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Clinical activity of lirafugratinib (RLY-4008), a highly selective FGFR2 inhibitor, in patients with advanced *FGFR2*-altered solid tumors: the ReFocus study

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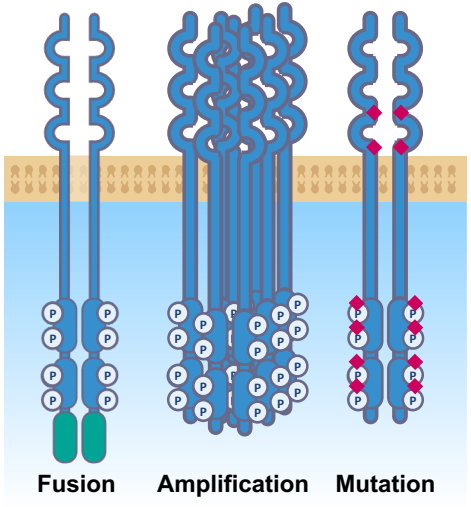
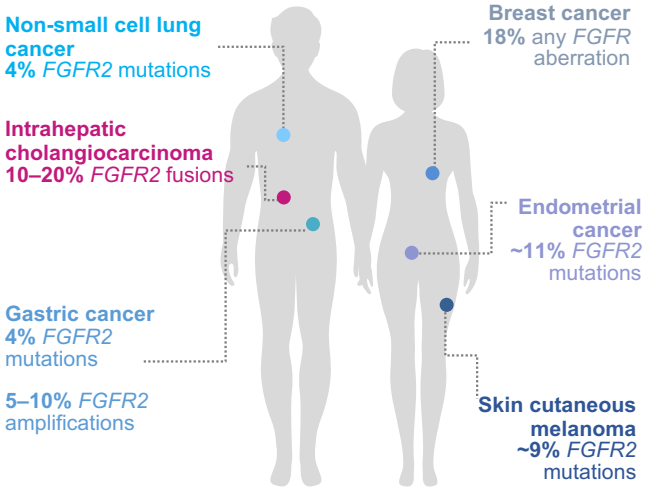
Oncogenic Activation of FGFR2 Drives Multiple Cancers, But Selective Targeting of FGFR2 Has Not Been Achieved

FGFR2 is a clinically validated oncogene[1]



FGFR2 alterations drive multiple solid tumor types[2-4]



Pan-FGFR inhibitors approved in only 2 solid tumor indications

	Phase 2 Response Rate	DoR (mo)	% of patients with… (All grades)	
			Hyper phosphatemia[9] (FGFR1 off-isoform toxicity)	Diarrhea (FGFR4 off-isoform toxicity)
Pemigatinib[5]	36% (CCA)	9.1 (CCA)	94%	47%
Futibatinib[6]	42% (CCA)	9.7 (CCA)	88%	39%
Erdafitinib[7]	32% (Urothelial Carcinoma)	5.4 (Urothelial Carcinoma)	76%	47%
Infigratinib[8]	23% (CCA)	5.0 (CCA)	90%	24%

Infigratinib withdrawn

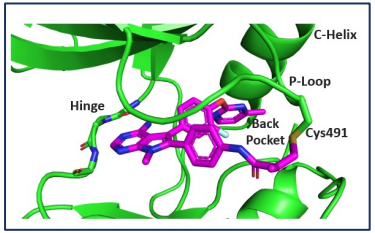
1. Babina IS and Turner NC. *Nat Rev Cancer*. 2017;17:318–332; 2. Krook MA, et al. *Br J Cancer* 2021;124:880–892; 3. Helsten T, et al. *Clin Cancer Res*. 2016;22:259–267; 4. Li J et al, *Front Oncol* 2021; 11: DOI=10.3389/fonc.2021.644854 5. PEMAZYRE® (pemigatinib). Highlights of prescribing information; Pemazyre (pemigatinib) [package insert]. Wilmington, DE Incyte; 2020; ESMO 2019; 6. LYTGOBI® (futibatinib). Highlights of prescribing information; Lytgobi (futibatinib) [package insert]. Princeton, NJ Taiho Oncology; 2022 7. BALVERSA (erdafitinib) Highlights of prescribing information; Balversa (erdafitinib) [package insert]. Horsham, PA Janssen. 8. Truseltiq(infigratinib) [package insert]. Brisbane, CA QED Therapeutics; 2021 9. As defined by increased serum phosphate except for infigratinib which is not specified

CCA: Cholangiocarcinoma, FGFRi: fibroblast growth factor receptor, FGFRi: fibroblast growth factor receptor inhibitor

CCA: cholangiocarcinoma; DoR: duration of response

Lirafugratinib:
The First Highly Selective FGFR2 Inhibitor

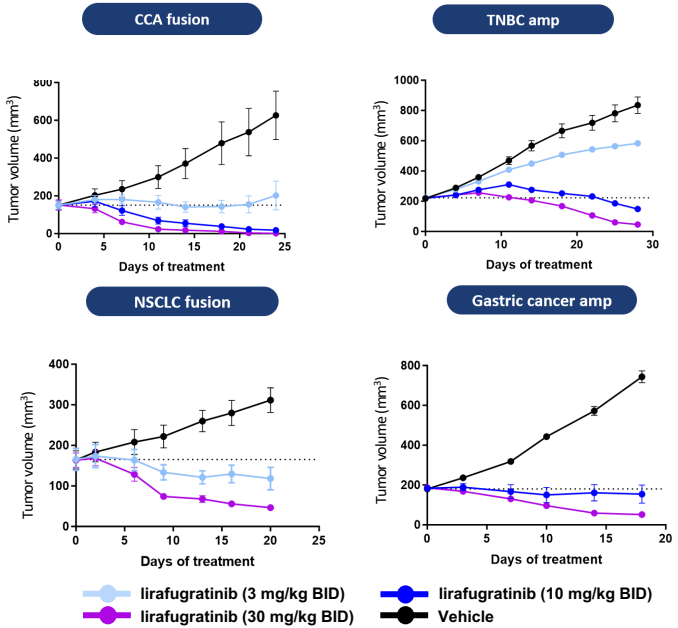
In contrast to pan-FGFRi, lirafugratinib is a potent and selective FGFR2 inhibitor



Lirafugratinib selectively inhibits FGFR2 based on unique conformational dynamics[1]

Inhibitor	Mechanism of Action	Biochemical IC50 (nM)[2-5]			
		FGFR1	*FGFR2*	*FGFR3*	*FGFR4*
Lirafugratinib	**Irreversible FGFR2 selective**	**864.3**	**3.1**	**274.1**	**17,633**
Infigratinib	**Reversible Pan-FGFRi**	**1.1**	**1**	**2**	**61**
Pemigatinib	**Reversible Pan-FGFRi**	**0.39**	**0.46**	**1.2**	**30**
Futibatinib	**Irreversible Pan-FGFRi**	**1.8**	**1.4**	**1.6**	**3.7**

Lirafugratinib has potent in vivo activity across *FGFR2* alterations and tumor types



1. Schönherr H. et al. Presented at MedChem GRC meeting; August 7-12,2022. 2. Goyal L. et al. Presented at AACR Annual Meeting; April-9-14;2021. 3.Truseltiq(infigratinib) [package insert]. Brisbane, CA QED Therapeutics; 2021. 4. Pemazyre(pemigatinib) [NDA]. Wilmington, DE;2019. www.accessdata.fda.gov/drugsatfda_docs/nda/2020/213736Orig1s000ChemR.pdf Accessed August 25,2022. 5. Sootome H. et al. *Cancer Res.* 2020;80(22):4986-4997.
BID: twice daily dosing; CCA fusion: intrahepatic cholangiocarcinoma PDX (FGFR2-TTC28 fusion); TNBC amp: MFM-223 triple negative breast cell line (FGFR2-amplified); NSCLC fusion: lung adenocarcinoma PDX (FGFR2-CCDC6 fusion); Gastric cancer amp: SNU-16 cell line (FGFR2-amplified)

ReFocus Design and Milestones

Part 1: Dose Escalation –
MTD/RP2D, safety, PK-PD, anti-tumor activity

Advanced *FGFR2*-altered solid tumors
- Bayesian Optimal Interval Design
- Enrollment per local diagnostic assessment
- Lirafugratinib administered orally QD, BID, or QDi

First patient treated 9/2020 → RP2D 12/2021

Lirafugratinib RP2D: 70 mg QD

Part 2: Dose Expansion –
ORR/DoR per RECIST 1.1, safety per CTCAE v5

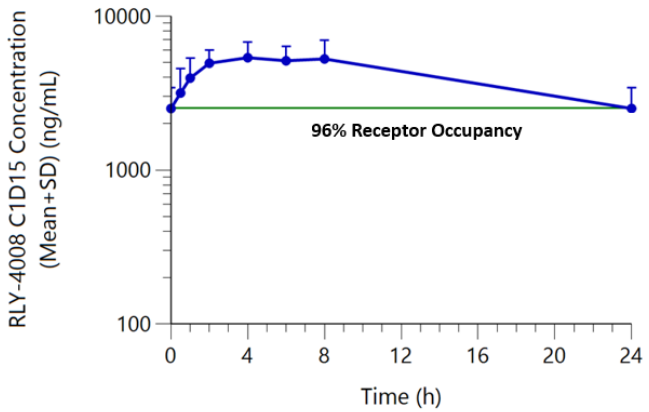
		Enrollment
Cholangiocarcinoma (CCA)		
Pivotal cohort	FGFR2-fusion+ CCA without prior FGFRi *(N=100)*	LPI 9/2023
Pivotal supportive	FGFR2-fusion+ CCA with prior FGFRi *(N=50)*	LPI 12/2022
	FGFR2-fusion+ CCA with no prior Tx *(N=20)*	ongoing
	Any FGFR2-mutant/amplified CCA *(N=20)*	ongoing
Advanced solid tumors with *FGFR2* alterations (*excluding CCA*)		
	FGFR2-fusion+ solid tumors *(N=50)*	ongoing
	FGFR2-amplified solid tumors *(N=50)*	ongoing
	FGFR2-mutant solid tumors *(N=50)*	ongoing

BID: twice daily dosing; CCA: cholangiocarcinoma; CTCAE: common terminology criteria for adverse events; DoR: duration of response; LPI: last patient in; MTD: maximum tolerated dose; PK/PD: pharmacokinetics/pharmacodynamics; ORR: objective response rate; QD: once daily dosing; QDi: once daily dosing, 3 weeks on, 1 week off; RP2D: recommended Phase 2 dose

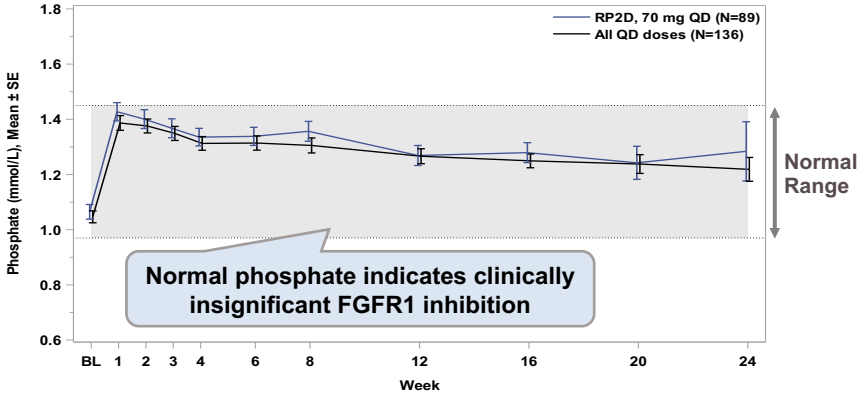
ReFocus: Early Clinical Validation of Lirafugratinib in Patients with Cholangiocarcinoma

Irreversible FGFR2 Inhibition Provides Robust Target Coverage Without FGFR1-Related Hyperphosphatemia

96% Receptor Occupancy at 70 mg RP2D



Normal Phosphate Levels at RP2D



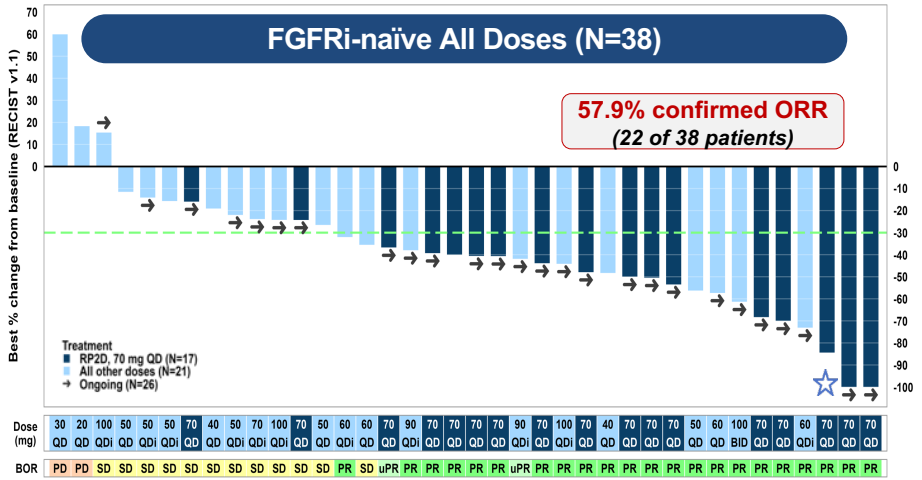
≥96% predicted median receptor occupancy at 70 mg QD RP2D; Effective half-life ~18-26h supports QD dosing

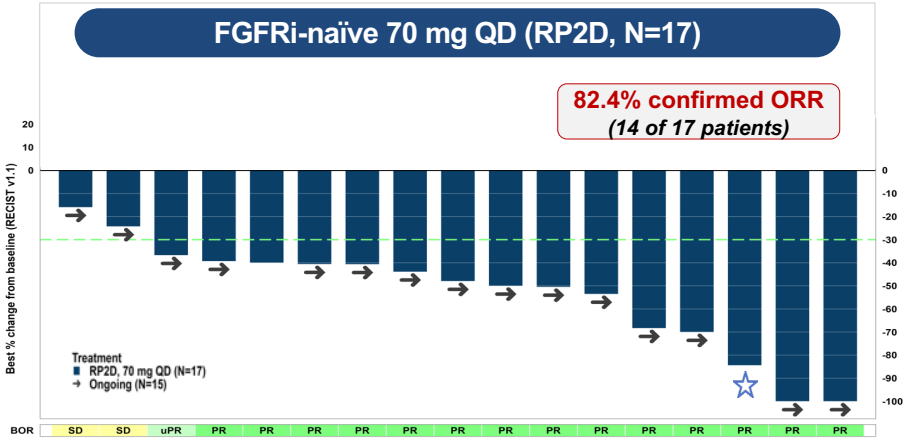
Annals of Oncology (2022) 33 (suppl_7): S808-S869. 10.1016/annonc/annonc1089
ORR: QD: once daily dosing; RP2D: recommended Phase 2 dose

Data as of 01 Aug 2022

ReFocus: Early Clinical Validation of Lirafugratinib in Patients with Cholangiocarcinoma

Robust Initial Efficacy in Cholangiocarcinoma with *FGFR2*-Fusion/Rearrangement





☆ = resection with curative intent

ORR: objective response rate; QD: once daily dosing; RP2D: recommended Phase 2 dose

Data as of 01 Aug 2022

ReFocus: Solid Tumor Patient Baseline Characteristics (excluding cholangiocarcinoma)

Parameter	Efficacy Pop. (N=84)	Safety Pop. (N=124)
Female, n (%)	**51 (61)**	**74 (60)**
Age (years), median (range)	**62 (33, 84)**	**62 (20, 84)**
Race, n (%)		
White	46 (55)	65 (52)
Asian	12 (14)	19 (15)
Other/Unknown	26 (31)	40 (32)
ECOG PS, n (%)		
0	31 (37)	49 (40)
1	52 (62)	70 (56)
2	1 (1)	2 (2)
Number of prior lines of systemic therapy, median (range)	**2.5 (0, 11)**	**3 (0,14)**
Number of prior lines of systemic therapy, n (%)		
0	2 (2)	2 (2)
1	14 (17)	23 (19)
2	26 (31)	35 (28)
≥3	42 (50)	64 (52)
Prior systemic therapy, n (%)		
Chemotherapy	79 (94)	118 (95)
FGFR inhibitor	0	21 (17)

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 gland	2 (2)
Others*	15 (18)
FGFR2 oncogenic alteration, n (%) by local testing	
FGFR2 fusion or rearrangement	26 (31)
FGFR2 amplification**	34 (40)
FGFR2 mutation	24 (29)

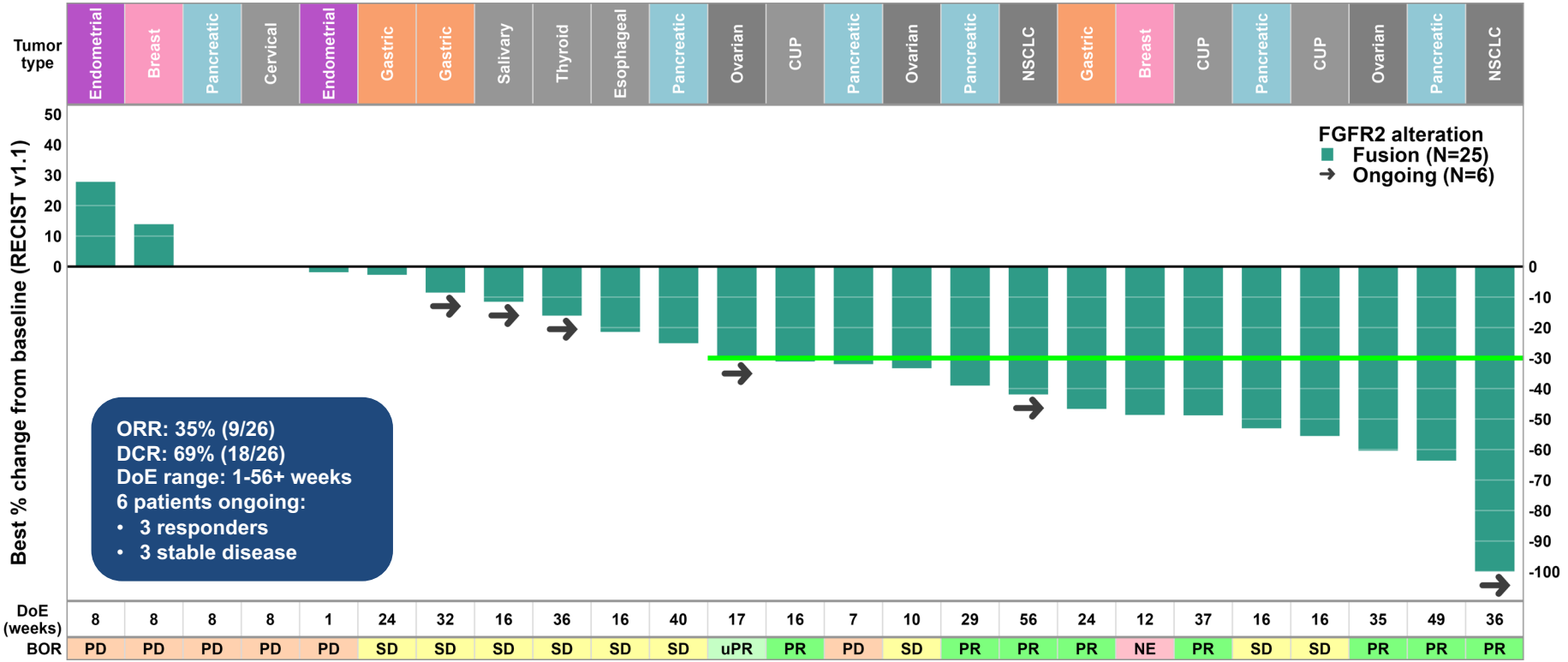
*Includes ameloblastic, ampullary, cervical, duodenal, esophageal, fallopian, melanoma, orbita, thyroid

**Amplification defined 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)

Safety population includes 124 FGFR inhibitor (FGFRi)-naive and pretreated patients with tumors other than CCA, with FGFR2 fusions, amplifications, or mutations by local testing, and who received ≥1 dose of lirafugratinib administered at the recommended phase 2 dose. Efficacy population includes 84 patients in the safety population who were FGFRi-naive, had measurable disease, and either had ≥1 post-baseline tumor assessment or discontinued treatment before 1st postbaseline tumor assessment. CUP: carcinoma of unknown primary; ECOG: Eastern Cooperative Oncology Group; NSCLC: non-small cell lung cancer

Preliminary data as of 23 Aug 2023

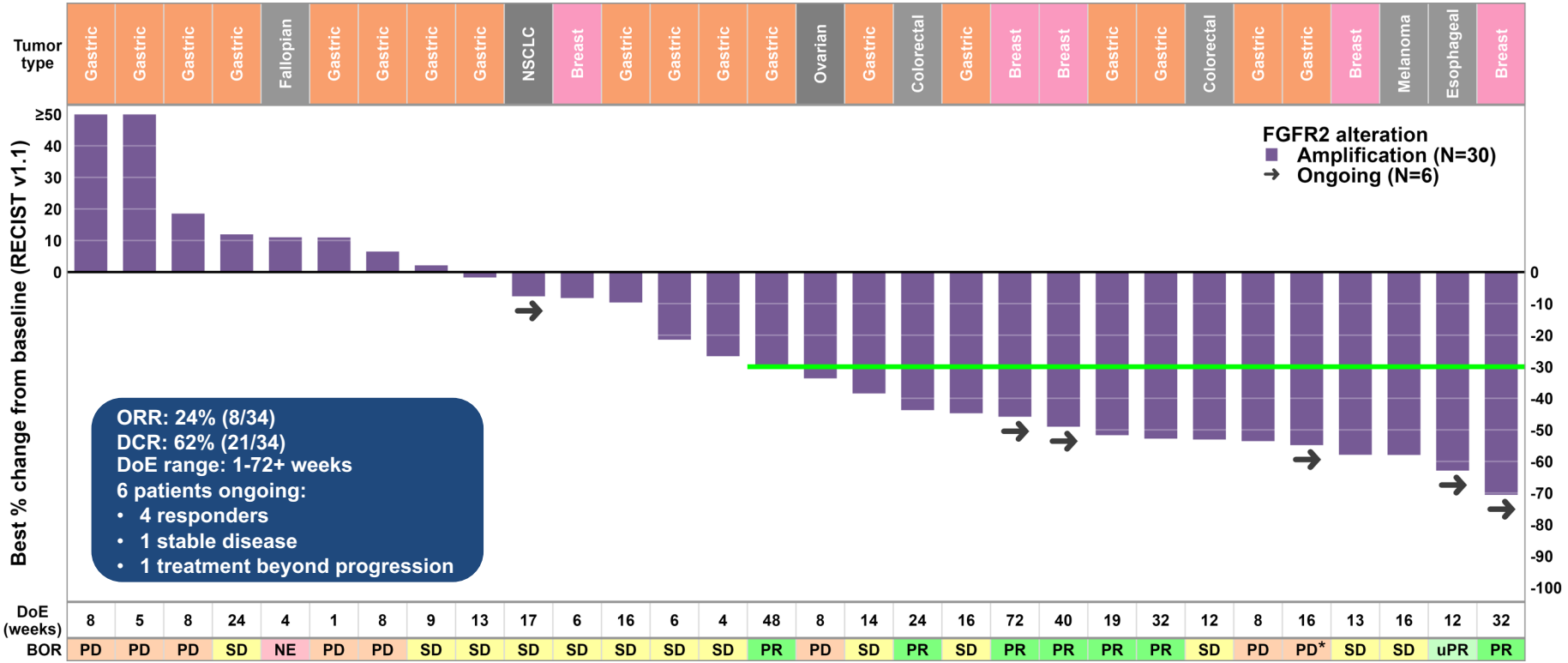
Solid Tumors with *FGFR2*-Fusion/Rearrangement: Radiographic Tumor Regression and Response per RECIST 1.1



Waterfall includes patients with post-baseline scans. Objective response rate (ORR) calculation includes 26 efficacy evaluable patients
BOR: best overall response; CUP: carcinoma of unknown primary; DCR: disease control rate; DoE: duration of exposure; NSCLC: non-small cell lung cancer

Preliminary data as of 23 Aug 2023

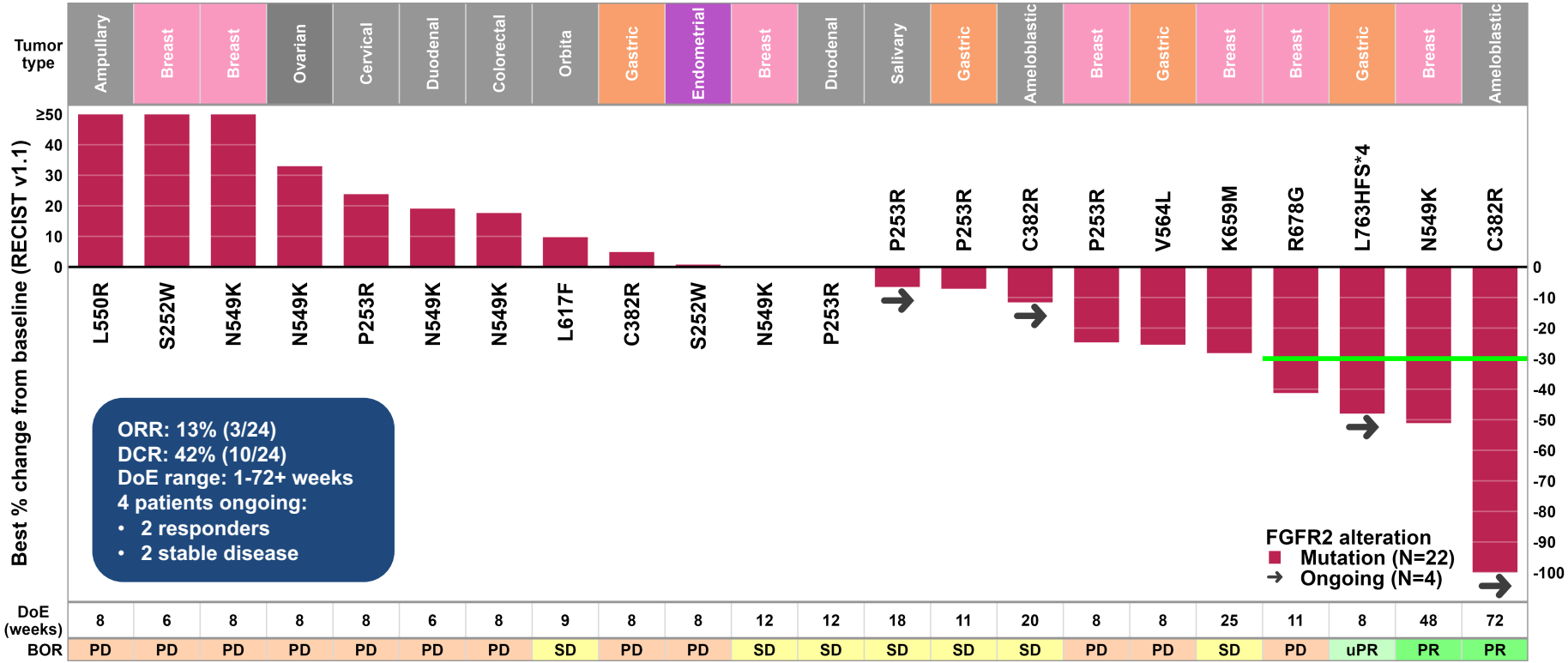
Solid Tumors with *FGFR2* Amplification: Radiographic Tumor Regression and Response per RECIST 1.1



Waterfall includes patients with post-baseline scans. Objective response rate (ORR) calculation includes 34 efficacy evaluable patients
BOR: best overall response; DCR: disease control rate; DoE: duration of exposure; NSCLC: non-small cell lung cancer; *TBP: Treated Beyond Progression

Preliminary data as of 23 Aug 2023

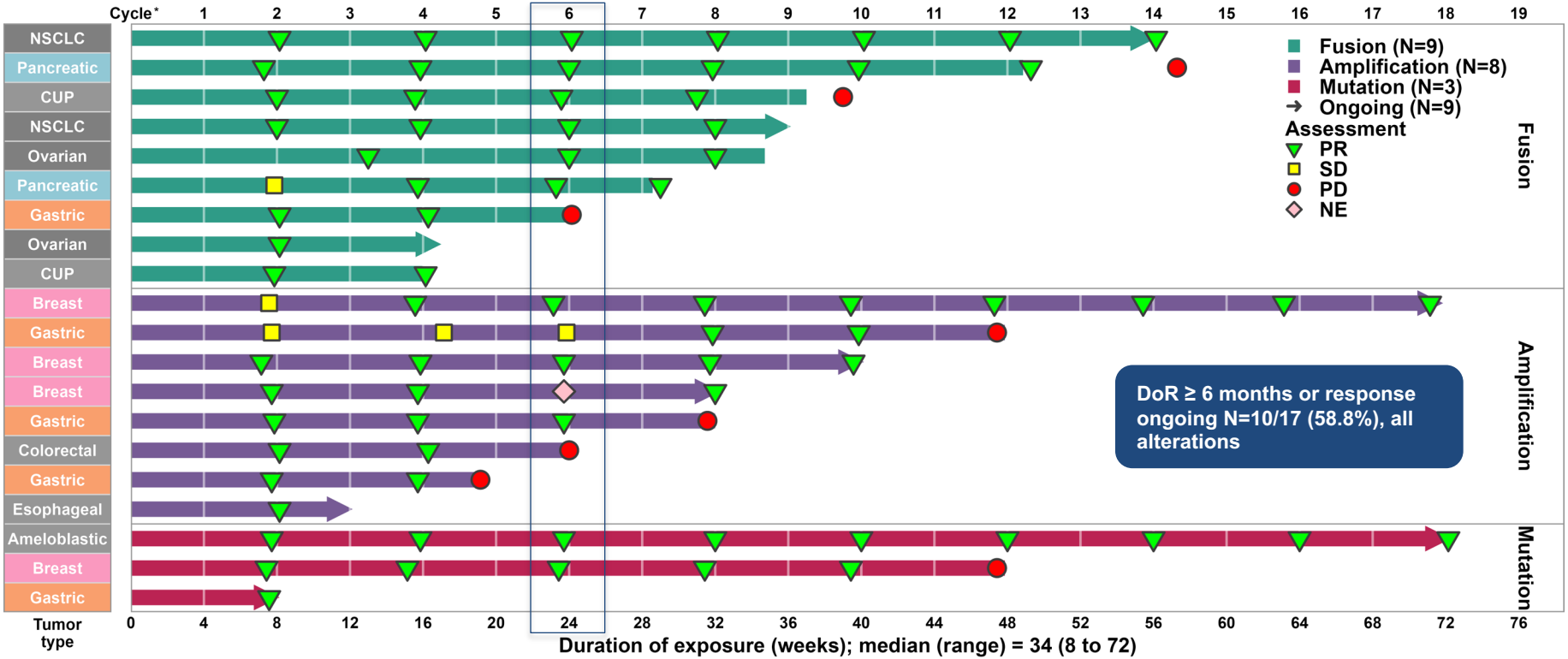
Solid Tumors with Select *FGFR2* Mutations: Radiographic Tumor Regression and Response per RECIST 1.1



Waterfall includes patients with post-baseline scans. Objective response rate (ORR) calculation includes 24 efficacy evaluable patients
BOR: best overall response; DCR: disease control rate; DoE: duration of exposure

Preliminary data as of 23 Aug 2023

Responses Are Durable Across Solid Tumors with *FGFR2* Alterations



CUP: carcinoma of unknown primary; DoR: duration of response; NE: non-evaluable; NSCLC: non-small cell lung cancer; PD: progressive disease; PR: partial response; SD: stable disease

* Cycle length = 28 days

Preliminary data as of 23 Aug 2023

Efficacy Across *FGFR2* Alterations

Efficacy Parameter	Fusion N=26	Amplification N=34	Mutation N=24
Best Overall Response, n (%)			
Partial response*	9 (35)	8 (24)	3 (13)
Stable disease	9 (35)	13 (38)	7 (29)
Progressive disease	6 (23)	9 (26)	12 (50)
Not evaluable**	2 (8)	4 (12)	2 (8)
ORR n (%) **95% CI**	9 (35) 17, 56	8 (24) 11, 41	3 (13) 3, 32
DoR, months, min, max	1.9+, 11.5	2.7+, 12.8+	9.2, 14.9+
Disease control rate, n (%) **95% CI**	18 (69) 48, 86	21 (62) 44, 78	10 (42) 22, 63

*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

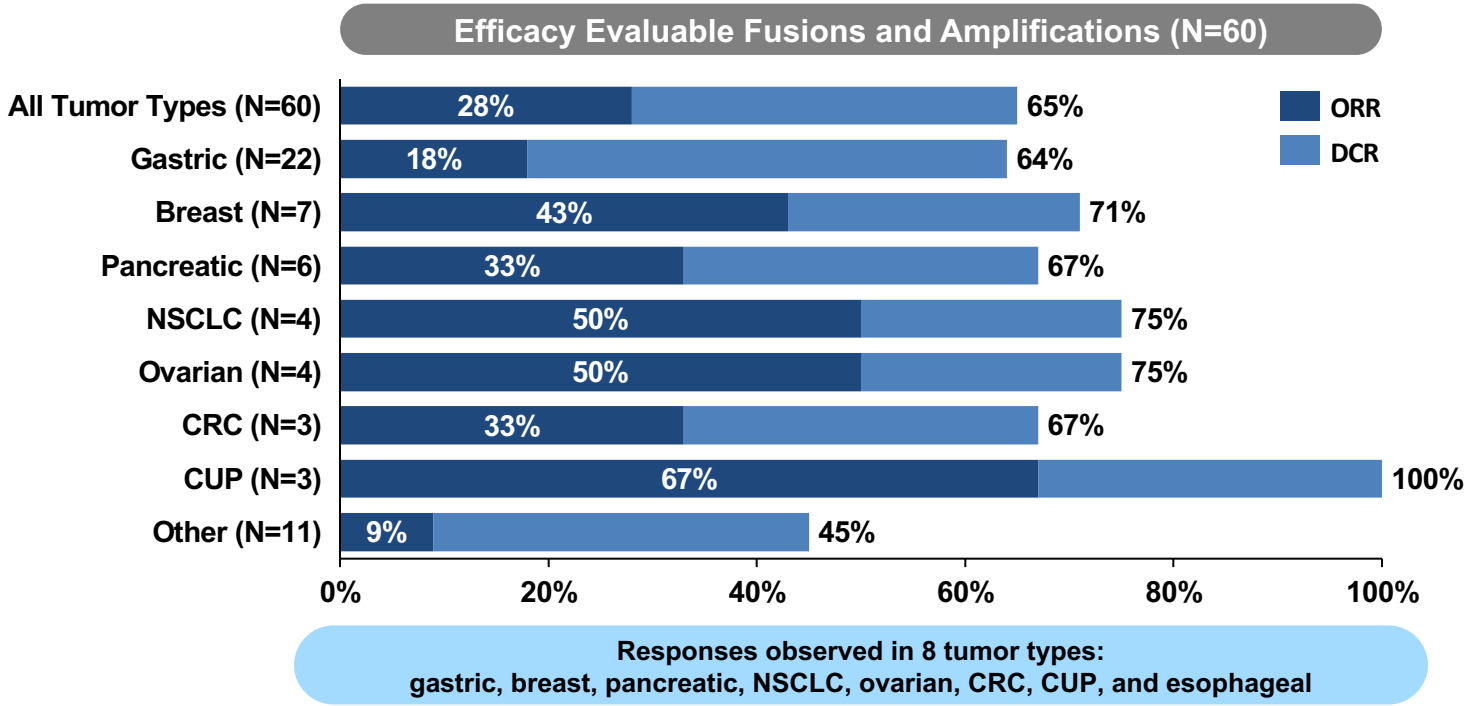
** Including N=2 fusion: 1 patient who discontinued due to death before first post-baseline scan and 1 patient with 1 post-baseline scan that did not meet the minimum duration of > 8 weeks from baseline for SD; N=4 amplification: 3 patients who discontinued due to progressive disease before first post-baseline 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

+: response ongoing at time of data cutoff

DoR: duration of response among confirmed responders; ORR: objective response rate; uPR: unconfirmed partial response

Preliminary data as of 23 Aug 2023

Responses Observed Across Diverse Tumor Types with *FGFR2* Fusion/Rearrangement and Amplification



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: ampullary, cervical, endometrial, esophageal, fallopian, melanoma, salivary, thyroid;
DCR: disease control rate; CRC: colorectal; CUP: carcinoma of unknown primary; NSCLC: non-small cell lung cancer; ORR: objective response rate; uPR: unconfirmed partial response

Preliminary data as of 23 Aug 2023

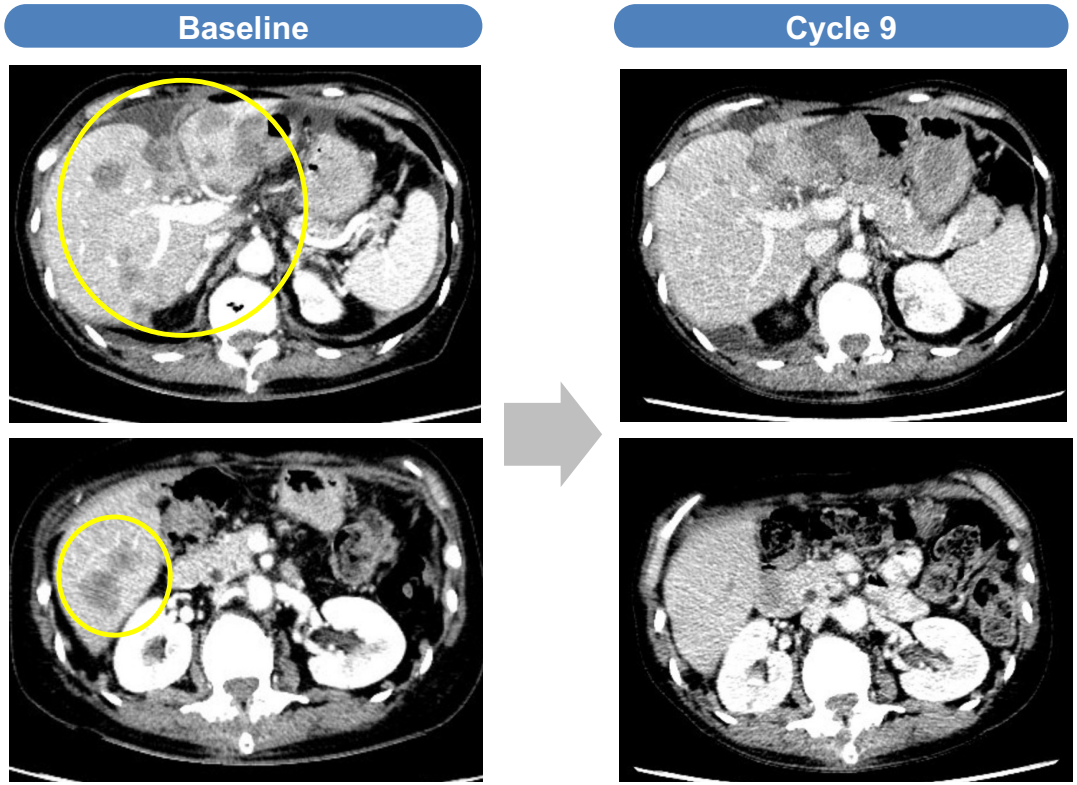
Marked Response in a Patient with Heavily Pretreated HR+ HER2- Breast Cancer with *FGFR2* Amplification

Patient Profile

- 66 yo 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 Lirafugratinib

- *FGFR2* ctDNA cleared at Week 4
- Initial PR at Week 16, confirmed at Week 23
- Patient ongoing treatment at Week 72



Courtesy Dr Tai, NCC Singapore

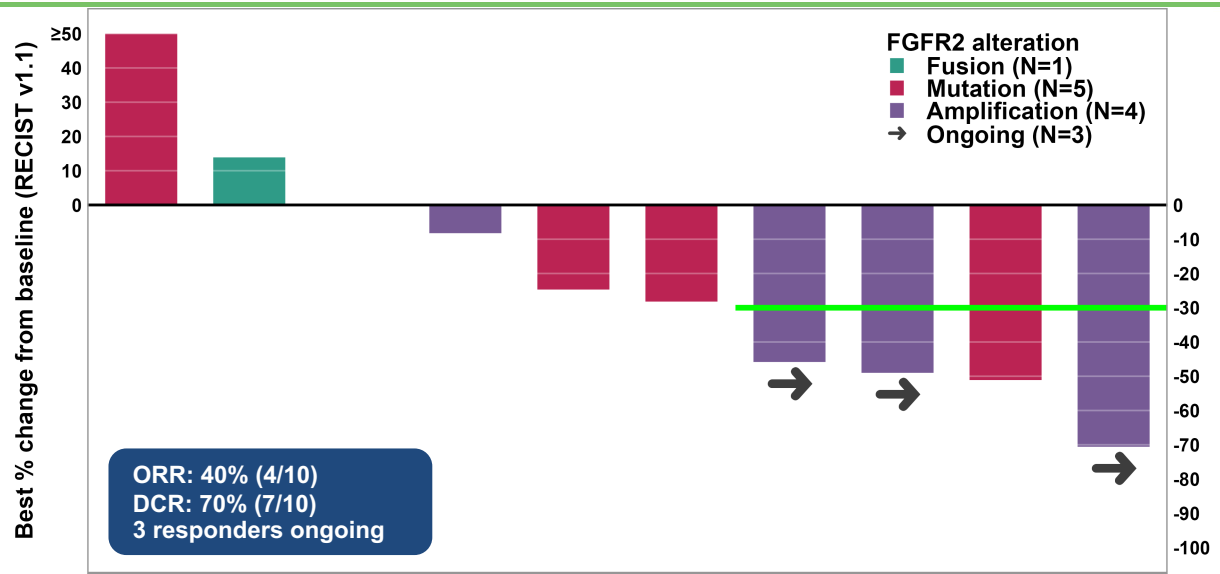
ctDNA: circulating tumor DNA; HR+HER2-: hormone receptor positive, human epidermal growth factor receptor 2 negative; mBC: metastatic breast cancer

Preliminary data as of 23 Aug 2023

Promising Activity In Patients with Heavily Pretreated HR+ HER2- Breast Cancer with *FGFR2* Alterations

Of 14 patients with Breast Cancer, 10 with HR+ HER2- disease:

- Median 7 prior lines (range 3-11)
- 70% with ESR1 mutations
- 70% with tumor shrinkage/DCR
- 40% with partial responses



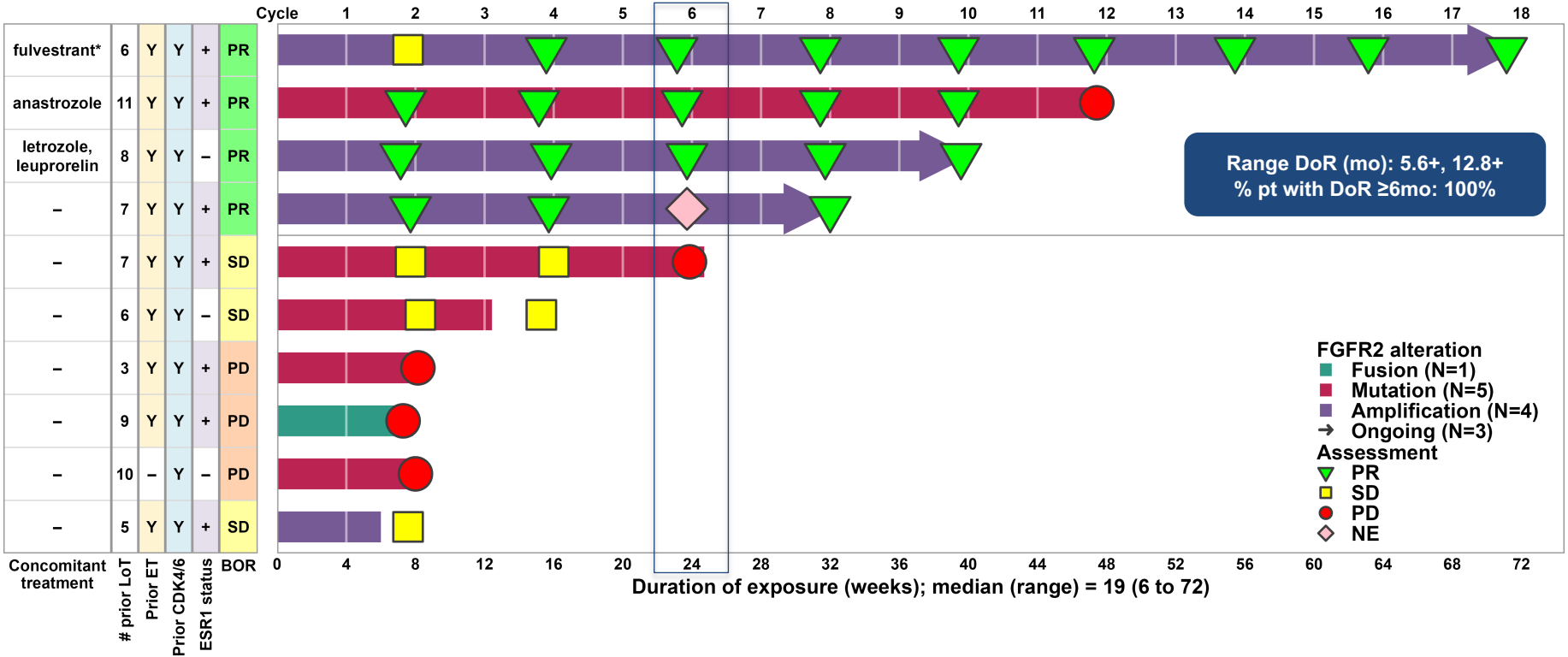
DoE (weeks)	8	8	12	6	8	25	72	40	48	32
BOR	PD	PD	SD	SD	PD	SD	PR	PR	PR	PR
Concomitant treatment	–	–	–	–	–	–	fulvestrant*	letrozole, leuprorelin	anastrozole	–
# prior LoT	10	9	6	5	3	7	6	8	11	7
Prior ET	–	Y	Y	Y	Y	Y	Y	Y	Y	Y
Prior CDK4/6	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
ESR1 status	–	+	–	+	+	+	+	–	+	+

* Patient was treated with a single dose of concomitant fulvestrant

BOR: best overall response; DCR: disease control rate; DoE: duration of exposure; LoT: lines of treatment; mPFS: median progression free survival; ORR: objective response rate; PD: progressive disease; PR: partial response; SD: stable disease

Preliminary data as of 23 Aug 2023

Response and duration across HR+ HER2- Breast Cancer



* Patient was treated with a single dose of concomitant fulvestrant

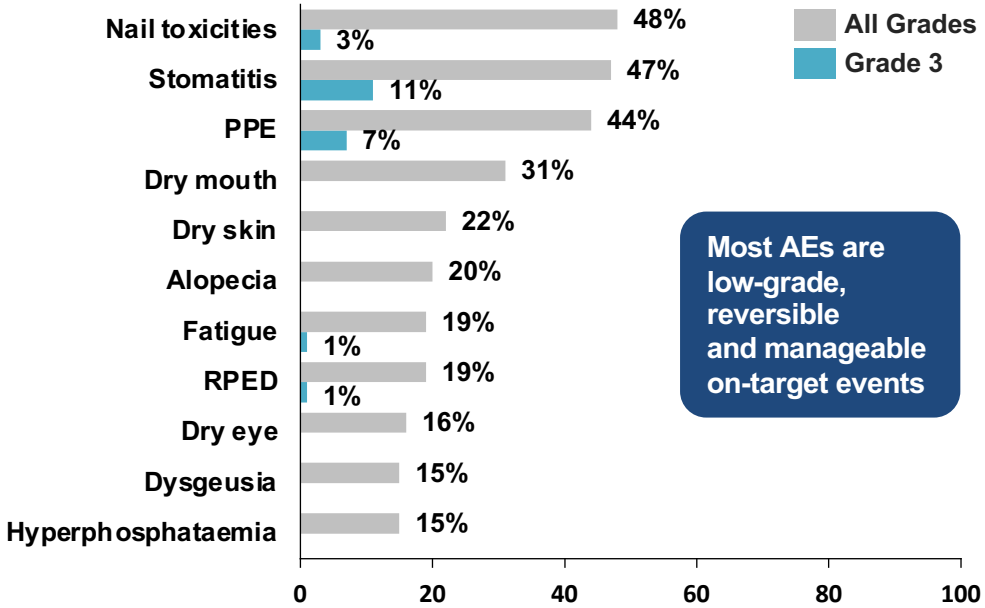
BOR: best overall response; DoR: duration of response; LoT: lines of treatment; NE: non-evaluable; PD: progressive disease; PR: partial response; SD: stable disease

Preliminary data as of 23 Aug 2023

Lirafugratinib Safety in Patients with Solid Tumors

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

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

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

Interruption, n (%)	59 (47.6%)
Reduction, n (%)	44 (35.5%)
Discontinuation, n (%)	1 (0.8%)

Treatment ongoing: N=38 (30.6%)
Discontinued from study treatment N=86 (69.4%):
- Due to progressive disease N=73 (58.9%)
- Due to adverse event N=3 (2.4%; 2 unrelated)

No treatment-related Grade 4/5 AEs

Preliminary data as of 23 Aug 2023

Conclusions

ReFocus data validate lirafugratinib as the first highly selective FGFR2 inhibitor active across oncogenic driver alterations

Encouraging response rates and initial durability across refractory solid tumors augment promising efficacy previously demonstrated in cholangiocarcinoma (ORR 58%-82%)
Solid tumors other than CCA:

- *FGFR2* Fusion/Rearrangement: 35% ORR; duration of response range 1.9+ to 11.5
- *FGFR2* Amplification: 24% ORR; duration of response range 2.7+ to 12.8+ mo
- *FGFR2* Mutation: 13% ORR; duration of response range 9.2 to 14.9+ in a subset of tumors across a heterogeneous mutation spectrum
- Durable responses observed across 9 tumor types other than CCA, with promising initial signal across FGFR2 alterations in refractory HR+HER2- breast cancer (40% ORR; 70% DCR; N=10)

Efficacy in patients with FGFR2-altered solid tumors together with lirafugratinib's differentiated safety profile (minimal off-isoform toxicity) suggest broad therapeutic potential

Clinical development in cholangiocarcinoma and across solid tumors continues in ReFocus

+ Indicates treatment ongoing

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