - All responders had a duration of response of at least 6 months
- All 14 patients were very heavily pre-treated, with a median of six prior lines of therapy
    - All patients had received prior targeted therapies
    - Nearly all patients had received prior chemotherapy/ADC (93%)
    - The vast majority of patients had received prior endocrine therapy (79%) and prior CDK4/6 (71%)

Early Tumor-Agnostic Signal in FGFR2-Amplifications

There were signals of activity in patients with a range of FGFR2-amplified tumor types.

- Eight of 34 patients experienced a PR (24% ORR)
    - PRs seen across tumor types, including gastric, breast, colorectal, and esophageal
- Six patients remain on treatment as of data cut-off, including four responders, one patient with stable disease and one patient who continued treatment beyond disease progression
- Forty-three percent of confirmed responders experienced a duration of response of at least 6 months

Additional Signals

Early, promising efficacy signals were seen in patients with FGFR2-fusions and amplifications across eight tumor types, including gastric, breast, pancreatic, NSCLC, ovarian, colorectal, esophageal, and

carcinoma of unknown primary origin. In addition, three of the 24 patients with FGFR2 mutations achieved a PR (breast, gastric and ameloblastic tumors).

Safety Data Remain Generally Consistent with Previously Reported Profile

The safety analysis from the tumor agnostic cohorts, as of the data cut-off date, was generally consistent with the analysis from the 2022 ESMO data disclosure.

- Most treatment-related adverse events were expected FGFR2 on-target, low-grade, monitorable, generally manageable and largely reversible
- There were no observed Grade 4 or 5 adverse events
- Off-target toxicities of hyperphosphatemia and diarrhea continued to be clinically insignificant

Lirafugratinib Next Steps

- Continue enrollment in the three tumor agnostic cohorts
    - The company expects to report additional clinical data and a regulatory update in 2024
- Enrollment is complete in the pivotal expansion cohort in patients with FGFR2-fusion CCA who have not previously received an FGFR inhibitor
- Near-term commercial readiness activities for CCA will be paused and aligned with the broader tumor agnostic opportunity

The AACR-NCI-EORTC presentation and poster are available on the Relay Therapeutics website under Publications: https://relaytx.com/publications/.

Pipeline Updates

The company will continue to prioritize and expand further PI3Kα mutant selective development, including:

- RLY-2608: continue ongoing ReDiscover trial with focus on RLY-2608 + fulvestrant cohorts
    - Initiate triplet combination with RLY-2608 + fulvestrant + CDK4/6 by the end of 2023
- Next PI3Kα clinical data update expected in 2024
- Additionally, Relay Therapeutics has decided to pause further development efforts on RLY-2139 (CDK2 inhibitor)

Cash Runway Extended

With the decision to pause CCA commercial readiness and RLY-2139 development, Relay Therapeutics expects its cash, cash equivalents and investments will be sufficient to fund its current operating plan into the second half of 2026.

Conference Call Information

Relay Therapeutics will host a conference call and live webcast today, Thursday, October 12, 2023, at 5:30 p.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-4008 (lirafugratinib)

RLY-4008 (lirafugratinib) 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, lirafugratinib 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, lirafugratinib demonstrated strong activity against known clinical on-target resistance mutations in cellular and in vivo preclinical models. Lirafugratinib 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 FGFRi-naïve FGFR2-fusion CCA. To learn more about the clinical trial of lirafugratinib, please visit here.

ReFocus Trial Background

RLY-4008 (lirafugratinib) is currently being evaluated in a global Phase 1/2 clinical trial (ReFocus) in patients with FGFR2-altered CCA and multiple other solid tumors including a single-arm, potentially registration-enabling cohort for FGFRi-naïve FGFR2-fusion CCA. The Phase 1 dose escalation has been completed, and 70 mg QD has been selected as the registrational dose. The expansion cohorts were initiated in December 2021 and now consist of seven different cohorts based on FGFR2 alteration and tumor type. Of the seven cohorts, the potential pivotal cohort consists of approximately 100 previously treated, FGFRi-naïve FGFR2-fusion CCA patients.

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

RLY-4008; the expected therapeutic benefits of its programs; and the expected cash runway. 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, such as COVID-19, 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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Exhibit 99.2

RELAY® THERAPEUTICS

RLY-4008 (lirafugratinib) in FGFR2-Altered Solid Tumors

October 2023

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 the progress and timing of the clinical development of the programs across our portfolio, including the expected therapeutic benefits of our programs, timing of enrollment completion, and potential efficacy and tolerability; the timing of clinical data updates across our pipeline; the possibility that unconfirmed results from these trials will not be confirmed by additional data as our clinical trials progress; the potential of RLY-2608 or RLY-5836 to address a major unmet medical need; expectations regarding our pipeline, operating plan, use of capital, expenses and other financial results; our cash runway projection; the competitive landscape and potential market opportunities for our product candidates; the expected strategic benefits under our collaborations; our ability to successfully establish or maintain collaborations or strategic relationships for our product candidates; expectations regarding current and future interactions with the U.S. Food and Drug Administration (FDA); our ability to manufacture our product candidates in conformity with the FDA's requirements; the capabilities and development of our Dynamo™ platform; our plans to develop, manufacture and commercialize our current product candidates and any future product candidates; and the implementation of our business model and strategic plans for our 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, or the negative thereof, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

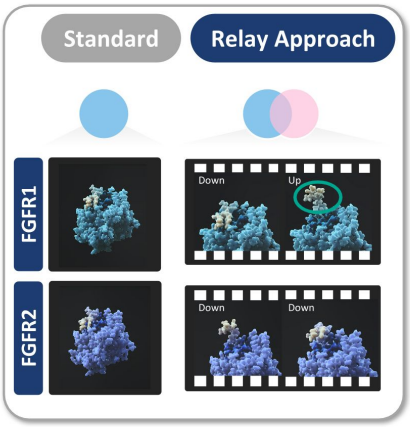
Any forward-looking statements in this presentation are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation, including, without limitation, risks associated with: the impact of global economic uncertainty, geopolitical instability, 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 of any current or planned clinical trials or the development of our drug candidates; the risk that the preliminary 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; 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.

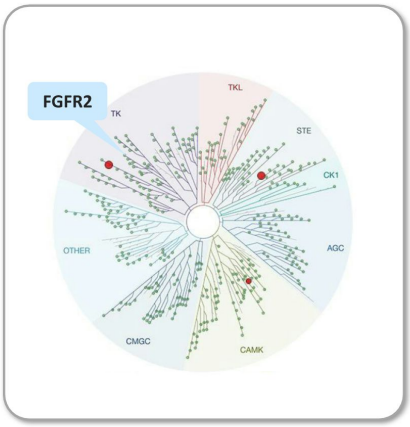
This presentation contains trademarks, trade names and service marks of other companies, which are the property of their respective owners.

RLY-4008 – Embodies The Power of Our R&D Engine

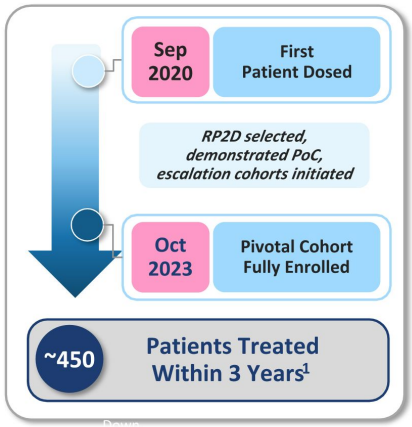
Motion Based Drug Design…



…Created First Known Selective FGFR2



Strong Clinical Execution Drives Rapid Pathway to Potential Registration



1. RLY-4008-101 treated patient total as of 29 Sept 2023

RLY-4008 (lirafugratinib) – Initial Clinical Efficacy Observed Across Tumor Types

Broad Activity Across Alteration and Tumor Types

24-40% cORR[1] in FGFR2-altered, non-CCA advanced solid tumors *at Triple Meeting 2023 interim readout*

Objective Response Rate

- **40%** HR+ Breast Cancer (all alts)
- **35%** All Fusions
- **24%** All Amplifications

Add'l signals (ORR) observed in:
- Gastric: 19% (5 of 26 pt)
- NSCLC: 50% (2 of 4 pt)
- Ovarian: 50% (2 of 4 pt)

Majority of responders with durability ≥ 6 months[3]

Global Patients[4] ~85k[5]

Cholangiocarcinoma Cohort Continues to Mature

58-82% cORR in fusion+, FGFRi-naïve CCA[2]

- Differentiated profile
- Pivotal cohort fully enrolled

Global Patients[4] ~6k

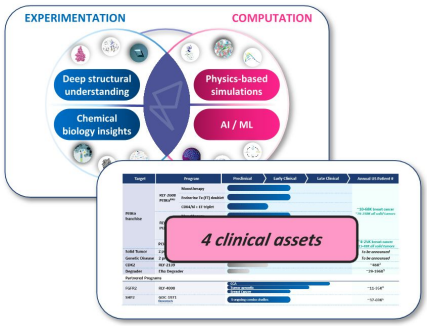
cORR = Confirmed Objective Response Rate; ORR = Objective Response Rate

Sources: ACS; SEER; Globocan; World Bank; 3rd party sources; 1. ORR includes 2 unconfirmed partial responses that confirmed post data cut off; 2. Range reflects all doses to 70mg QD RP2D, ESMO 2022 interim readout; 3. As of 23 Aug 2023; 4. Global patient totals reflect annual incidence; 5. 85K is inclusive of HR+ breast cancer (all FGFR2 alterations) and advanced solid tumors with FGFR2 amplifications or fusions (excluding breast cancer)

Preliminary data as of 23 Aug 2023

Relay Tx – Patient-Driven

Productive In-House R&D Engine…



…Focusing Investment…

RLY-4008	Pre-clinical
Pause CCA commercial build & align with TA	Pause CDK2 at IND

Extend Cash Runway & Enable Execution Focus

…To Create Long Term Value

FGFR2	PI3Kα Mutant Selective Franchise		
RLY-4008	RLY-2608	RLY-5836	H1047R specific

Addresses large patient population

Tumor agnostic (TA) focus	HR+ /HER2- Breast Cancer[1] (US Patients)	2L	1L	(Neo) adjuvant
		~14k	~18k	~120k

Continue Enrollment | **Initiate CDK4/6 Triplet by YE 2023**

~$872M

Cash, cash equivalents and investments as of the end of 2Q 2023

Current cash, cash equivalents and investments are expected to be sufficient to fund current operating plan into 2H 2026

Sources: Global Data product sales; Global Data HER2-/HR+ Breast Cancer Global Forecast; 3rd party data

1. Includes prevalent PI3Kα mutated HR+/HER2- patients receiving therapy in Neoadjuvant/Adjuvant setting (includes incident patients in 2023 receiving endocrine or non-endocrine therapy in Neo/Adjuvant settings [~50k], and patients diagnosed in previous years with local/regional disease receiving sequential endocrine therapy in 2023 [~69k]), and prevalent PI3Kα mutated HR+/HER2- metastatic patients receiving therapy in 1L or 2L setting

FGFR2 – Tumor Agnostic Opportunity

	Tumor Agnostic		Tumor Specific		
					
Indication	**All Solid Tumors: FGFR2 Fusions**	**All Solid Tumors: FGFR2 Amplifications**	**CCA: Fusions**	**HR+ Breast Cancer: All Alterations[2]**	**Gastric Cancer: All Alterations[2]**
US patients per year	~13k	~7k	~1k	~9k	~2k
Global patients per year[1]	Up to ~43k	Up to ~34k	Up to ~6k	Up to ~28k	Up to ~67k

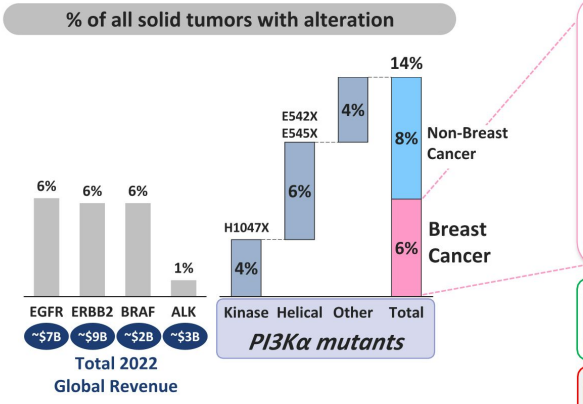
Current data suggests potentially large global opportunity

1. Incidence; Global includes US, EU4+UK, Japan, China; 2. Alterations include fusions, amplifications and mutations

Sources: ACS; SEER; Globocan; World Bank; 3rd party sources; Cholangiocarcinoma EU website; Jpn J Clin Oncol 2021, June, Tsujie; CCA News, 2021 Yr in review, "FGFR2 Fusion and/or Rearrangement Profiling in Chinese Patients with Intrahepatic CCA"; Nature, Jan 2012, K Matsumoto; Clin Cancer Res, May 2013, L Xie; Br J Cancer, Feb 2014, X Su; Ann Translational Med, Oct 2020, Yi Sun; Life (Basel), Jan 2022, C Lengyel; Am J Cancer Res, 2021, W Gu

PI3Kα Represents a Major Market Opportunity

PI3Kα is the most frequently mutated kinase in solid tumors



HR+/HER2- Breast Cancer represents a significant market with high unmet need

~150k US PI3Kα Mutation HR+/HER2- Breast Cancer Patients[1]

Patient Segment *(PI3Kα mutated)*	2L	1L	(Neo) Adjuvant
US Patients	~14k	~18k	~120k

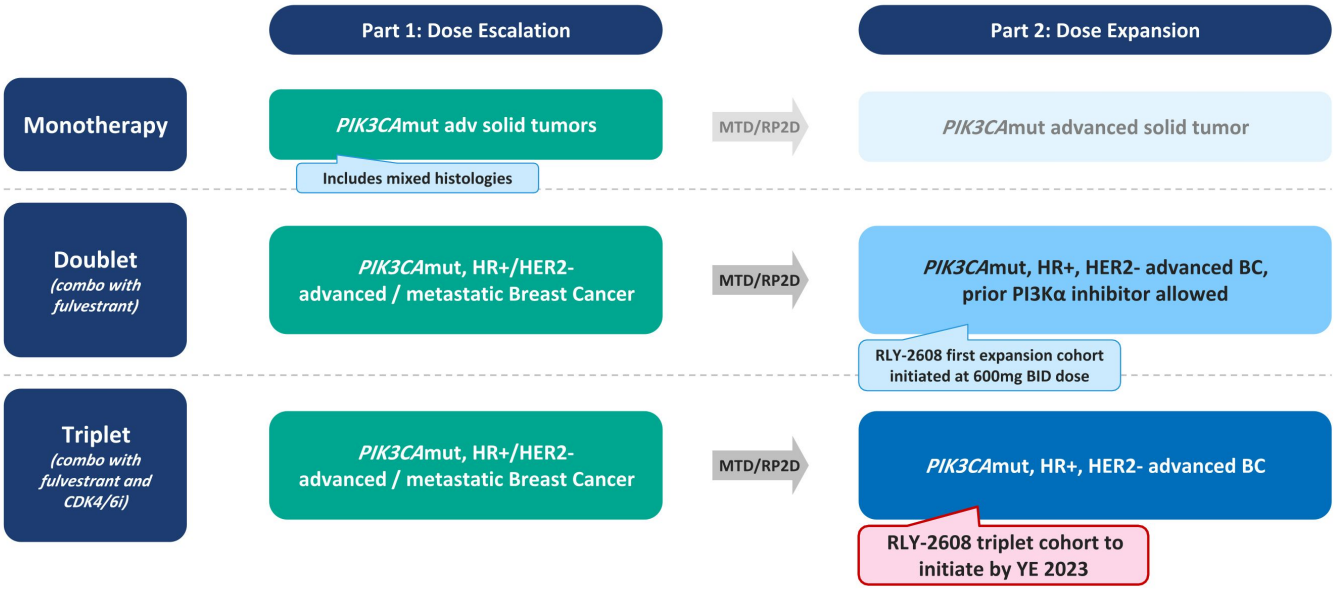
Relay Tx	RLY-2608 RLY-5836	Initial observed tolerability profile enables potential earlier lines of use
Current Tx	Piqray	Approved
	Capivasertib	Filed[2]
	Inavolisib	Ph 3[2]

Broad earlier use potentially unlikely due to tolerability challenges

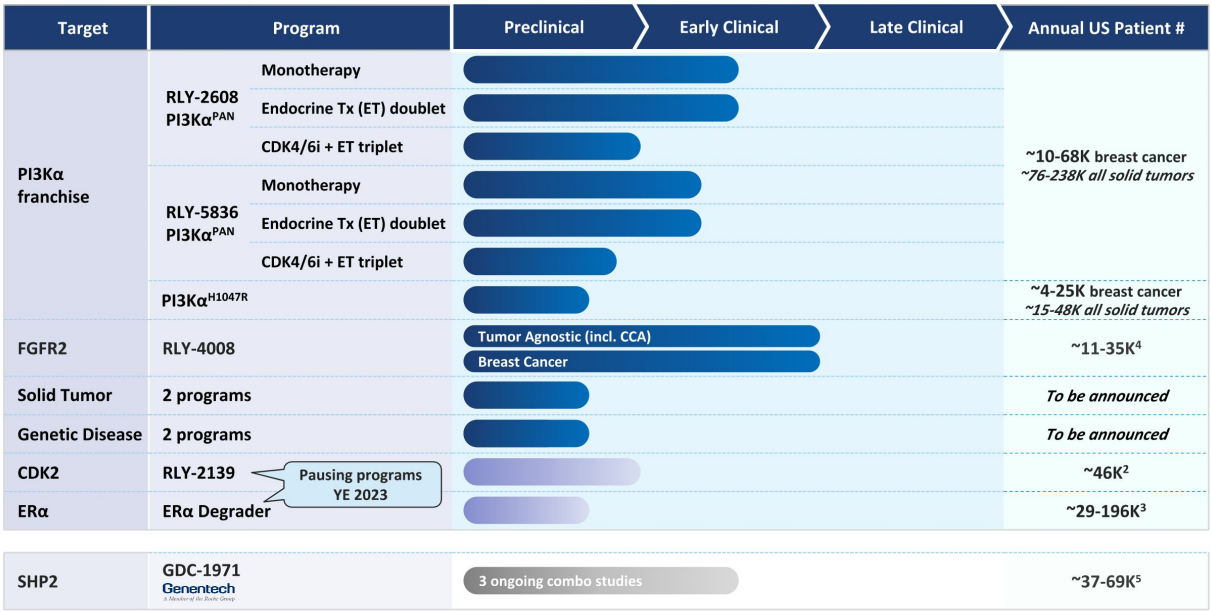
RLY-2608 Triplet Trials with CDK4/6 inhibitors to be initiated before YE 2023

1. Includes prevalent PI3Kα mutated HR+/HER2- patients receiving therapy in Neoadjuvant/Adjuvant setting (includes incident patients in 2023 receiving endocrine or non-endocrine therapy in Neo/Adjuvant settings [~50k], and patients diagnosed in previous years with local/regional disease receiving sequential endocrine therapy in 2023 [~69k]), and prevalent PI3Kα mutated HR+/HER2- metastatic patients receiving therapy in 1L or 2L setting; 2. Phase 3 trials are focused in patients with early progression on endocrine therapy (during or within 12 months of completing adjuvant treatment); Sources: Global Data product sales; Global Data HER2-/HR+ Breast Cancer Global Forecast; 3rd party data

PI3Kα Franchise Moving Rapidly to Triplet Combinations



Relay Tx's Execution & Capital Focus on Highest Value Opportunities



Note: Unless otherwise indicated, patient #'s refer to total annual number of US patients with late-line cancers compared to comprehensive annual incidence that may be amenable to treatment with our programs

1. Unless otherwise indicated, all breast cancer patient numbers refer to HR+/HER2- breast cancer tumors; 2. ~46K HR+/HER2- breast cancer patients expected to receive CDK 4/6 inhibitors in adjuvant setting, first-line setting, and second-line setting in 2023, per Decision Resources Breast Cancer Market Forecast report dated June 2022; 3. HR+/HER2- US late-line breast cancer patients compared to HR+/HER2- US incident breast cancer patients; 4. FGFR2 altered late-line solid tumors compared to comprehensive annual FGFR2 altered incident solid tumors including additional FGFR gene fusions and rearrangements resulting from truncation of the protein at exon 18 and all breast cancer patients with FGFR2 alterations; 5. SHP2 combo only includes KRAS G12C in lung and colorectal, EGFR mutations in lung, and ALK fusions in lung

Relay Tx – Capital, Team & Execution Focus to Deliver on Key Milestones

Breast Cancer Franchise

RLY-2608 RLY-5836 (PI3Kα^{PAN})

- Initial RLY-2608 data in 1H 2023
- RLY-5836 clinical start in 2Q 2023
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- ERα development candidate nomination in 2023
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Pausing both programs YE 2023

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- Tumor Agnostic expansion cohorts data in 2H 2023 (2023 Triple)
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- Ongoing combo trials; Genentech controls data disclosures

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To be announced

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5+ undisclosed programs in preclinical development and additional early-stage efforts across platform

~$872M

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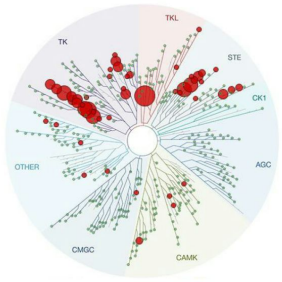
Current cash, cash equivalents and investments are expected to be sufficient to fund current operating plan into 2H 2026

FGFR2 – Limitations of Current CCA and Non-CCA Treatment Options

Limited Selectivity

Approved Pan-FGFRis are non-specific across FGFR family



Limited Tolerability

High rates of off-target toxicity (esp. FGFR1,4)

FDA Approved Compound[1]	% of Patients with Hyperphosphatemia	% of Patients with Diarrhea
Pemigatinib	93%	39%
Futibatinib	88%	33%
Erdafitinib	71%	59%

Chemo and other late line therapies have high rates of AEs and dose modifications

Limited Target Coverage

E.g., pemigatinib 13.5mg QD achieves 76% inhibition of FGFR2 at trough[2]

Limited Efficacy

CCA

36-42% ORR in currently approved tx[1] *(in fusion+ CCA, FGFRi-naïve pt)*

Non-CCA Solid Tumors

0-15% ORR in approved late-line tx[3] *(based on NCCN guidelines)*

mPFS 1-5mo in non-CCA solid tumors

1. Sources: Pemigatinib – prescribing information; futibatinib – prescribing Information; erdafitinib – prescribing information; (note: AEs are reflective of respective label indications); 2. From pemigatinib NDA review documents: "Pemigatinib 13.5 mg daily provided 76% inhibition of ex vivo phosphorylated FGFR2α at trough"; 3. Reflects reported ORRs in key randomized studies evaluating NCCN recommended regimens for recurrent/metastatic patients (second/third line or later) for the following tumor types: HR+ breast cancer, gastric cancer, pancreatic cancer, NSCLC, ovarian cancer, and head and neck (studies on slide 23).

RLY-4008 (lirafugratinib) – ReFocus Trial Design

Part 1: Dose Escalation

Unresectable or metastatic solid tumors

FGFR2 alterations per local assessment

Both FGFRi-naïve & FGFRi-treated allowed

RLY-4008 RP2D: 70 mg QD

Part 2: Dose Expansion

Cholangiocarcinoma (CCA)

Pivotal cohort

FGFR2-fusion+ CCA without prior FGFRi *(N=100)*

Pivotal supportive

FGFR2-fusion+ CCA with prior FGFRi *(N=50)*

FGFR2-fusion+ CCA with no prior treatment *(N=20)*

Any FGFR2-mutant/amplified CCA *(N=20)*

Advanced solid tumors with FGFR2 alterations (excluding CCA)

FGFR2-fusion+ solid tumors *(N=50)*

FGFR2-amplified solid tumors *(N=50)*

FGFR2-mutant solid tumors *(N=50)*

Today's Disclosure

Baseline Characteristics – Heavily Pre-Treated Patients Across 18 Tumor Types

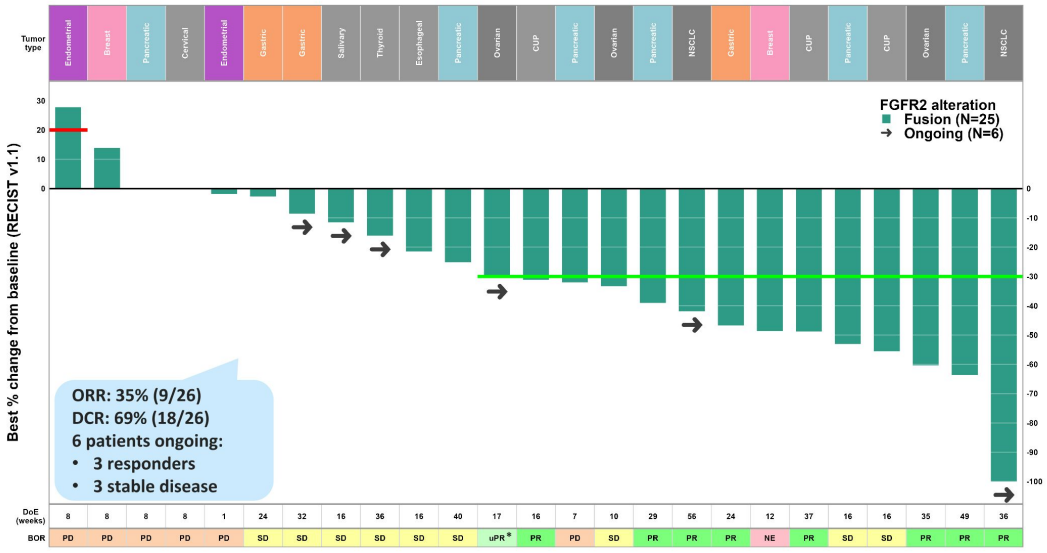
Parameter	Efficacy Population (N=84)
Sex, n (%)	
Female	51 (61)
Age (years), median (range)	62 (33, 84)
Race, n (%)	
White	46 (55%)
Asian	12 (14%)
Other/Unknown	26 (31%)
ECOG PS, n (%)	
0	31 (37%)
1	52 (62%)
2	1 (1%)
Prior lines of systemic therapy, n (%)	
0	2 (2%)
1	14 (17%)
2	26 (31%)
≥3	42 (50%)
Prior systemic therapy, n (%)	
Chemotherapy	79 (94%)
FGFR inhibitor	0

Parameter	Efficacy Population (N=84)
Tumor types, n (%)	
Gastric cancer	26 (31%)
Breast Cancer	14 (17%)
Pancreatic	7 (8%)
Ovarian	5 (6%)
Colorectal	4 (5%)
NSCLC	4 (5%)
Endometrial	4 (5%)
CUP	3 (4%)
Salivary	2 (2%)
Others[1]	15 (18%)
FGFR2 oncogenic alteration, n (%) by local testing	
FGFR2 fusion or rearrangement	26 (31%)
FGFR2 amplification[2]	34 (40%)
FGFR2 mutation	24 (29%)

1. *Includes ameloblastic, ampullary, cervical, duodenal, esophageal, fallopian, melanoma, orbita, thyroid
2. Amplification define as FGFR2 locus with copy number ≥8 in tumor tissue or validated by next generation sequencing (NGS). No amplification cutoff is defined for circulating tumor DNA (ctDNA)

Note: Efficacy population includes 84 patients with *FGFR2* fusions, amplifications, or mutations by local testing who had measurable disease and ≥1 post-baseline tumor assessment

Tumor Responses Observed Across Multiple FGFR2-Fusion Solid Tumors



Indication	PR	SD	N	ORR	DCR
All Fusions	9	9	26	35%	69%
NSCLC	2	0	2	100%	100%
Ovarian	2	1	3	67%	100%
Pancreatic	2	2	6	33%	67%
Gastric	1	2	3	33%	100%
Breast	0	0	2	0%	0%
Other	2	4	10	20%	60%

BOR = Best Overall Response:

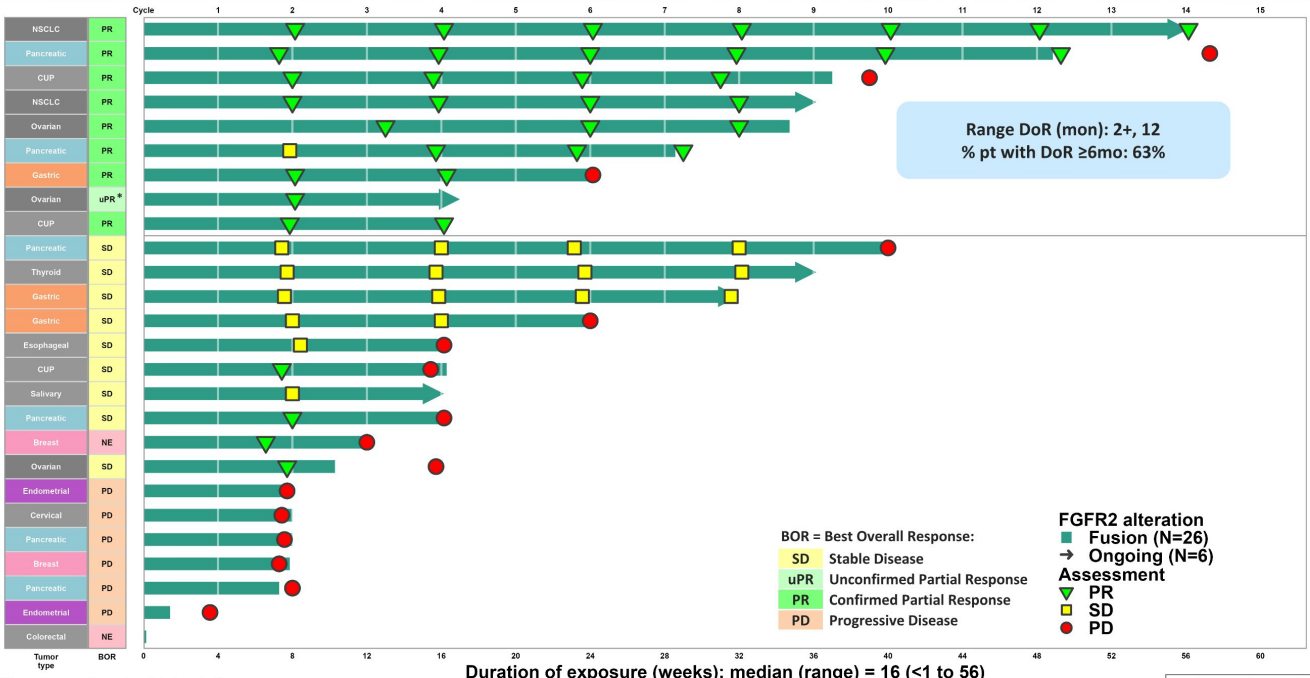
SD	Stable Disease
uPR	Unconfirmed Partial Response
PR	Confirmed Partial Response
PD	Progressive Disease

Consistent activity signal seen across a range of tumor types

Note: Waterfall includes patients with post-baseline scans. ORR calculation includes 26 efficacy evaluable patients; ORR = Objective Response Rate; DCR = Disease Control Rate
* Response confirmed post data cutoff

Preliminary data as of 23 Aug 2023

Durable Responses Observed Across FGFR2-Fusion Solid Tumors

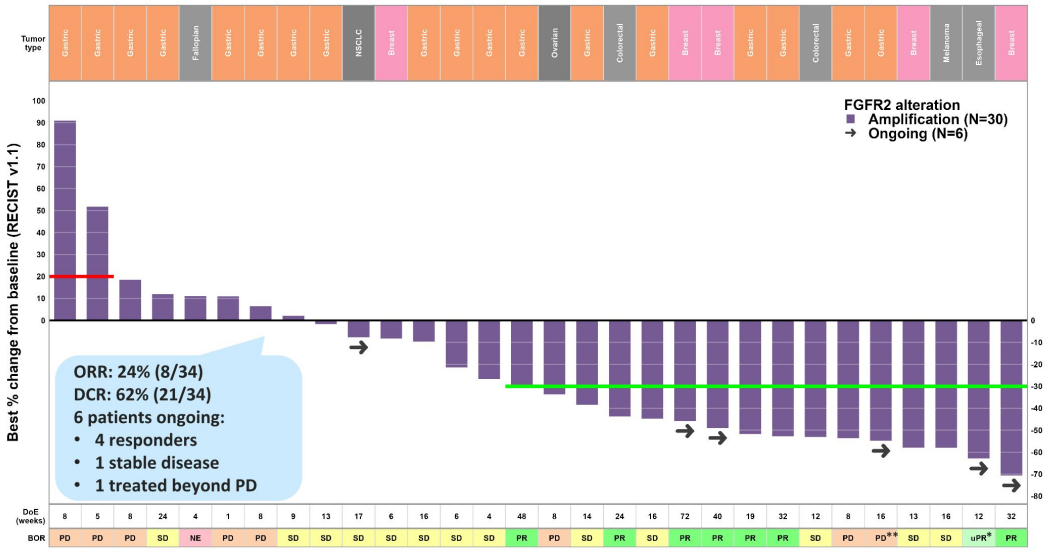


Duration of exposure (weeks); median (range) = 16 (<1 to 56)

* Response confirmed post data cutoff

Preliminary data as of 23 Aug 2023

Early Signal in FGFR2-Amplifications Driven by Key Tumor Types



Indication	PR	SD	N	ORR	DCR
All Amps	8	13	34	24%	62%
Breast	3	2	5	60%	100%
Colorectal	1	1	2	50%	100%
Gastric	3	8	19	16%	58%
NSCLC	0	1	2	0%	50%
Other	1	1	6	17%	33%

BOR = Best Overall Response:

SD	Stable Disease
uPR	Unconfirmed Partial Response
PR	Confirmed Partial Response
PD	Progressive Disease

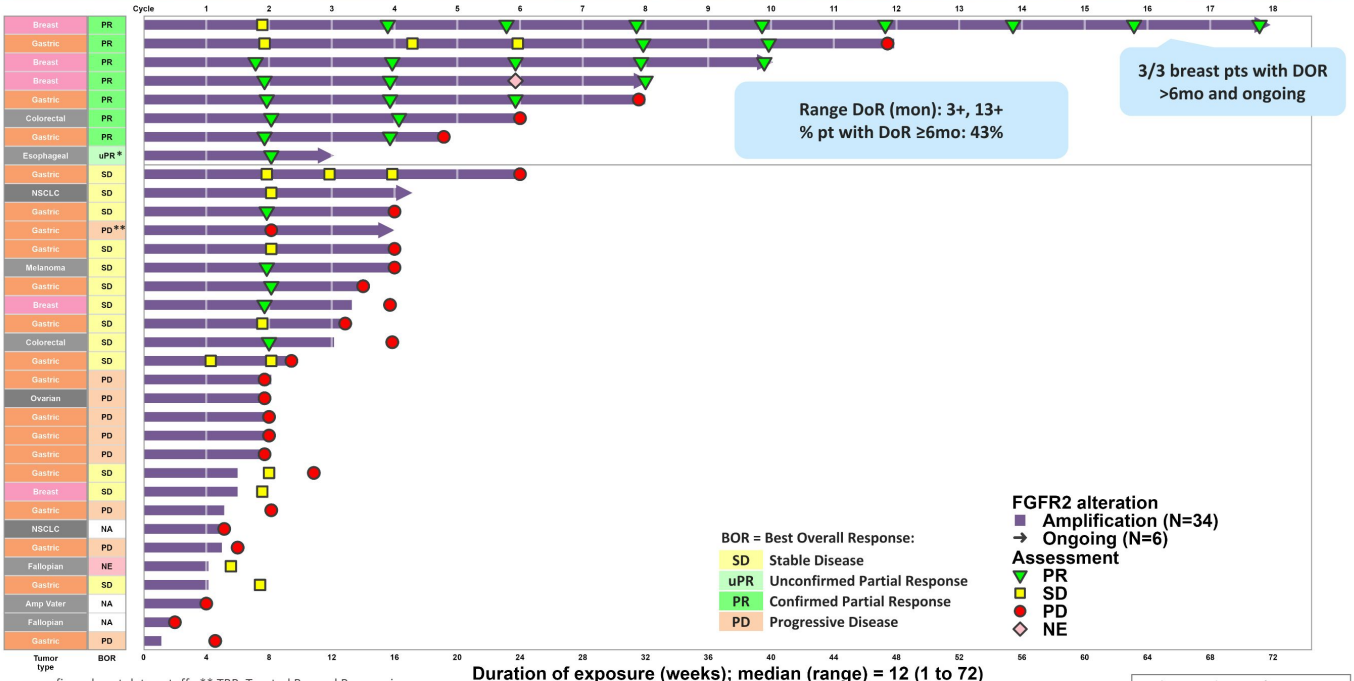
Encouraging gastric cancer signal where current approved last line of treatment yields 4% ORR, <4mo mPFS[1]

Note: Waterfall includes patients with post-baseline scans. ORR calculation includes 34 efficacy evaluable patients; ORR = Objective Response Rate; DCR = Disease Control Rate

1. Bang 2018 Ann Oncol 29:2052 (n=186); These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.; * Response confirmed post data cutoff; ** TBP: Treated Beyond Progression

Preliminary data as of 23 Aug 2023

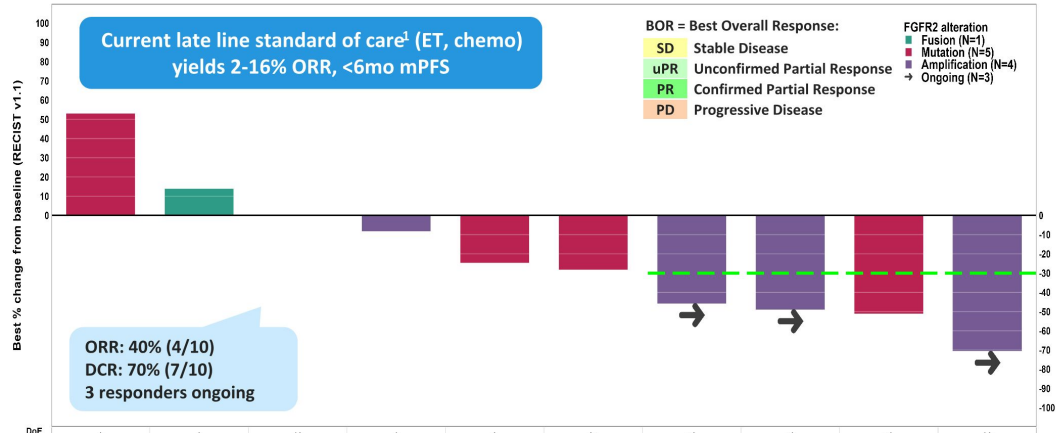
Durable Responses Observed Across FGFR2-Amplification Solid Tumors



* Response confirmed post data cutoff; ** TBP: Treated Beyond Progression

Preliminary data as of 23 Aug 2023

Strong Signal in HR+/HER2- Breast Cancer



DoE (weeks)	8	8	12	6	8	25	72	40	48	32
BOR	PD	PD	SD	SD	PD	SD	PR	PR	PR	PR
Subtype	HR+/HER2-	HR+/HER2-	HR+/HER2-	HR+/HER2-	HR+/HER2-	HR+/HER2-	HR+/HER2-*	HR+/HER2- ^	HR+/HER2- ^^	HR+/HER2-
Prior LoT	10	9	6	5	3	7	6	8	11	7
Prior ET?	-	Y	Y	Y	Y	Y	Y	Y	Y	Y
Prior CDK4/6?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
ESR1 status	-	+	-	+	+	+	+	-	+	+

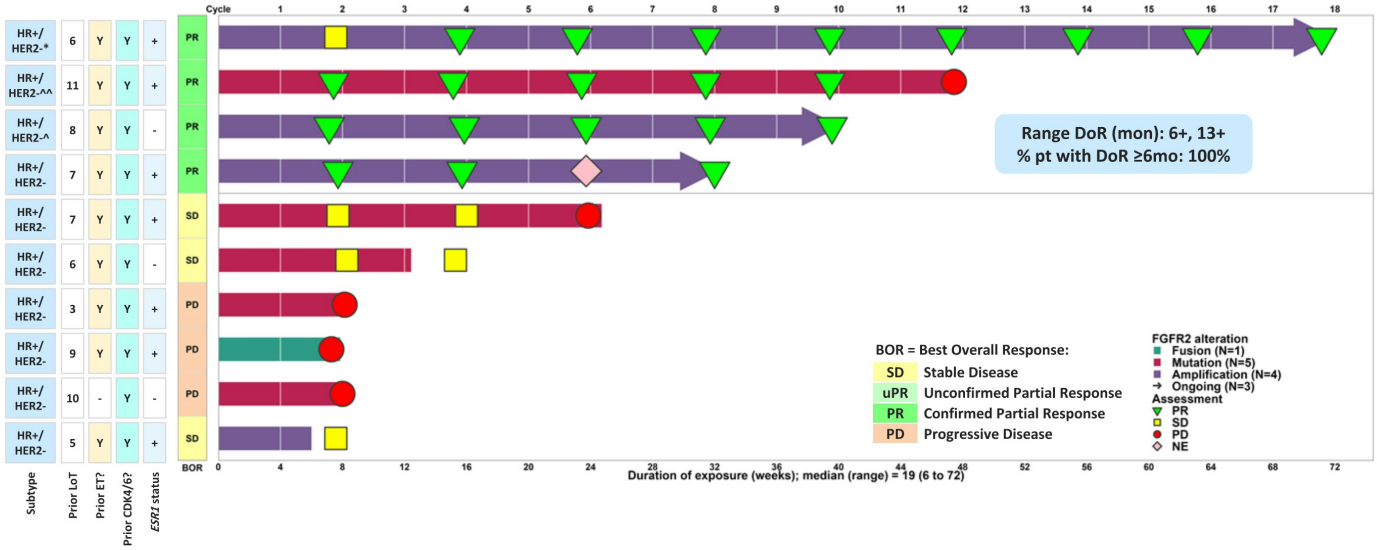
Median 7 prior lines of systemic therapy

ESR1 alteration status per central testing; ORR = Objective Response Rate; DCR = Disease Control Rate

* Local HER2 result equivocal and patient was treated with a single dose of concomitant fulvestrant; ^ Patient treated with concomitant letrozole and leuprorelin; ^^ Patient treated with concomitant anastrozole; 1. Reflects reported ORRs in key randomized studies evaluating NCCN recommended regimens for recurrent/metastatic patients (second/third line or later) for HR+ breast cancer (studies on slide 23). These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

Preliminary data as of 23 Aug 2023

Multiple Long-Term Responses Observed in Heavily Pre-Treated HR+/HER2- Breast Cancer



* Local HER2 result equivocal and patient was treated with a single dose of concomitant fulvestrant; ^ Patient treated with concomitant letrozole and leuprorelin; ^^ Patient treated with concomitant anastrozole

Preliminary data as of 23 Aug 2023

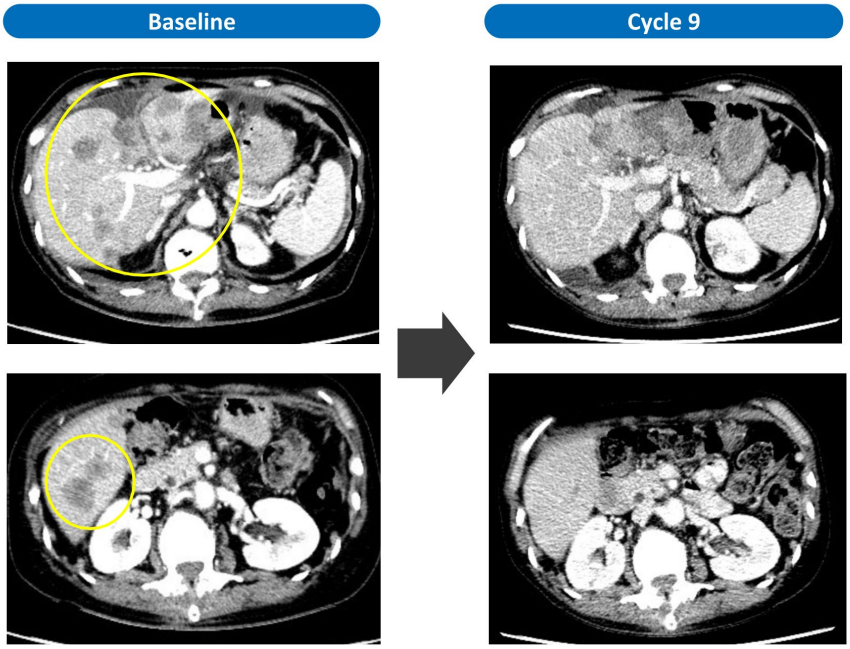
Durable cPR in Heavily Pre-Treated FGFR2-Amplified HR+ Breast Cancer

Patient Profile

- 66yr female with HR+/HER2- mBC*
- FGFR2 amplification (copy number: 10)
- 6 prior lines of therapy, including endocrine therapy, CDK4/6 inhibitor, and chemotherapy

Impact of RLY-4008

- ctDNA cleared at C2
- Initial PR at Cycle 5, Max 46% tumor regression
- Patient ongoing treatment at Cycle 19
- Generally tolerable safety profile with dose mods
  - Maintained cPR on 20mg QD
- Treated with a single dose of concomitant fulvestrant, otherwise single agent RLY-4008



* Local HER2 result equivocal

Courtesy Dr Tai, NCC Singapore

Preliminary data as of 23 Aug 2023

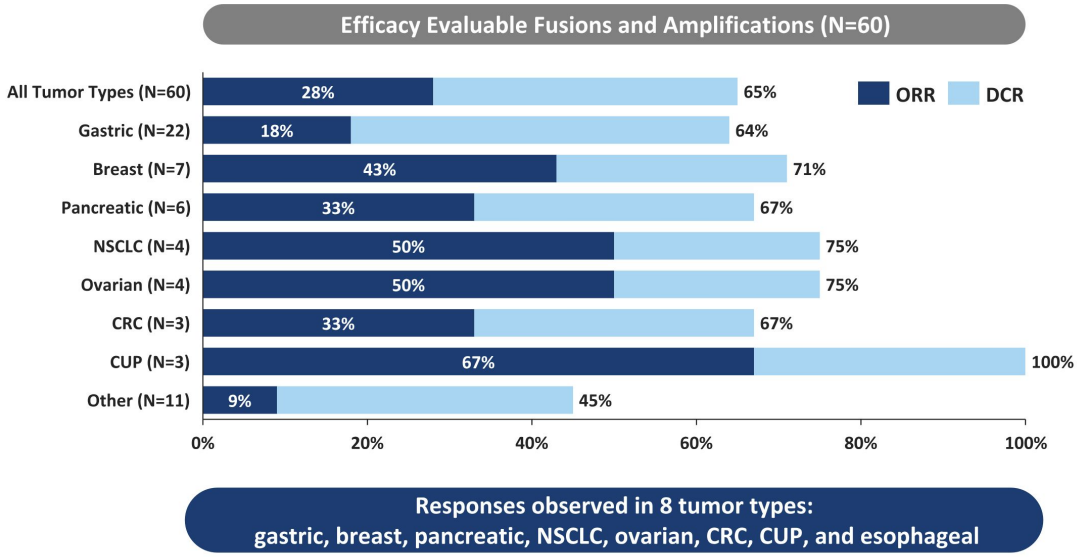
ORR & DCR by FGFR2 Alteration Types

Efficacy Parameter	Fusion N=26	Amplification N=34	Mutation N=24
Best Overall Response, n (%)			
Partial response, n (%)*	9 (35%)	8 (24%)	3 (13%)
Stable disease, n (%)	9 (35%)	13 (38%)	7 (29%)
Progressive disease, n (%)	6 (23%)	9 (26%)	12 (50%)
Not evaluable, n (%)**	2 (8%)	4 (12%)	2 (8%)
ORR n (%) 95% CI	9 (35%) 17, 56	8 (24%) 11, 41	3 (13%) 3, 32
Disease control rate, n (%) 95% CI	18 (69%) 48, 86	21 (62%) 44, 78	10 (42%) 22, 63

ORR = Objective Response Rate; DCR = Disease Control Rate
*Including ongoing 1 uPR in ovarian cancer patient with FGFR2 fusion, confirmed after data extraction, 1 ongoing uPR in esophageal cancer patient with FGFR2 amplification, and 1 ongoing uPR in gastric cancer patient with FGFR2 mutation
** Including N=2 fusion: 1 patient who discontinued due to death before first post-baseline scan and 1 patient with 1 post-baseline scan that did not meet the minimum duration of > 8 weeks from baseline for SD; N=4 amplification: 3 patients who discontinued due to progressive disease before first post-baseline scan and 1 patient with 1 post-baseline scan that did not meet the minimum duration of > 8 weeks from baseline for SD; N=2 mutation: 2 patients who discontinued due to progressive disease before first post-baseline scan

Preliminary data as of 23 Aug 2023

Encouraging ORR Across FGFR2 Fusions and Amplifications in Key Tumor Types



Responses observed in 8 tumor types:
gastric, breast, pancreatic, NSCLC, ovarian, CRC, CUP, and esophageal

ORR = Objective Response Rate; DCR = Disease Control Rate
Note: ORR includes PR + 1 ongoing uPR in ovarian cancer patient with *FGFR2* fusion confirmed after data extraction, 1 ongoing uPR in esophageal cancer patient with FGFR2 amplification
Other includes: ampula vater, cervical, endometrial, esophageal, fallopian, melanoma, salivary, thyroid; ORR = Objective Response Rate; DCR = Disease Control Rate

Preliminary data as of 23 Aug 2023

Current Limitations of Late Line Standard of Care for FGFR2 Non-CCA Tumors

Tumor	Regimen(s)	Med Prior LoT	ORR
HR+ Breast Cancer[1,2]	Endocrine Tx[1], chemo[2]	1-3+	2-16%
Gastric Cancer[3]	Chemotherapy	2	4%
Pancreatic Cancer[4-6]	Chemotherapy	1-2	0-6%*
NSCLC[7,8]	Chemotherapy	2	6-7%
Ovarian[9,10]	Chemotherapy	1-2^	6-15%
HNSCC[11]	Cetuximab	1-2	7%

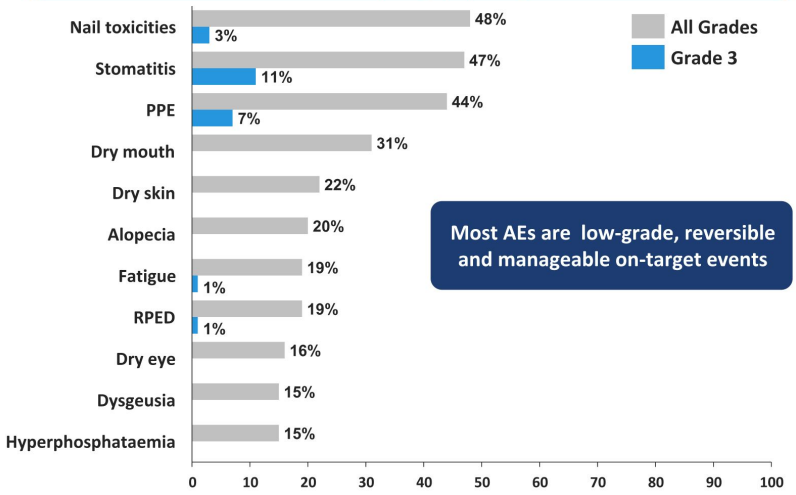
Table reflects NCCN recommended regimens. Median prior LoT and ORR are as reported in studies corresponding to each therapy

Sources: 1. Bidard 2022 J Clin Oncol 1:3246 (EMERALD, n=238), 2. ASCO 2022 #LBA3 (DB04, n=163), 3. Bang 2018 Ann Oncol 29:2052 (n=186), 4. Kobayashi 2023 BMC Cancer 21:177 (n=43), 5. Wang-Gillam 2016 Lancet 387:545 (NAPOLI-1, n=419), 6. Yoo 2009 Br J Cancer 101:10 (n=31), 7. Gidard 2009 J Thorac Oncol 4:1544 (n=173), 8. Shepherd 2000 J Clin Oncol 18:2095 (n=103), 9. ASCO 2023 #LBA5507 (MIRASOL, n=226), 10. Mutch 2007 J Clin Oncol 25:2811 (n=195), 11. Seiwert 2004 Ann Oncol 25:1813 (n=60); *ORR excludes 117 pts in NAPOLI-1 (70% ≤1 prior lines of therapy) treated with nanoliposomal irinotecan + fluorouracil + folinic acid, which is recommended for good performance status 2L pts (and less likely to be a 3L regimen) ^Platinum resistant ovarian cancer. Ovarian CTx: Paclitaxel, liposomal doxorubicin, topetecan, or gemcitabine; Breast CTx: capecitabine, eribulin, gemcitabine, paclitaxel, nab-paclitaxel; Pancreatic Cancer CTx: FOLFOX, 5-FU + fluorouracil, modified FOLFIRI3, NSCLC CTx: Docetaxel, gemcitabine, pemetrexed; Gastric Cancer: Paclitaxel or irinotecan

RLY-4008 (lirafugratinib) – Safety Profile Consistent with Previous Data

Consistent, manageable safety profile that minimizes off-isoform toxicity

Treatment-related AEs ≥15%
*Solid Tumor; 70mg QD (N=124)**



Most AEs are low-grade, reversible and manageable on-target events

Treatment-Related Dose Modifications
*Solid Tumor; 70mg QD (N=124)**

Interruption, n (%)	**59 (48%)**
Reduction, n (%)	**44 (36%)**
Discontinuation, n (%)	**1 (<1%)**

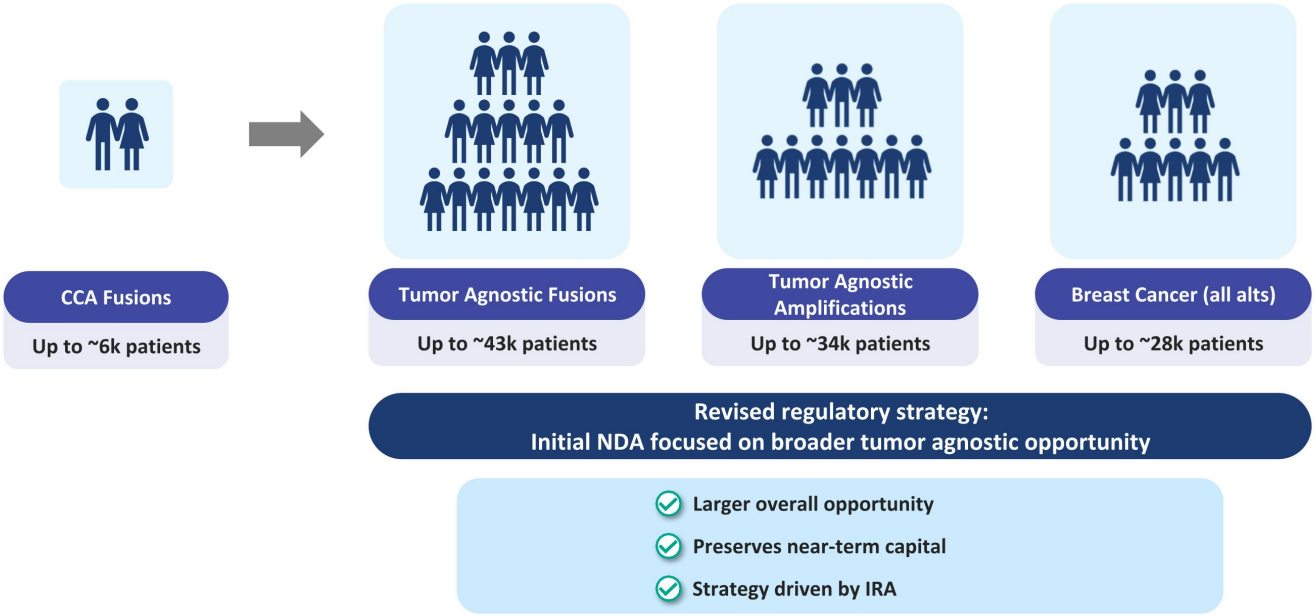
Treatment ongoing: N=38 (31%)
Discontinued from study treatment N=86 (69%):
- Due to progressive disease N=73 (59%)
- Due to adverse event N=3 (2.4%; 2 unrelated)

No treatment-related Grade 4/5 AEs

Safety population: FGFRi-naïve and FGFRi-pretreated non-CCA
PPE: Palmar-plantar erythrodysesthesia, RPED: retinal pigment epithelium detachment

Preliminary data as of 23 Aug 2023

RLY-4008 (lirafugratinib) – Regulatory Strategy to Address More Patients



Note: Patient totals shown are global incidence rates

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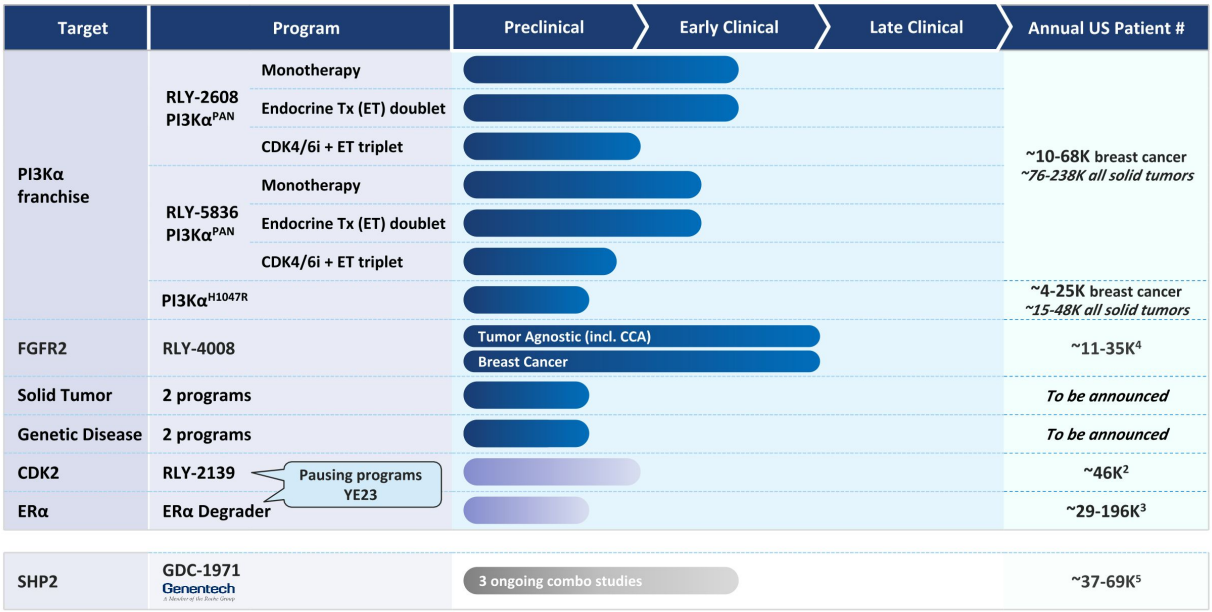

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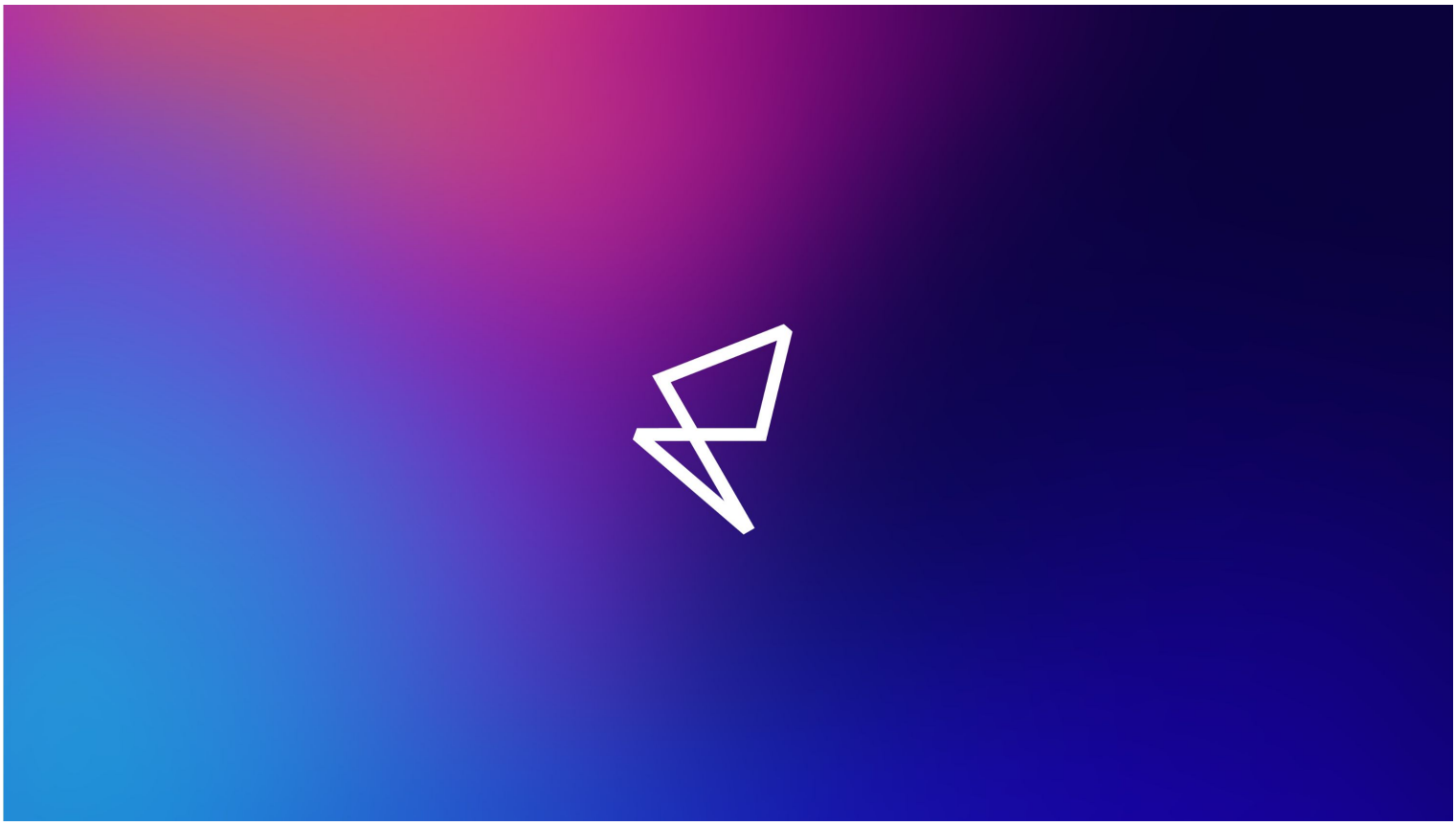
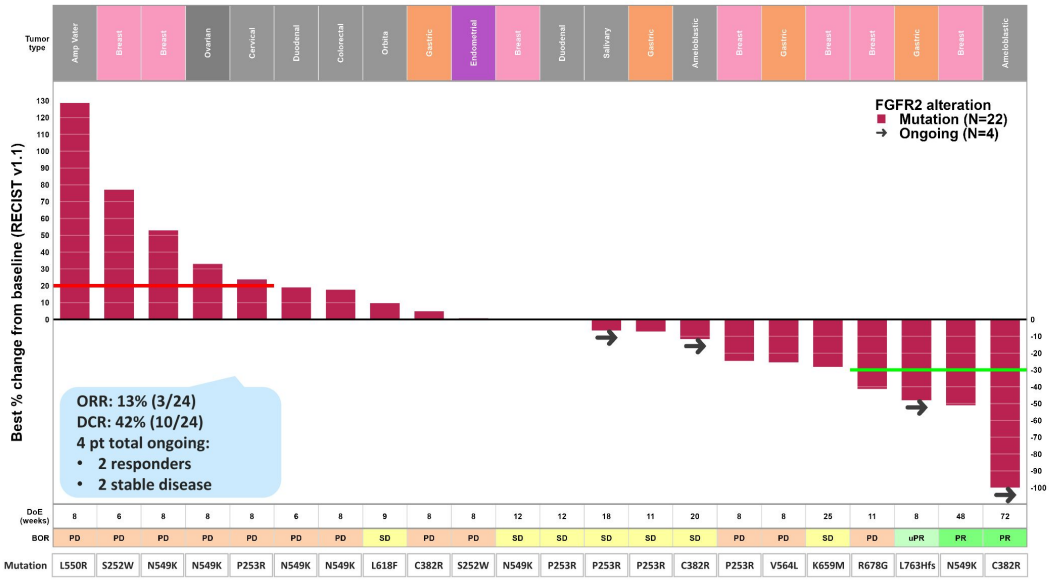


RLY-4008 – Non-CCA Mutations



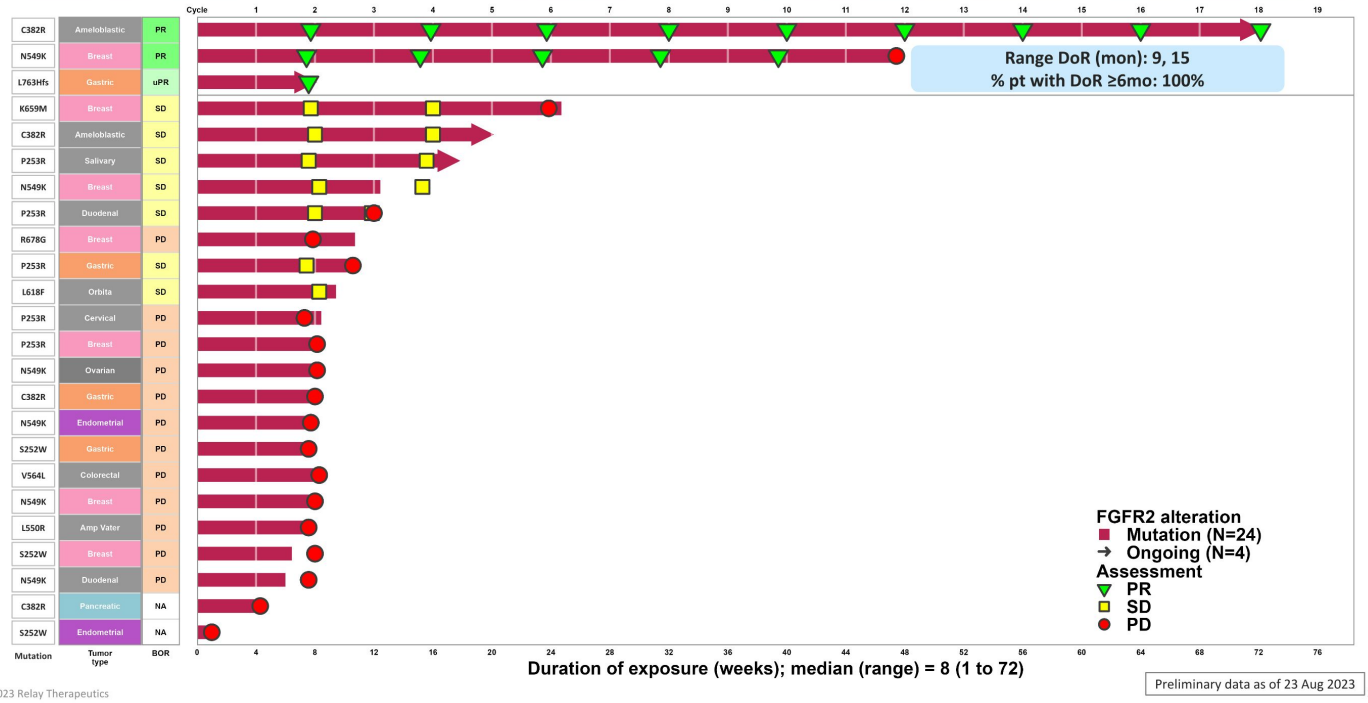
Indication	PR	SD	N	ORR	DCR
All Muts	3	7	24	13%	42%
Ameloblastic	1	1	2	50%	100%
Gastric	1	1	4	25%	50%
Breast	1	2	7	14%	43%
Salivary	0	1	1	0%	100%
Other	0	2	10	0%	20%

Add'l deep response (67% tumor reduction) in salivary gland cancer in pt previously treated with carboplatin/paclitaxel, lenvatinib

Note: ORR calculation includes 24 efficacy evaluable patients; mutations per local assessment

Preliminary data as of 23 Aug 2023

RLY-4008 – Non-CCA Mutations



Preliminary data as of 23 Aug 2023