



RELAY[®]
T H E R A P E U T I C S

2024 SABCS – RLY-2608 Data Update
December 2024

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1

ReDiscover Trial Update – RLY-2608 + Fulvestrant Doublet Data

- Dr. Sammons – overview of evolving treatment landscape
- Data summary

2

RLY-2608 – Other Updates

3

Next steps

RLY-2608 data presented at 2024 San Antonio Breast Cancer Symposium

PI3K α Mutations Represent a Large Commercial Opportunity

PI3K α mutations represent a large commercial opportunity

Breast Cancer

~140k pts
(prevalence¹)

Vascular Malformations

~170k pts
(prevalence²)

Non-Breast Cancer Solid Tumors

~90k pts
(incidence³)

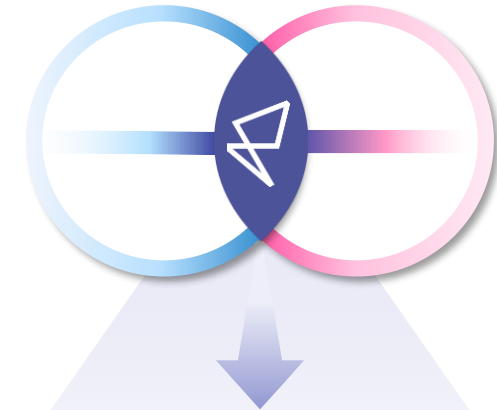
Non-selective PI3K α targeting has significant limitations

— Challenging Tolerability

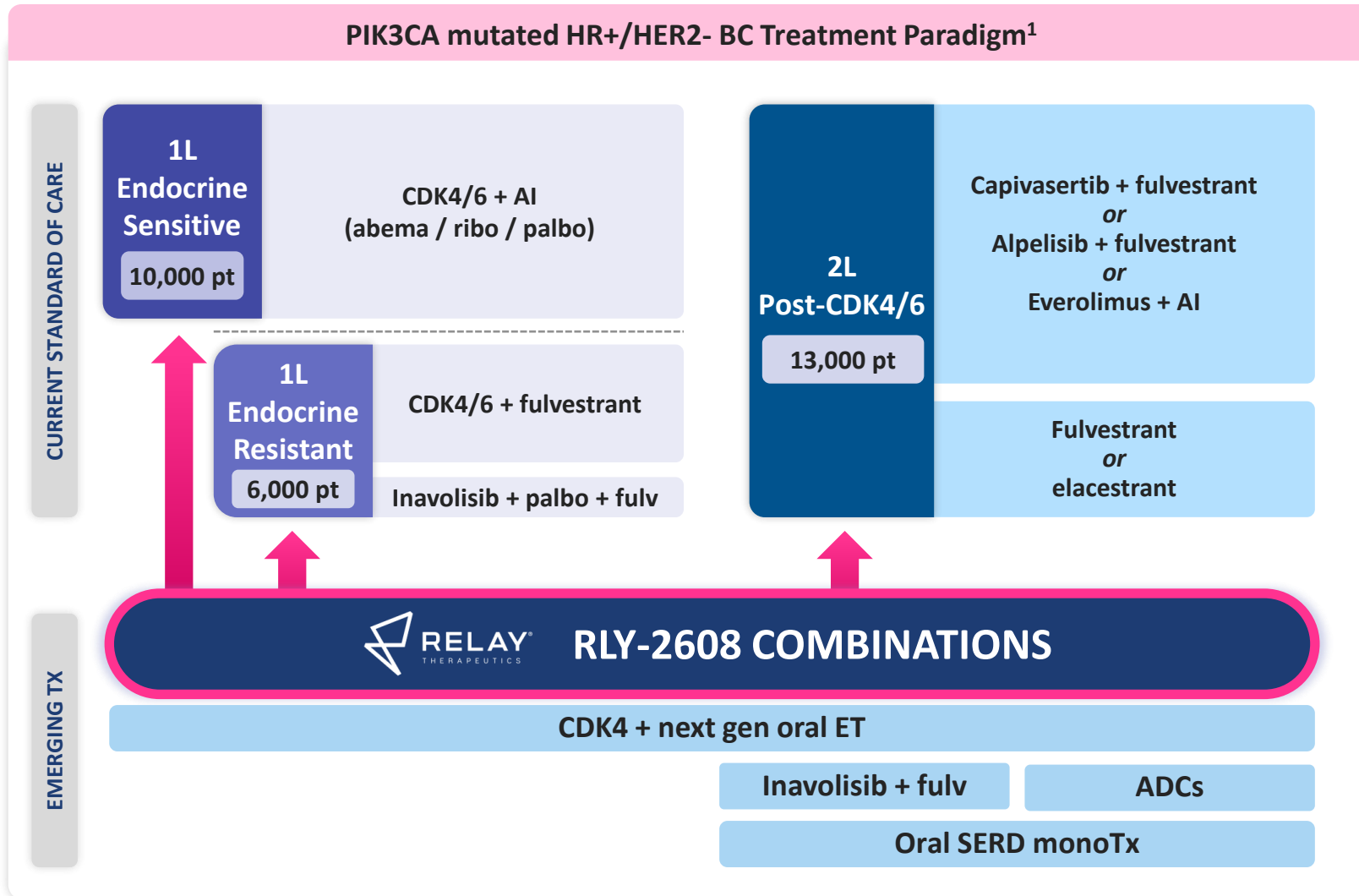
— Limited Efficacy

— Limited Combinability

Relay Tx's Dynamo[®] Platform created mutant selective molecule



Breast Cancer – Large Market for Mutant-Selective PI3K α Targeted Therapies



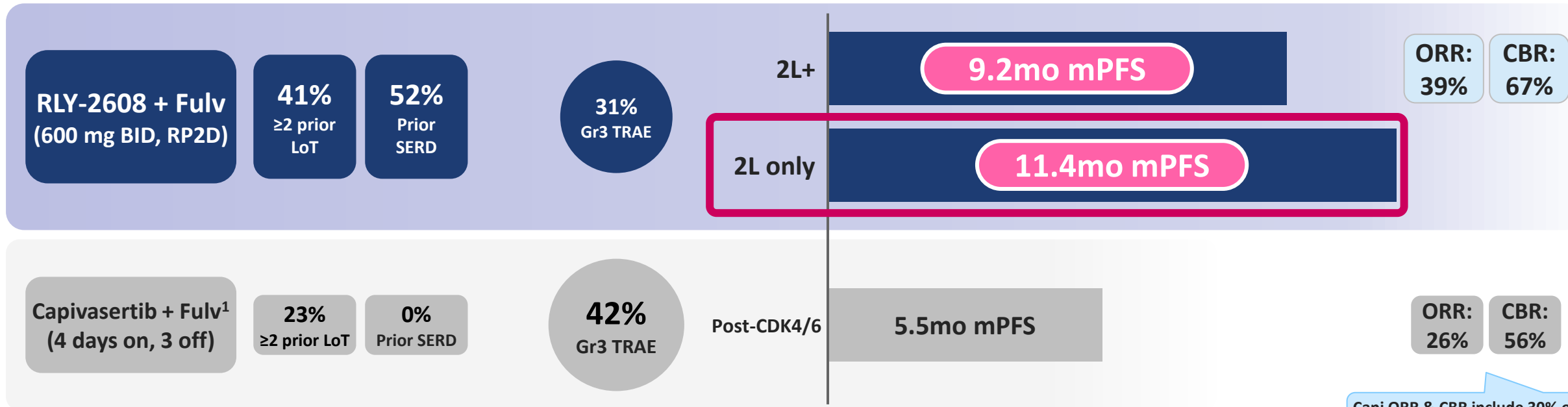
\$6B+
**Current PI3K α Pathway
 Total Addressable Market²**
*(Metastatic HR+/HER2-
 Breast Cancer)*

1. Prevalent US patient population with a PIK3CA mutation in each line of therapy, excluding PTEN co-mutations (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)
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RLY-2608 – Interim Clinical Data Continue to Show Clinically Meaningful PFS



More Heavily Pre-Treated Pt **Favorable Tolerability** **Favorable Efficacy**
*PIK3CA*mut, HR+/HER2- Advanced / Metastatic Breast Cancer (post CDK4/6)

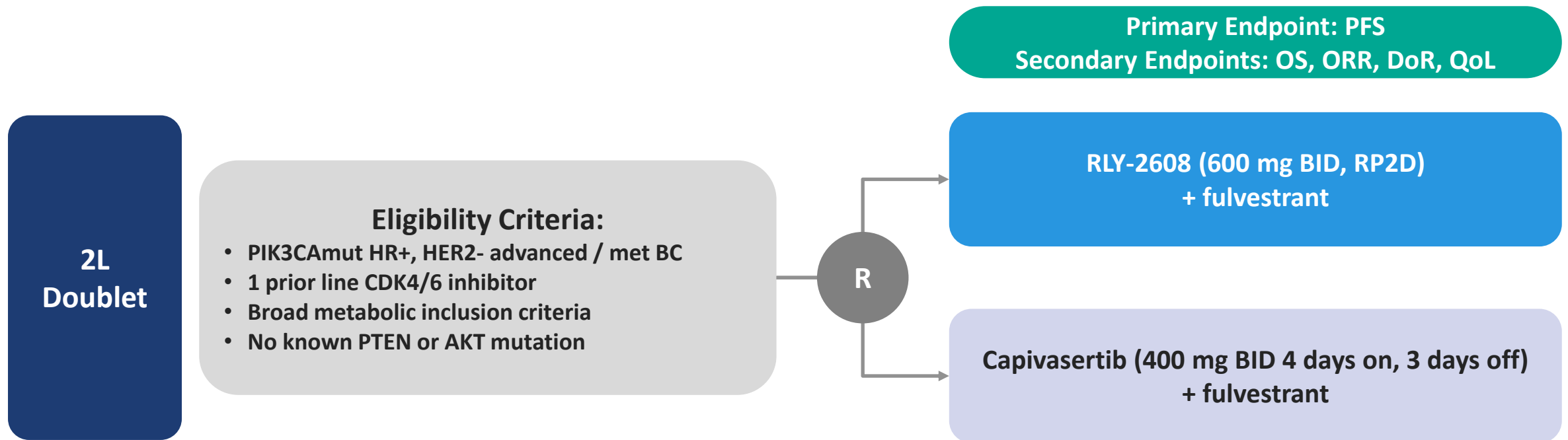


Capi ORR & CBR include 30% of pts who are CDK4/6 naïve

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

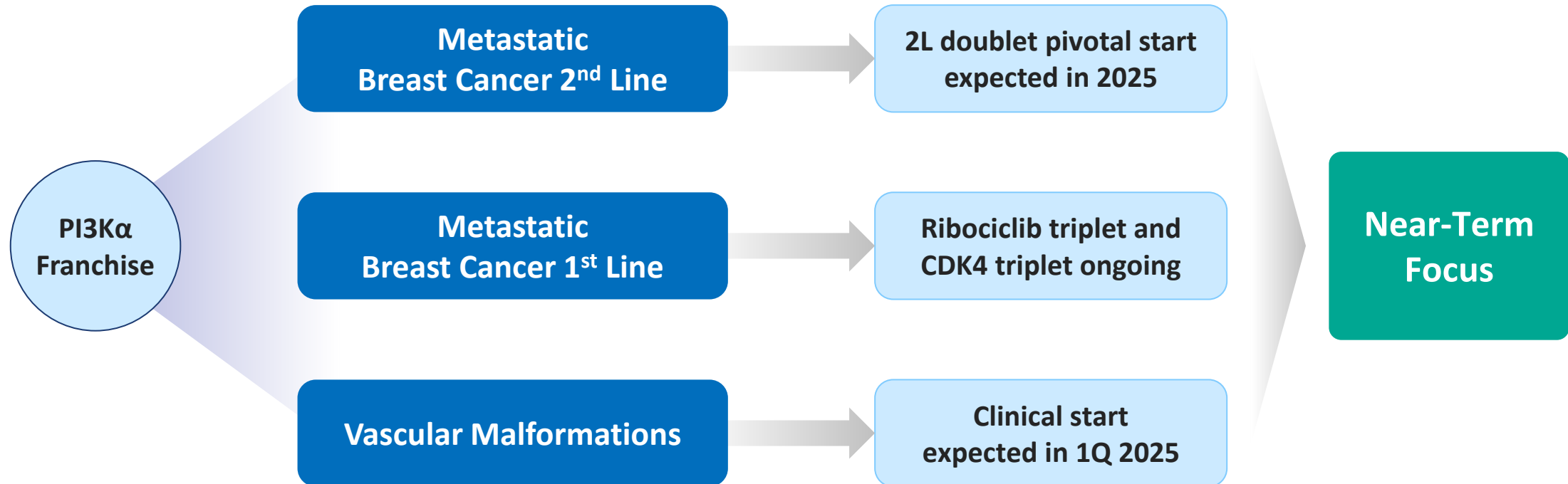
1. CAPitello-291: Turner N Engl J Med 2023; 388:2058-2070; 2. In CAPitello-291, CBR and ORR not reported for CDK4/6-experienced patient population; ORR = objective response rate, mPFS = median progression free survival, LoT = line of therapy (metastatic setting), SoC = Standard of Care, TRAE = treatment 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.

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

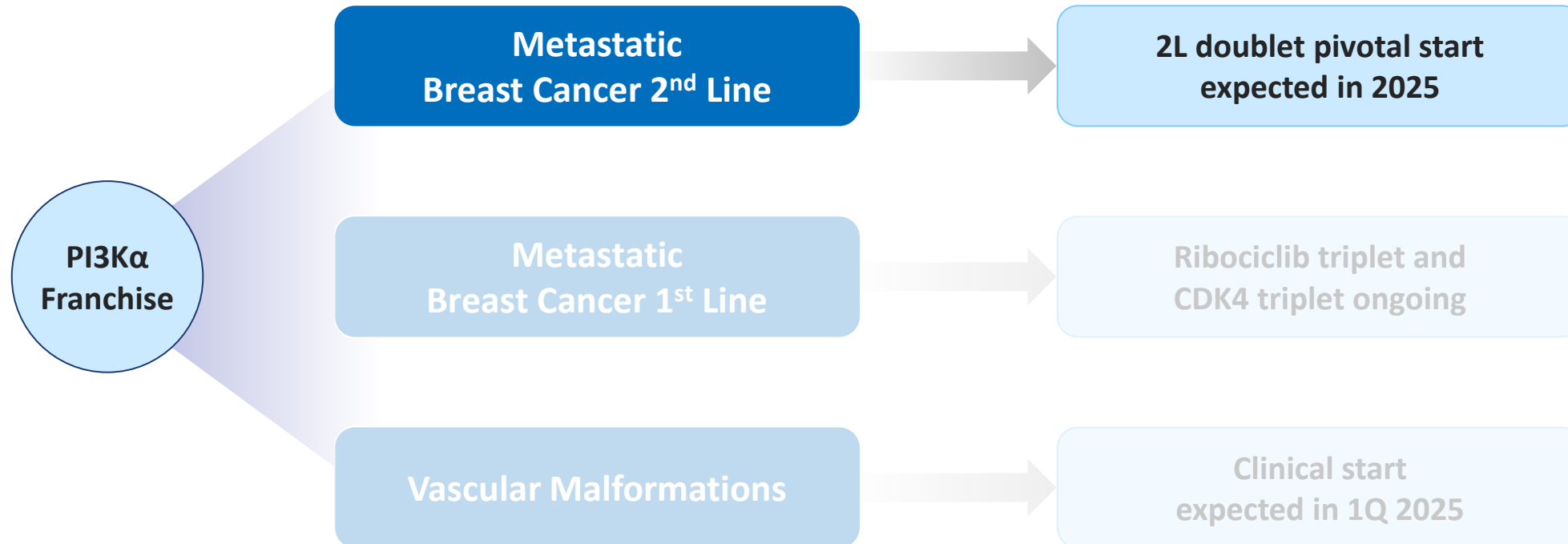


2L doublet pivotal start expected in 2025

*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



Team and Capital to Execute



Team and Capital to Execute

Large Unmet Need in Metastatic Breast Cancer



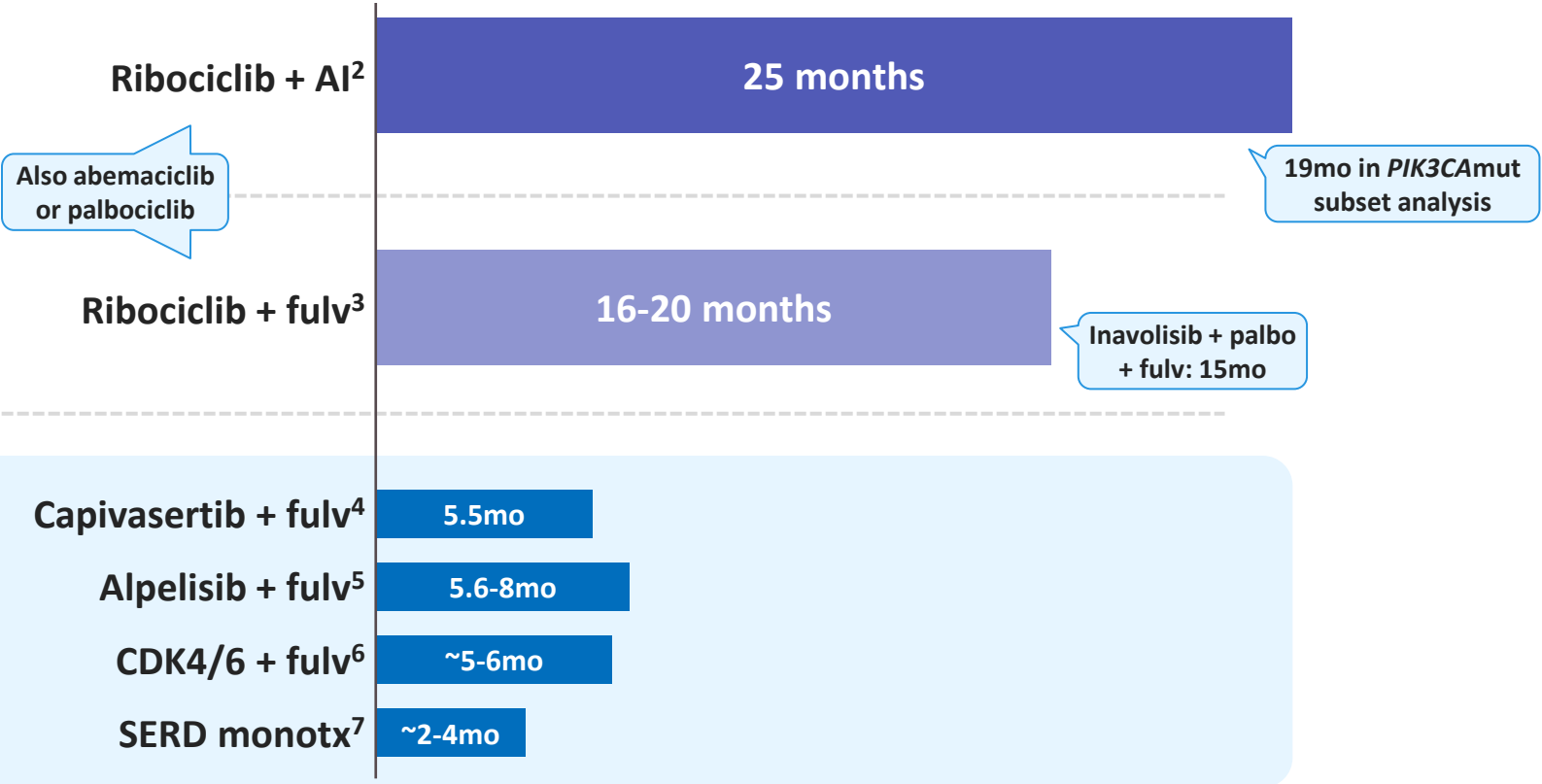
PIK3CAmut, HR+/HER2- mBC¹

**1L
Endocrine
Sensitive** **10,000
patients**

**1L
Endocrine
Resistant** **6,000
patients**

**2L
Post-CDK4/6** **13,000
patients**

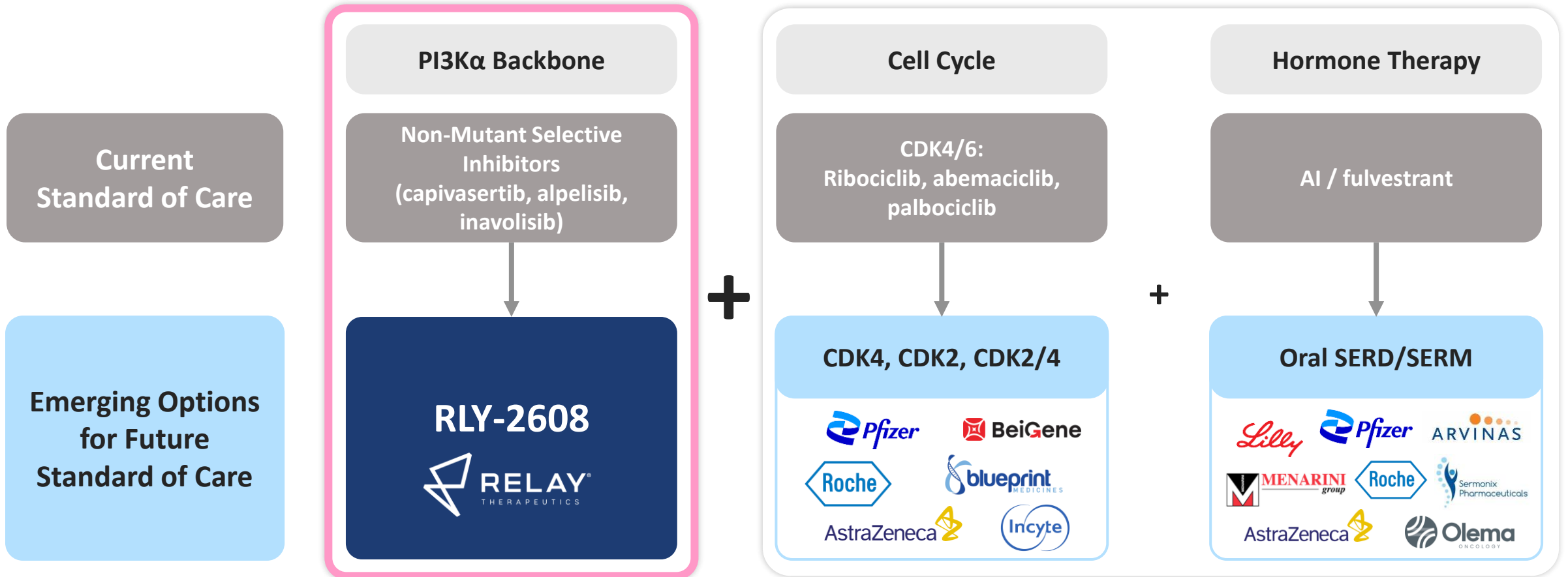
Median PFS of Current Standard of Care



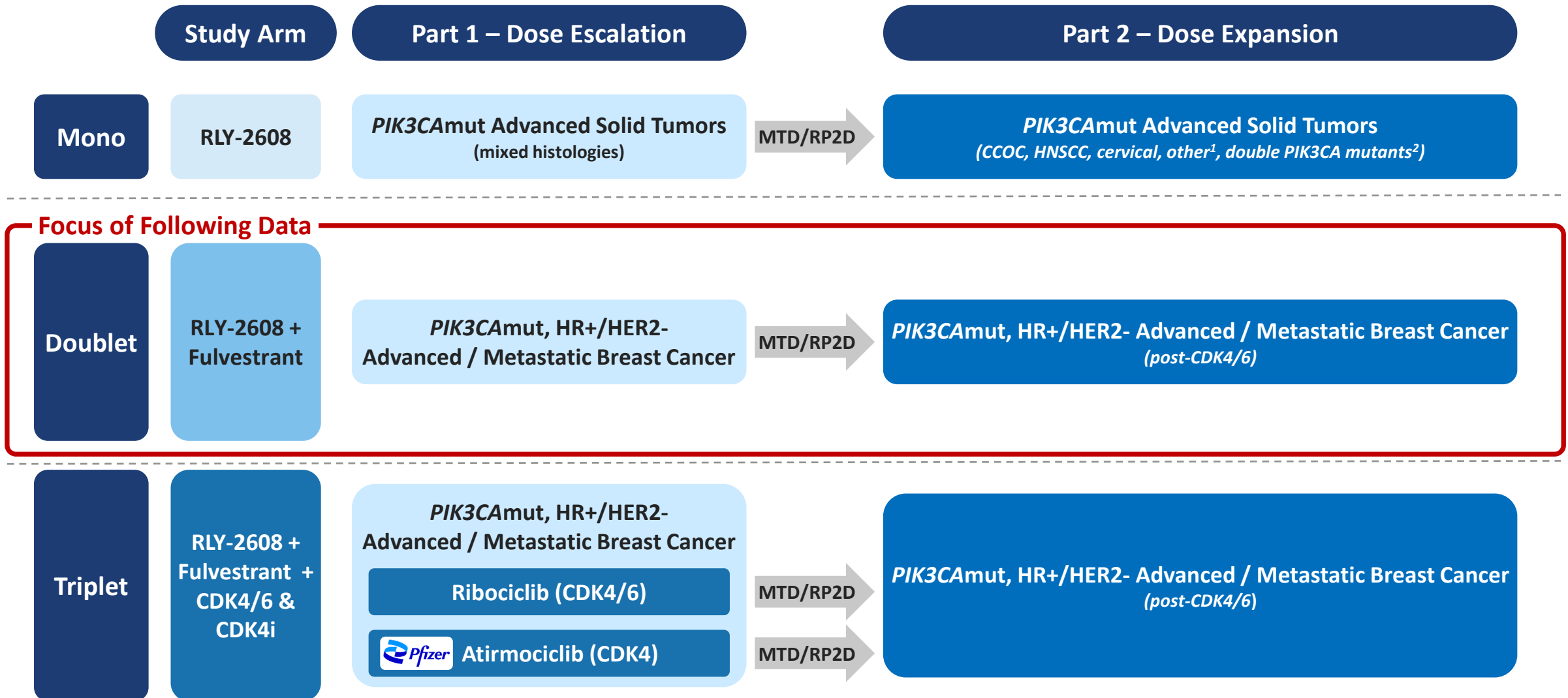
Large unmet need in 2L presents opportunity for well-differentiated targeted agent

Notes: 1. Prevalent US patient population with a PIK3CA mutation in each line of therapy, excluding PTEN co-mutations (Global Data HR+/HER2- Breast Cancer Global Forecast, November 2023; 3rd party source for alteration rate); 2. All-comers and PIK3CAmut sub-group, MONALEESA-2; 3. All-comers and PIK3CAmut sub-group, MONALEESA-3; 4. Turner N Engl J Med 2023; 388:2058-2070 (n=355); 5. Rugo 2021 Lancet Oncol 22:489, SABCS 2021 #P1-18-03; 6. MAINTAIN: Kalinsky 2023 J Clin Oncol 41:4004, postMONARCH: Kalinsky 2024 ASCO; 7. Elacestrant Prescribing Information © 2024 Relay Therapeutics

PIK3CAmut HR+/HER2- Breast Cancer Treatment Paradigm

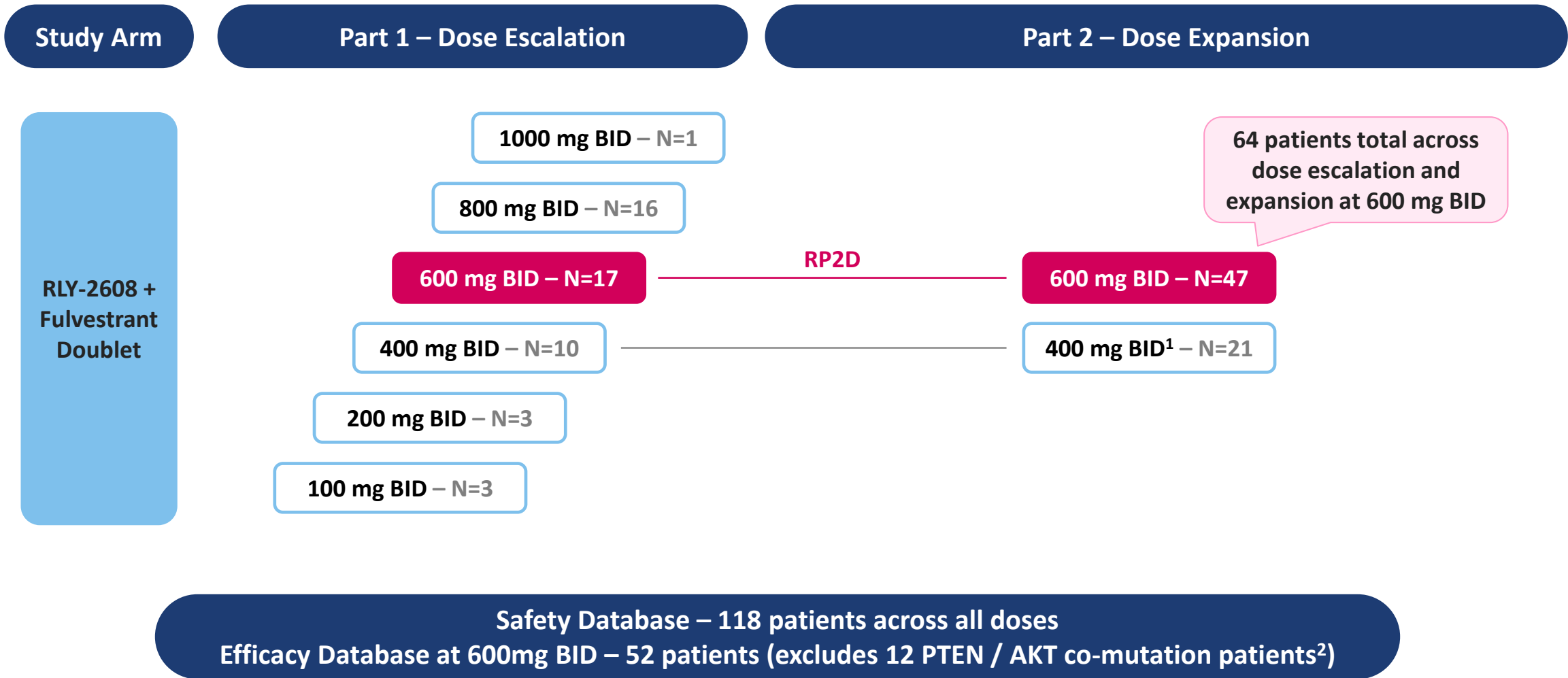


RLY-2608 – ReDiscover Trial Overview



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
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RLY-2608 – ReDiscover Trial Enrollment



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
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RLY-2608 – ReDiscover Trial Baseline Demographics

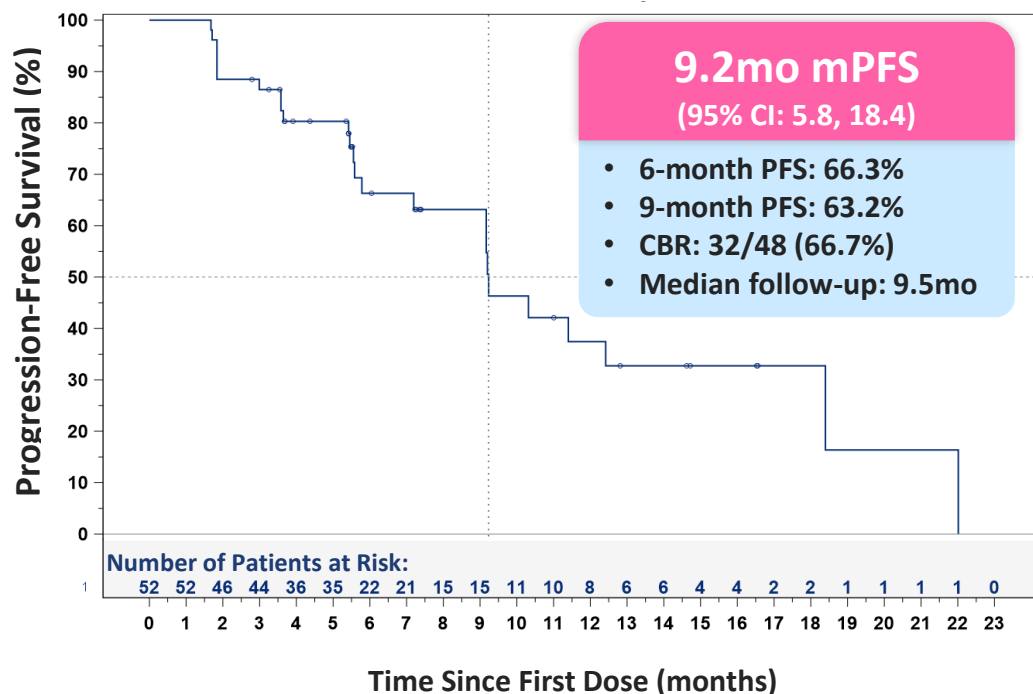


	RLY-2608 + Fulvestrant	
	All Patients (N=118)	600 mg BID (RP2D, N=64)
Age, Median (Range), Years	59.0 (34, 85)	59.0 (34, 80)
ECOG, 0 / 1, n (%)	69 (58.5) / 49 (41.5)	38 (59.4) / 26 (40.6)
Local PIK3CA Baseline Results		
Kinase Mutation, n (%)	57 (48.3)	31 (48.4)
Non-Kinase Mutations, n (%)	61 (51.7)	33 (51.6)
BMI \geq 30 or HbA1c \geq 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 (%)	62 (52.5)	38 (59.4)
2+, n (%)	56 (47.5)	26 (40.6)
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 (35.4)	18 (28.6)

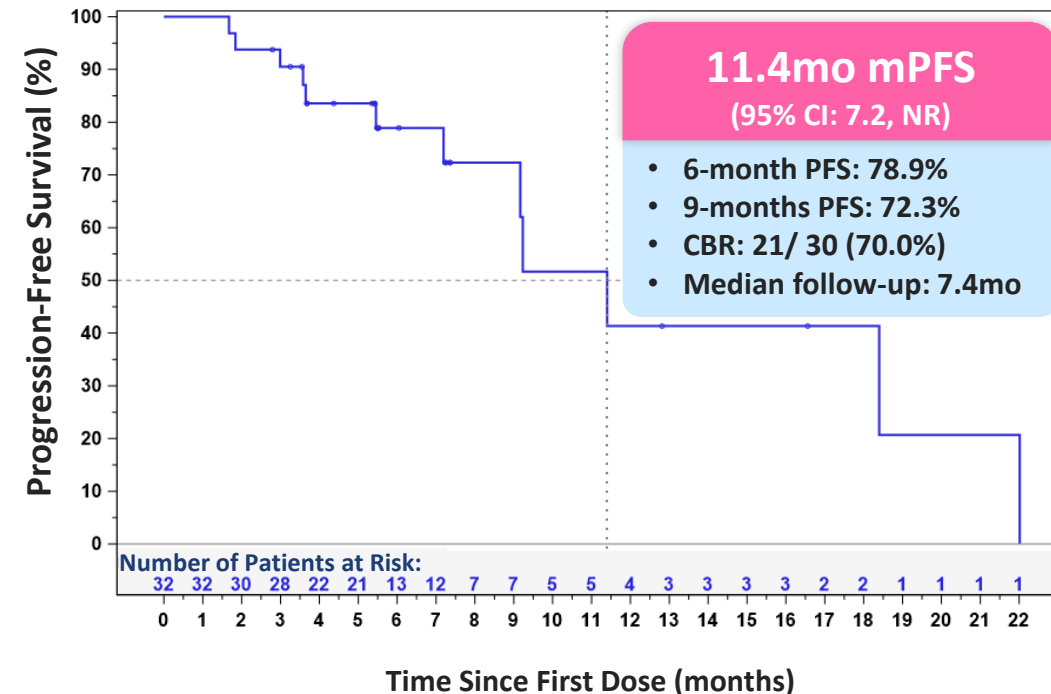
1. Visceral metastatic sites include brain, lung, liver, pleural, peritoneal involvement; 2. Three patients received prior CDK4/6 in the adjuvant setting which is allowed per protocol; 3. Percentage was based on pts with evaluable ctDNA data at baseline; ECOG = Eastern Cooperative Oncology Group performance status
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RLY-2608 600 mg BID (RP2D) + Fulvestrant Excluding PTEN / AKT Co-Mutations

All Patients (N=52)



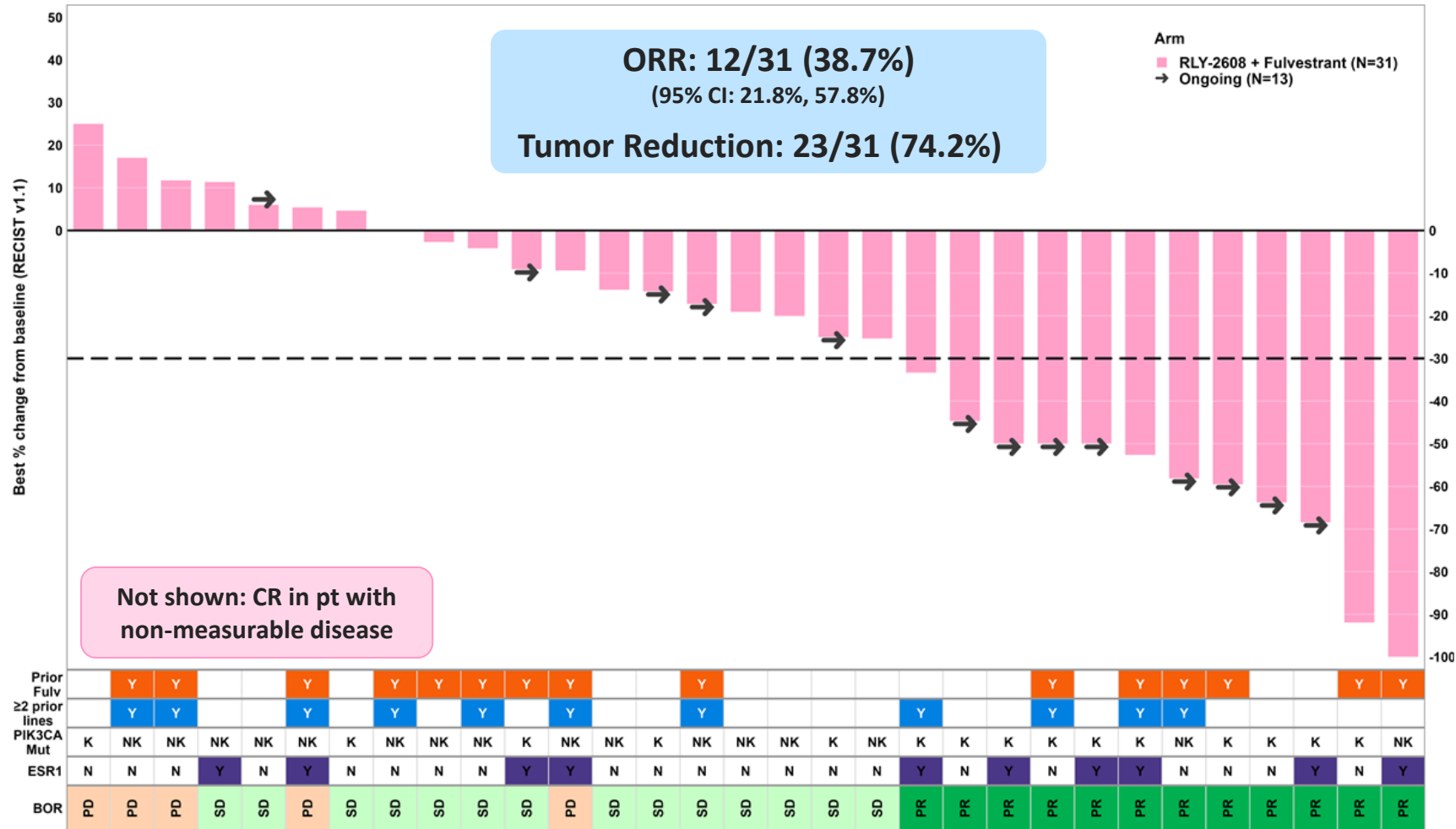
2L Patients (N=32)



RLY-2608 – Efficacy: Confirmed ORR 39%

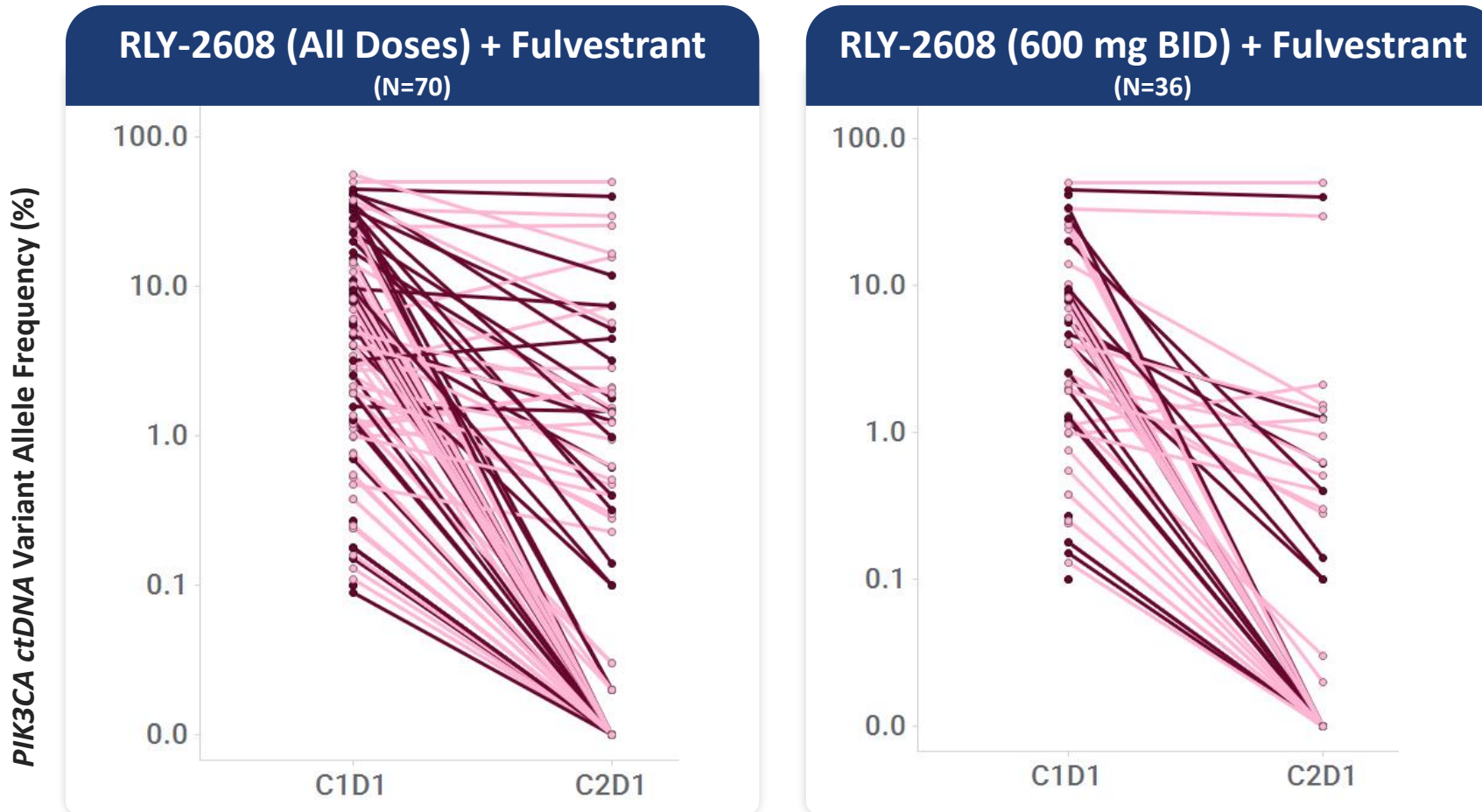


RLY-2608 600 mg BID (RP2D) + Fulvestrant Excluding PTEN / AKT Co-Mutations – Measurable Disease (N=31)



PIK3CA mutation: "K" = Kinase domain mutation, "NK" = Non-Kinase domain mutation; CR = Complete Response
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RLY-2608 – Efficacy: ctDNA Clearance



At 600 mg BID¹ (RP2D):

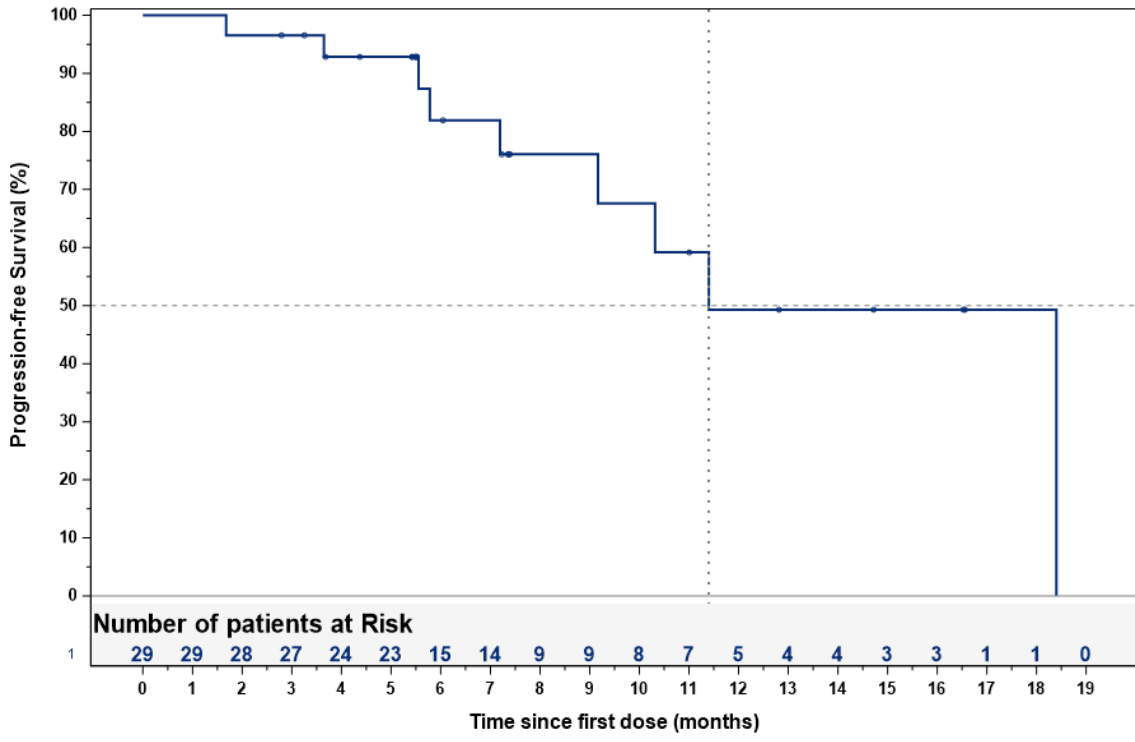
- 35 (97.2%) patients had decline in PIK3CA ctDNA
- 19 (52.8%) patients completely cleared PIK3CA ctDNA by C2D1

1. N=36 patients without PTEN/AKT co-alterations who have detectable PIK3CA at baseline and a paired C1D1-C2D1 ctDNA result are presented
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RLY-2608 – Efficacy: Kinase Mutations mPFS 11.4 Months & Confirmed ORR 67%

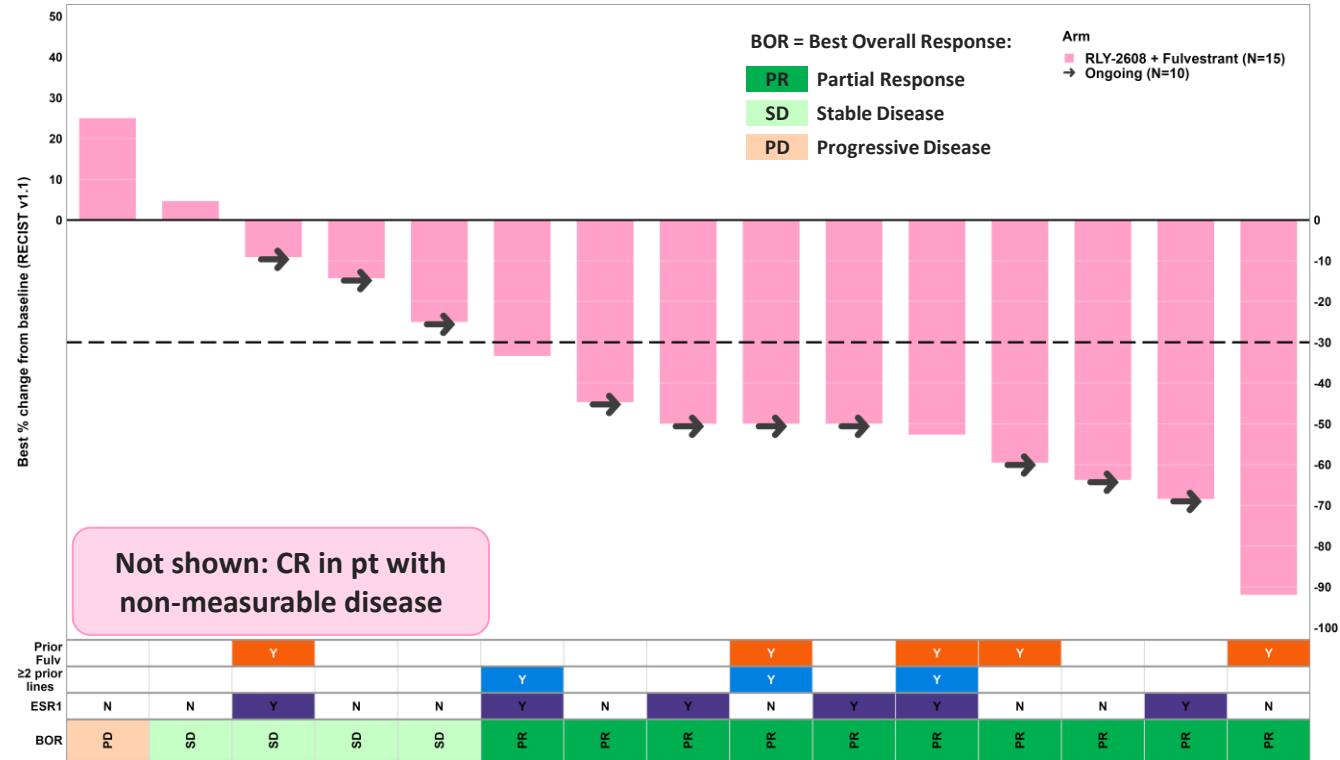


RLY-2608 600 mg BID (RP2D) + Fulvestrant Excluding PTEN / AKT co-mutations (N=29)



11.4 mo mPFS
(95% CI: 9.2, NR)

RLY-2608 600 mg BID (RP2D) + Fulvestrant Excluding PTEN / AKT – Measurable Disease (N=15)

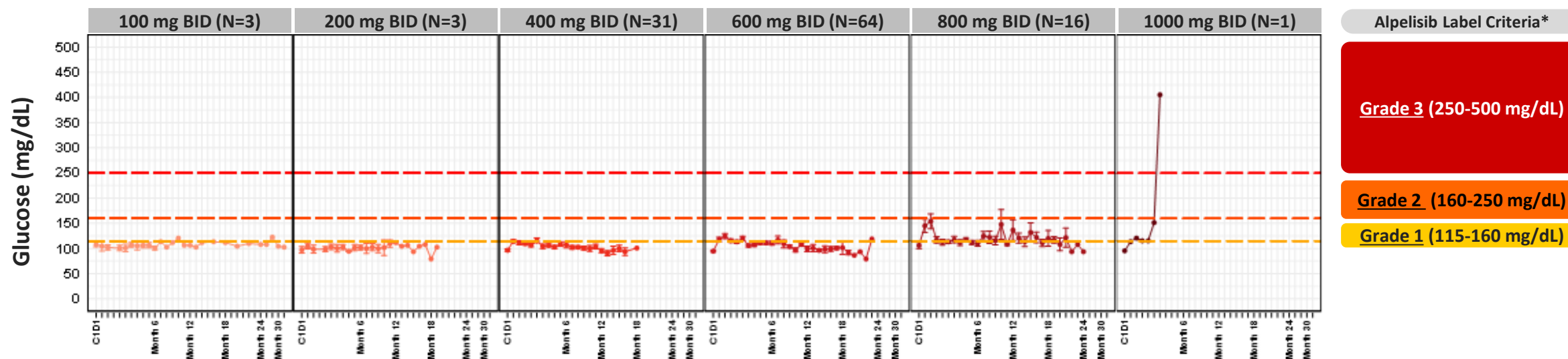


66.7% ORR
(10/15 pt, 95% CI: 38.4%, 88.2%)

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



RLY-2608 + Fulvestrant



Note: *Based on CTCAE version 4 criteria

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ReDiscover preliminary data as of 11/04/2024

RLY-2608 – Tolerability: TRAEs



		All Patients (N=118)		600mg BID (RP2D, N=64)	
		All Gr	Gr3	All Gr	Gr3
Any TRAE		92.4%	25.4%	93.8%	31.3%
TRAEs ≥15% of 600 mg BID	Hyperglycemia¹	42.4%	2.5%	46.9%	3.1%
	Nausea	41.5%	0.8%	50.0%	1.6%
	Fatigue¹	40.7%	8.5%	35.9%	9.4%
	Creatinine Increased	34.7%	0.8%	34.4%	1.6%
	Diarrhea	30.5%	1.7%	35.9%	3.1%
	Decreased Appetite	16.9%	0%	20.3%	0%
	Headache	15.3%	0.8%	20.3%	0%
	Hypokalaemia¹	15.3%	1.7%	17.2%	1.6%
	Vomiting	12.7%	0%	15.6%	0%
Other select TRAEs	Rash¹	11.9%	0.8%	10.9%	1.6%
	Stomatitis	3.4%	0.8%	4.7%	0%

27% Gr1 hyperglycemia
(no intervention required)

No Gr4-5 TRAEs

1: Hyperglycemia includes the MedDRA v26.0 Preferred Terms (PT): Hyperglycemia, Blood Glucose Increased, Glucose Tolerance Impaired; Fatigue includes the PTs: Fatigue, Asthenia; Hypokalemia includes the PTs: Hypokalemia and blood potassium decreased; Rash includes the PTs: Rash, Rash Macular, Rash Maculo-Papular

RLY-2608 – Tolerability: Dose Intensity and Modifications



		All Patients (N=118)	600mg BID (RP2D, N=64)
Dose Intensity	Relative Dose Intensity (%), Median	97%	94%
Dose Modifications Due to TRAE	Dose Reduction, n (%)	38 (32.2)	25 (39.1)
	Dose Interruption, n (%)	56 (47.5)	33 (51.6)
	Dose Discontinuation, n (%)	7 (5.9)	2 (3.1)
TRAEs Leading to Dose Reduction	Fatigue¹	12 (10.2)	6 (9.4)
	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 94% dose intensity with very low TRAE discontinuations at 600mg BID

Note: 1. Fatigue includes the PTs: Fatigue and Asthenia; TRAEs leading to Dose Reduction in more than 2 patients within 600 mg BID are presented.

PI3K α Inhibitors – Efficacy Profiles



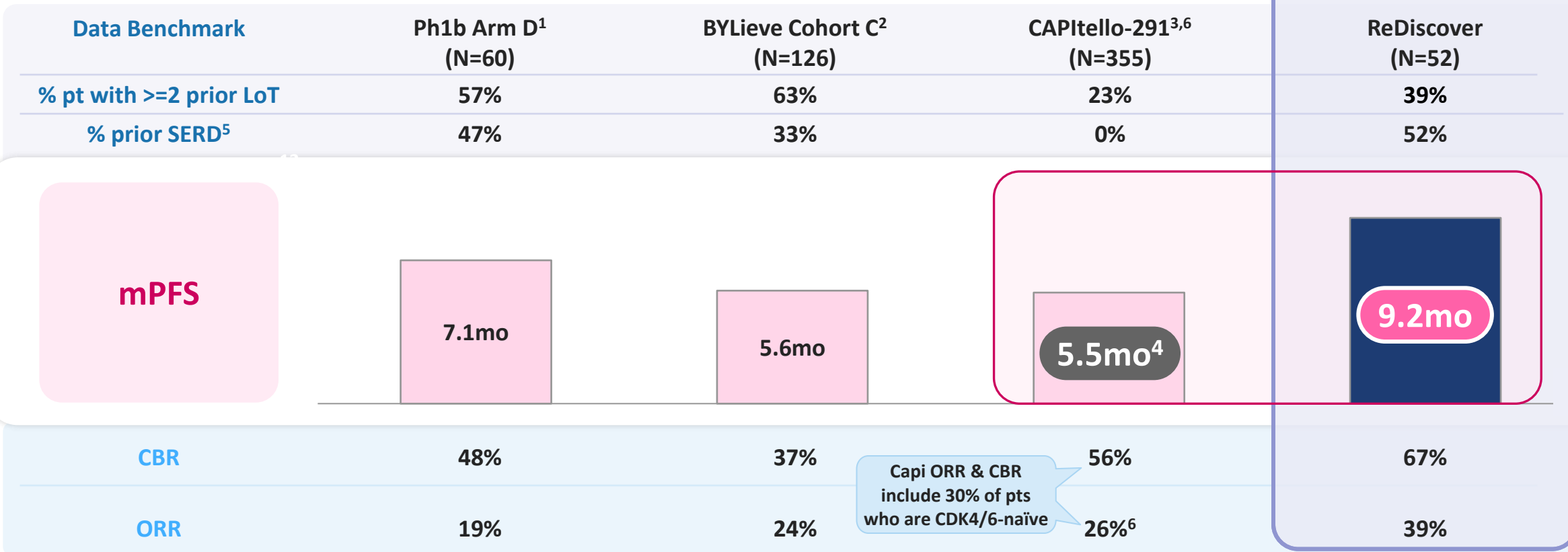
Doublet Combination Regimens

Inavolisib + fulvestrant
not approved

Alpelisib + fulvestrant
approved 2019

Capivasertib + fulvestrant
approved 2023

RLY-2608 + fulvestrant
(600mg BID, RP2D)



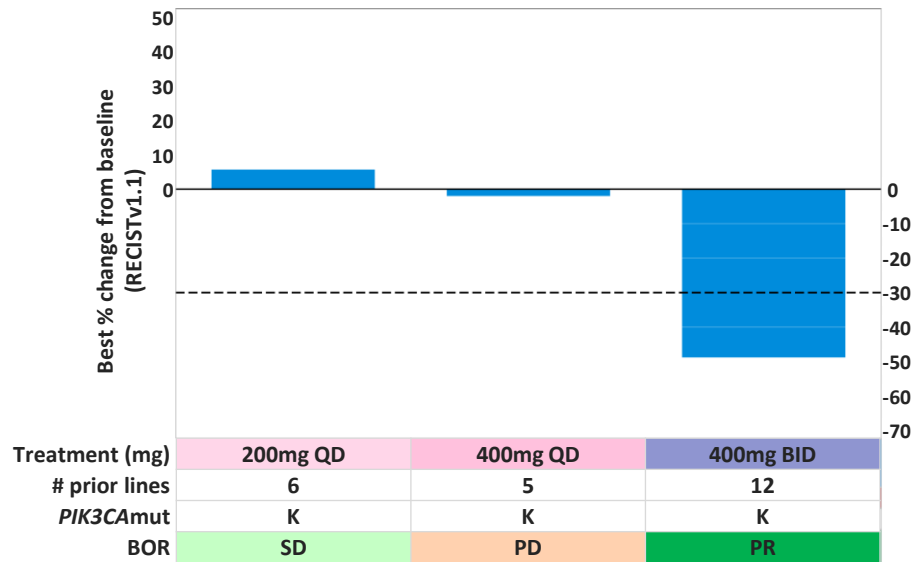
1. SABCS 2021 #P5-17-05 (n=60); 2. SABCS 2021 #PD-13-05; 3. Turner N Engl J Med 2023; 388:2058-2070 (n=355); 4. 5.5mo mPFS reported in CDK4/6-experienced patient sub-population of CAPitello-291; 5. Prior SERD includes fulvestrant and next-generation SERDs; 6. FDA Prescribing Information.
Note: These 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.

RLY-2608 – Monotherapy Activity in Breast Cancer



RLY-2608 Active as Monotherapy

All HR+/HER2- Breast Cancer Patients Across All Doses (N=3)*



**ORR: 1/3
(33%)**

**DCR: 2/3
(67%)**

No endometrial patients dosed*

Relay Tx Focus on Significant Commercial Opportunities

**2L
Breast Cancer**

13,000 pt

**1L
Breast Cancer**

Endocrine Sensitive

10,000 pt

Endocrine Resistant

6,000 pt

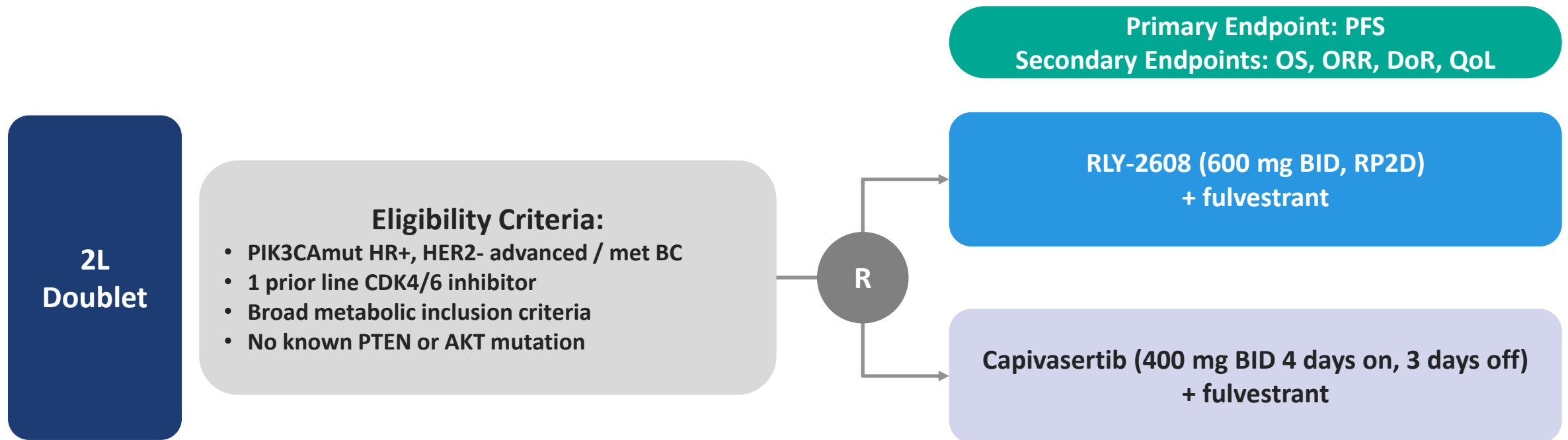
Vascular Malformations

170,000 pt

BC combinations & VMs are near-term development focus; other solid tumor development currently deprioritized

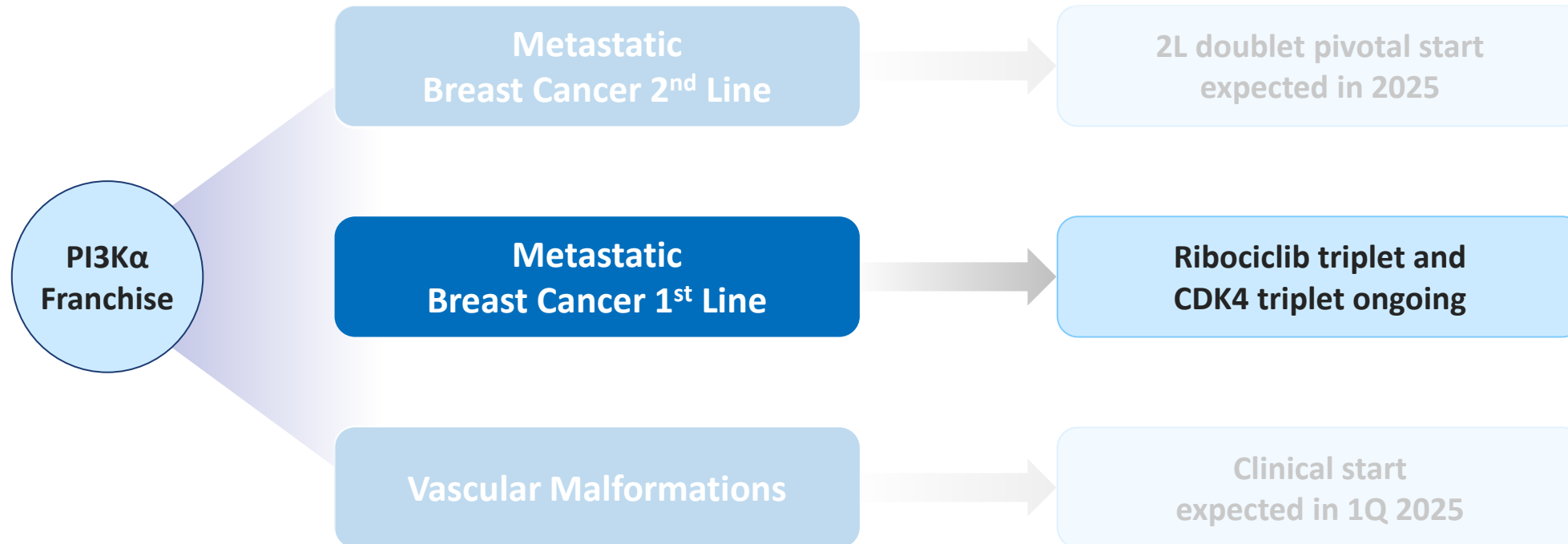
* Within efficacy evaluable population, which excludes PTEN co-mutated patients

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



Team and Capital to Execute

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

Triplets

RLY-2608
+
Fulvestrant

+

Ribociclib
(CDK4/6,
commercial SoC)



Dose Escalation

Currently dosing at biologically active doses of RLY-2608

RLY-2608
+
Fulvestrant

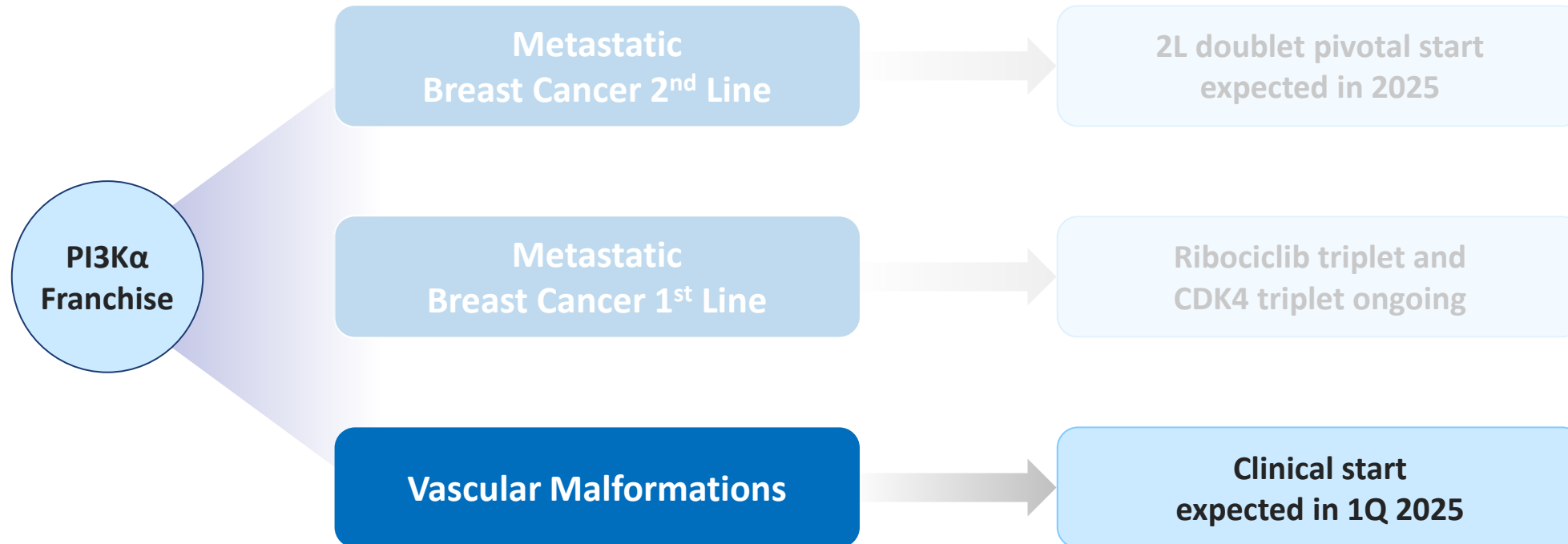
+

Atirmociclib
(CDK4, Pfizer)



Atirmociclib triplet has initiated

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



Team and Capital to Execute

Vascular Malformations – Over 170,000 US Patients

Vascular Malformation Types

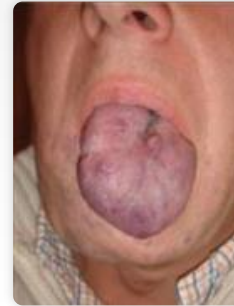
PIK3CA-Related Overgrowth Spectrum (PROS)



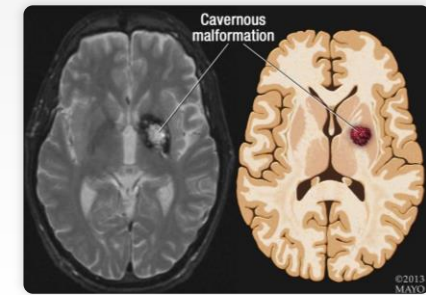
Lymphatic Malformation (LM)



Venous Malformation (VM)



Cerebral Cavernous Malformation (CCM)



US Patients

~5-15k

~80k

~100k

~120k

% PIK3CAmut

100%
~5-15k pt

80%
~65k pt

~20-25%
~20-25k pt

40-55%
~50-65k pt

Approved Therapies

Vioice® (alpelisib)

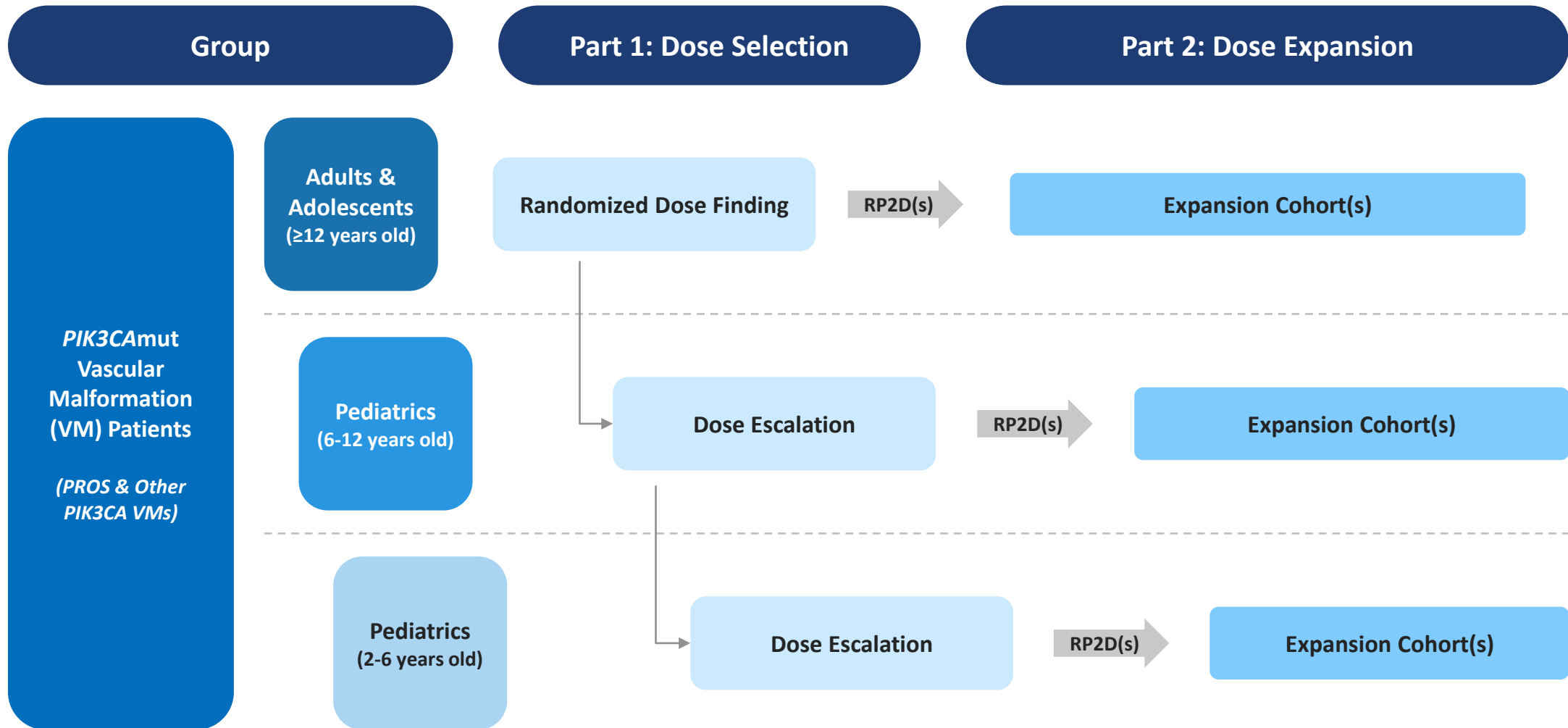
No approved systemic therapy

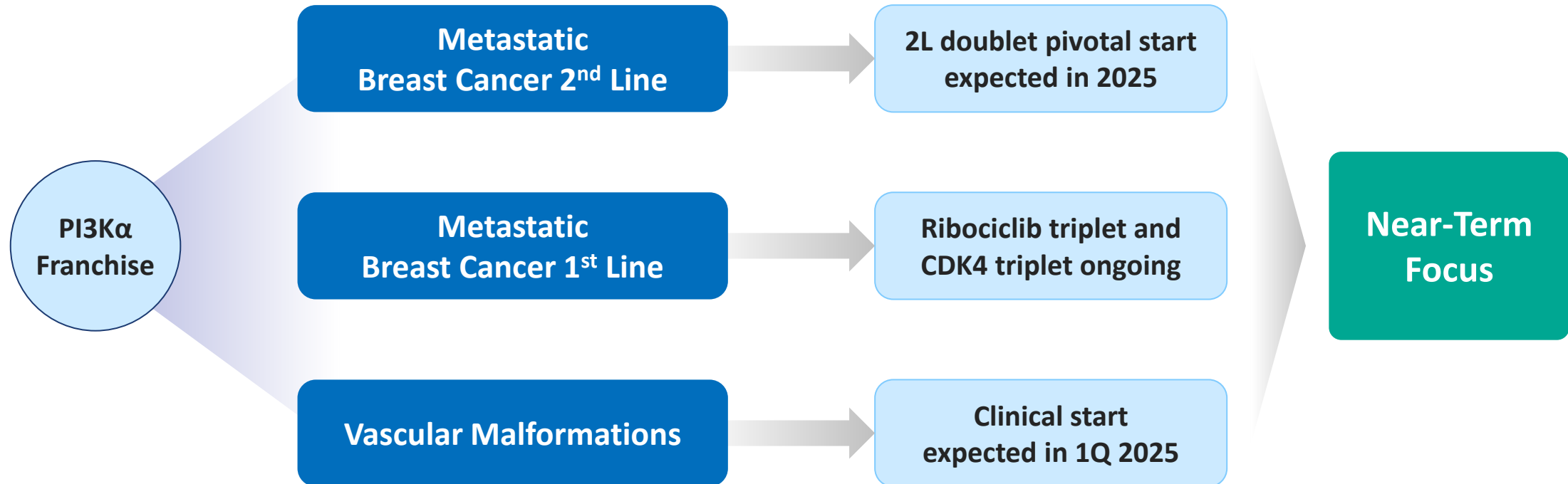
Total US pt across types

>300k pt

~170k pt
PIK3CAmut

Vascular Malformations – Proposed Study Design





Team and Capital to Execute

PI3K α Inhibitors – Tolerability Profiles



Doublet Combination Regimens

Inavolisib + fulvestrant
not approved

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RLY-2608 + fulvestrant
(600mg BID, RP2D)

Data Benchmark

	Ph1b Arm D ¹ (n=60)	BYLieve ² (n=127)	FDA Label ³ (n=355)	ReDiscover (n=64)
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All Grade 3+ TRAEs



Grade 3+ Hyperglycemia



Dose Discontinuation due TRAEs



Discontinuous dosing:
4 days on, 3 days off

34% of pt BMI \geq 30
and/or HbA1c \geq 5.7%

1. SABCS 2021 #P5-17-05; 2. Rugo 2021 Lancet Oncol 22:489; 3. FDA Prescribing Information; 4. CAPItello-291: Turner N Engl J Med 2023; 388:2058-2070.

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PI3K α Inhibitors – Tolerability Profiles



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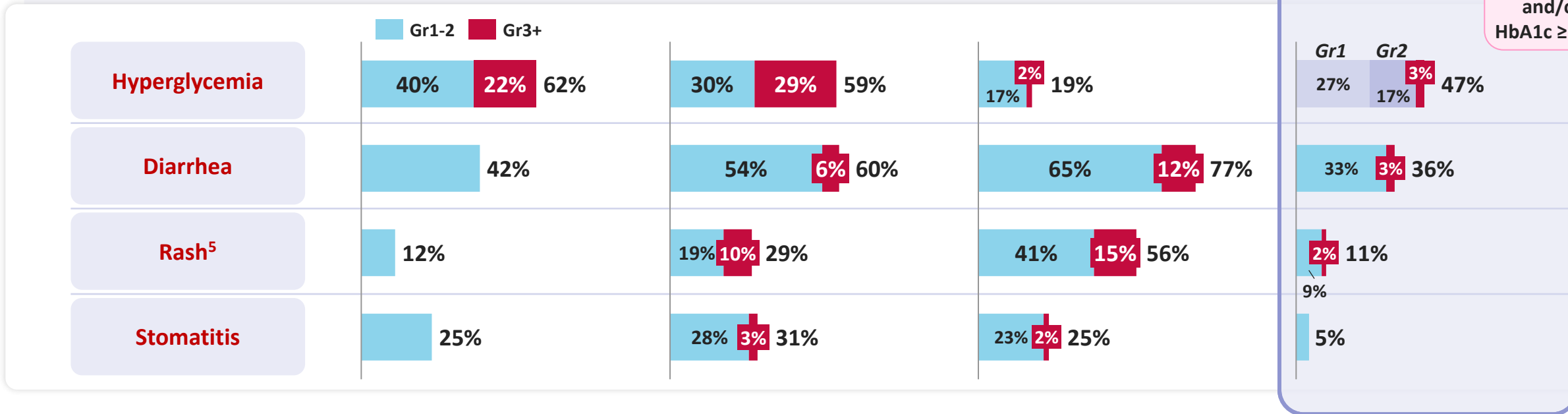
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Data Benchmark	Ph1b Arm D ¹ (n=60)	BYLieve ² (n=127)	FDA Label ³ (n=355)	ReDiscover (n=64)
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HbA1c Enrollment Criteria	<7%	≤6.4%	<8% ⁴	<7% <i>34% of pt BMI ≥30 and/or HbA1c ≥5.7%</i>
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1. SABCS 2021 #P5-17-05; 2. Rugo 2021 Lancet Oncol 22:489; 3. FDA Prescribing Information; 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.

PI3K α Inhibitors – Efficacy Profiles



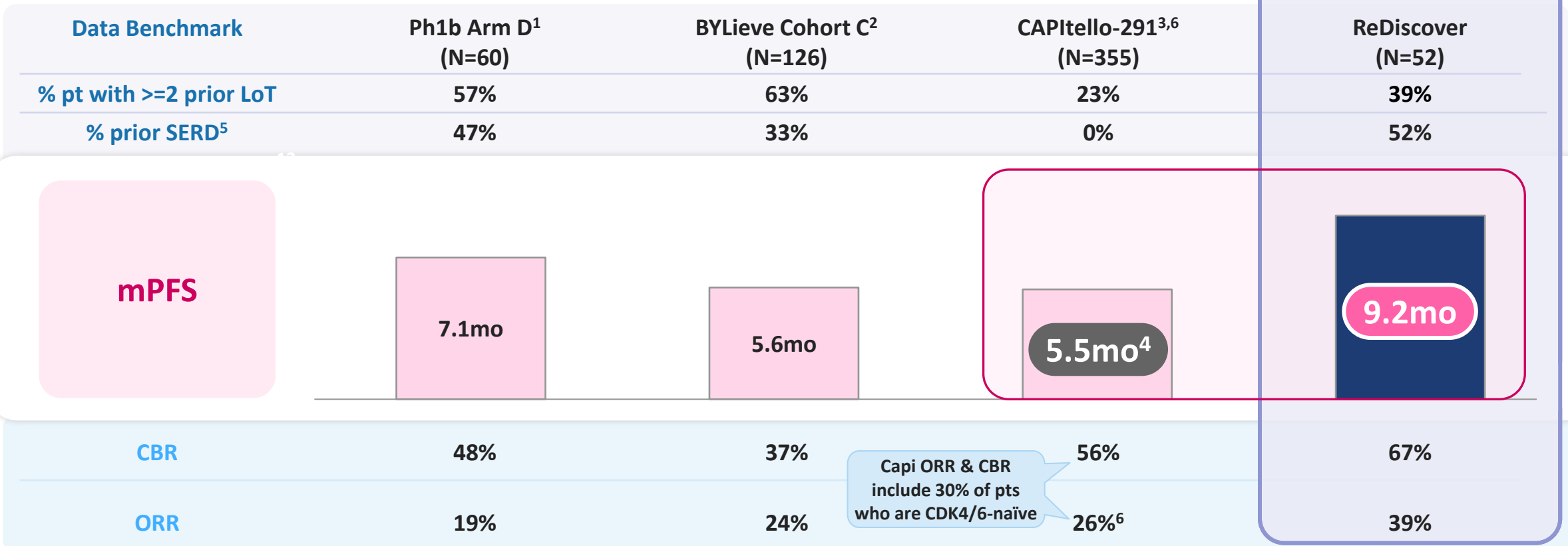
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(600mg BID, RP2D)



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. 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.

Large Unmet Need in Metastatic Breast Cancer



PIK3CAmut, HR+/HER2- mBC¹

Median PFS of Current Standard of Care

Potential Market Opportunity⁸

1L Endocrine Sensitive
10,000 patients

Ribociclib + AI²
25 months

Current Market Oppty

~\$4B

Future Market Oppty

~\$6-7B

Also abemaciclib or palbociclib

1L Endocrine Resistant
6,000 patients

Ribociclib + fulv³
16-20 months

~\$2B

RLY-2608 Potential to Drive Meaningful Improvement

~\$3-4B

2L Post-CDK4/6
13,000 patients

Capivasertib + fulv⁴ 5.5mo
Alpelisib + fulv⁵ 5.6-8mo
CDK4/6 + fulv⁶ ~5-6mo
SERD monox⁷ ~2-4mo

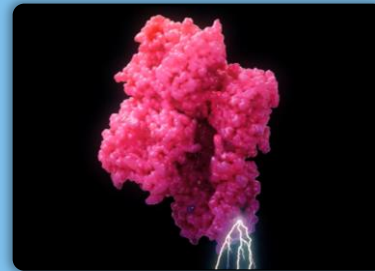
~\$2B

~\$3-4B

Notes: 1. Prevalent US patient population with a PIK3CA mutation in each line of therapy, excluding PTEN co-mutations (Global Data HR+/HER2- Breast Cancer Global Forecast, November 2023; 3rd party source for alteration rate); 2. All-comers and PIK3CAmut sub-group, MONALEESA-2; 3. All-comers and PIK3CAmut sub-group, MONALEESA-3; 4. Turner N Engl J Med 2023; 388:2058-2070 (n=355); 5. Rugo 2021 Lancet Oncol 22:489, SABCS 2021 #P1-18-03; 6. MAINTAIN: Kalinsky 2023 J Clin Oncol 41:4004, postMONARCH: Kalinsky 2024 ASCO; 7. Elacestrant Prescribing Information; 8. Informed by qualitative and quantitative primary market research performed in Q2 2024
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GENETIC DISEASE

Fabry Disease



SOLID TUMORS

NRAS-Driven Solid tumors



Program Updates

1st non-inhibitory
 α Gal chaperone

1st NRAS-selective
inhibitor

Large US Opportunity

~8,000 pts¹
(chronic treatment)

\$2B
current
market³

~28,000 pts²

Anticipated Milestones

Clinical start in 2H 2025

Clinical start in 2H 2025

1. Prevalence of Fabry patients, 2025 (National Fabry Disease Foundation, Nov 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)
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Relay Tx – Broad Precision Medicine Pipeline



	Target	Program	Preclinical	Early Clinical	Late Clinical	
BREAST CANCER	PI3K α	Endocrine Tx (ET) doublet	[Progress bar]			
		RLY-2608 (PI3K α ^{PAN})	Ribociclib + ET triplet	[Progress bar]		
		CDK4i + ET triplet	[Progress bar]			
		Other Novel Combinations	[Progress bar]			
	CDK2	RLY-2139	Paused; IND ready			
ER α	RLY-1013 (Degradar)	Advance to IND-ready				
GENETIC DISEASE	Fabry Disease	α Gal Chaperone	[Progress bar]			
	Vascular Malformations	RLY-2608 (PI3K α ^{PAN})	[Progress bar]			
		Other PI3K α ^{PAN}	[Progress bar]			
SOLID TUMORS	NRAS	NRAS-selective Inhibitor	[Progress bar]			
	PI3K α	RLY-2608	[Progress bar]			
	FGFR2	Lirafugratinib (RLY-4008)	Global Outlicense to Elevar Therapeutics			


DYNAMO® PLATFORM | 5 unnamed research programs

Anticipated 2025 Corporate Objectives

Breast Cancer
RLY-2608

- 2L pivotal trial start – 2025
- Full Ph1-2 data – 2025

Vascular Malformations
RLY-2608

- Clinical start – 1Q 2025

Fabry Disease
Pre-clinical

- Clinical start – 2H 2025

NRAS
Pre-clinical

- Clinical start – 2H 2025

Significant Capital to Achieve Goals

~\$840M

Cash as of the end of 3Q 2024

Expected to fund
current operating plan
into 2H 2027



DYNAMO® PLATFORM

5 unnamed research programs



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

