



## Company Overview

February 15, 2024

# Forward-Looking Statements

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# Forward-Looking Statements

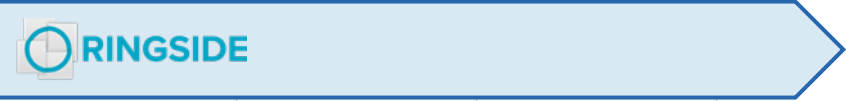
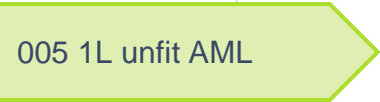

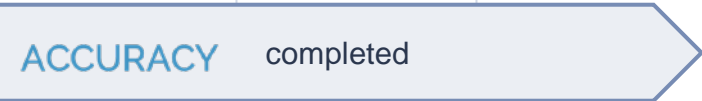
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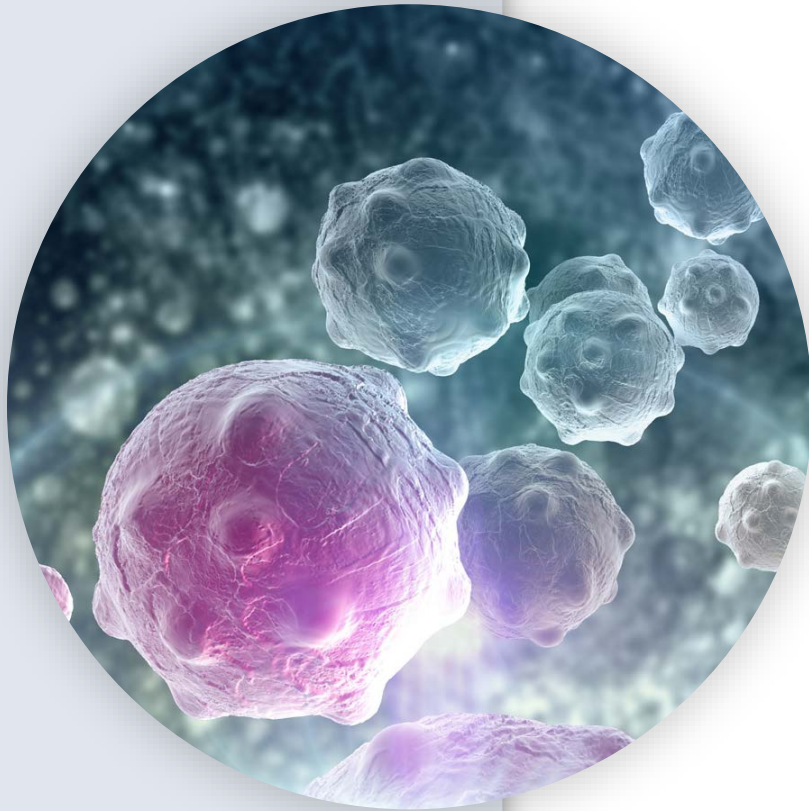
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# Investment Highlights

- ▶ Recently announced entering into an agreement with Immunome (Nasdaq: IMNM) for the sale of all assets relating to AL102 and AL101
  - ▶ Asset purchase agreement signed February 5, 2024. Closing subject to Ayala shareholder approval and other customary conditions
  - ▶ Immunome will pay Ayala \$20 million in cash and ~2.175M shares of IMNM stock plus up to \$37.5 million in development and commercial milestone payments for the assets
- ▶ Aspacytarabine, or aspa, (BST-236) in acute myeloid leukemia (AML)
  - ▶ Phase 1 of Aspa + venetoclax (AbbVie) in first-line unfit AML patients
- ▶ Management with deep experience in oncology and rare diseases with track record of bringing drugs through clinical development to approval
  - ▶ Combined company leadership Ken Berlin (CEO), Roy Golan (CFO), Andres Gutierrez (EVP CMO), Dana Gelbaum (General Manager & CBO)

# Combined Pipeline and Short- and Mid-Term Catalysts

Indication	Product	Preclinical	Phase 1	Phase 2	Phase 3	Catalysts
Desmoid	AL102					<ul style="list-style-type: none"> <li>○ Updated Ph2 data</li> <li>○ Enrollment completion</li> <li>○ Ph3 topline data</li> </ul>
AML	Aspacytarabine combo with venetoclax					<ul style="list-style-type: none"> <li>○ Initial read out</li> <li>○ Updated clinical data</li> </ul>
Prostate cancer	ADXS-504					<ul style="list-style-type: none"> <li>○ Initial clinical and PSA readout in 1H 2024</li> </ul>
R/M ACC	AL101					<ul style="list-style-type: none"> <li>○ Path for future development plan by 1H 2024</li> </ul>



## AL102 Once-Daily Oral Treatment of Desmoid Tumors

# Late-Stage, De-Risked Program with Attractive Commercial Opportunity



## **AL102 is an oral gamma secretase inhibitor (GSI) now in Phase 3 study in desmoid tumors (DTs)**

- GSIs represent a breakthrough in the treatment of DTs—a new class of drugs that has shown impressive data<sup>1</sup> in clinical trials; SpringWorks' GSI called OGSIVEO (nirogacestat) received FDA approval for DT on 11/27/23
- Maturing Phase 2 clinical data suggest that AL102 may be **best in class** versus nirogacestat



## **Addressing a locally-aggressive and invasive tumor with prevalence of >30K patients in the US and >45K patients in the EU, of which 6,600-8,000 in the US and 10,000-12,500 in the EU currently receive treatment annually**

- With potential superior efficacy and once-daily dosing, AL102 could seize significant market share
- AL102 could be a Fast-Follower poised to capitalize on first mover success in establishing market demand
- Nirogacestat price is set at WAC \$29K per month of treatment



## **Robust patent portfolio with granted patents (out to 2033)\* and additional patent filings (out to 2044)\***

- AL102 has FDA Orphan Drug Designation

# Maturing Phase 2 Clinical Data Suggest that AL102 may be Best in Class vs Nirogacestat

## Potential Superior Efficacy

- Tumor shrinkage by RECIST
- Volume reduction
- T2 reduction

## Once Daily Dosing

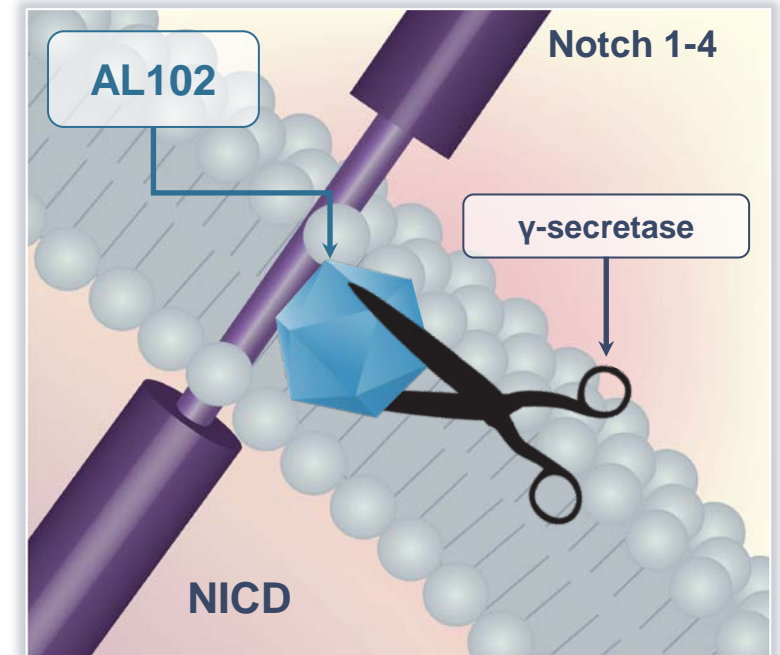
- Strongly preferred by patients

**AL102  
Best in  
Class**



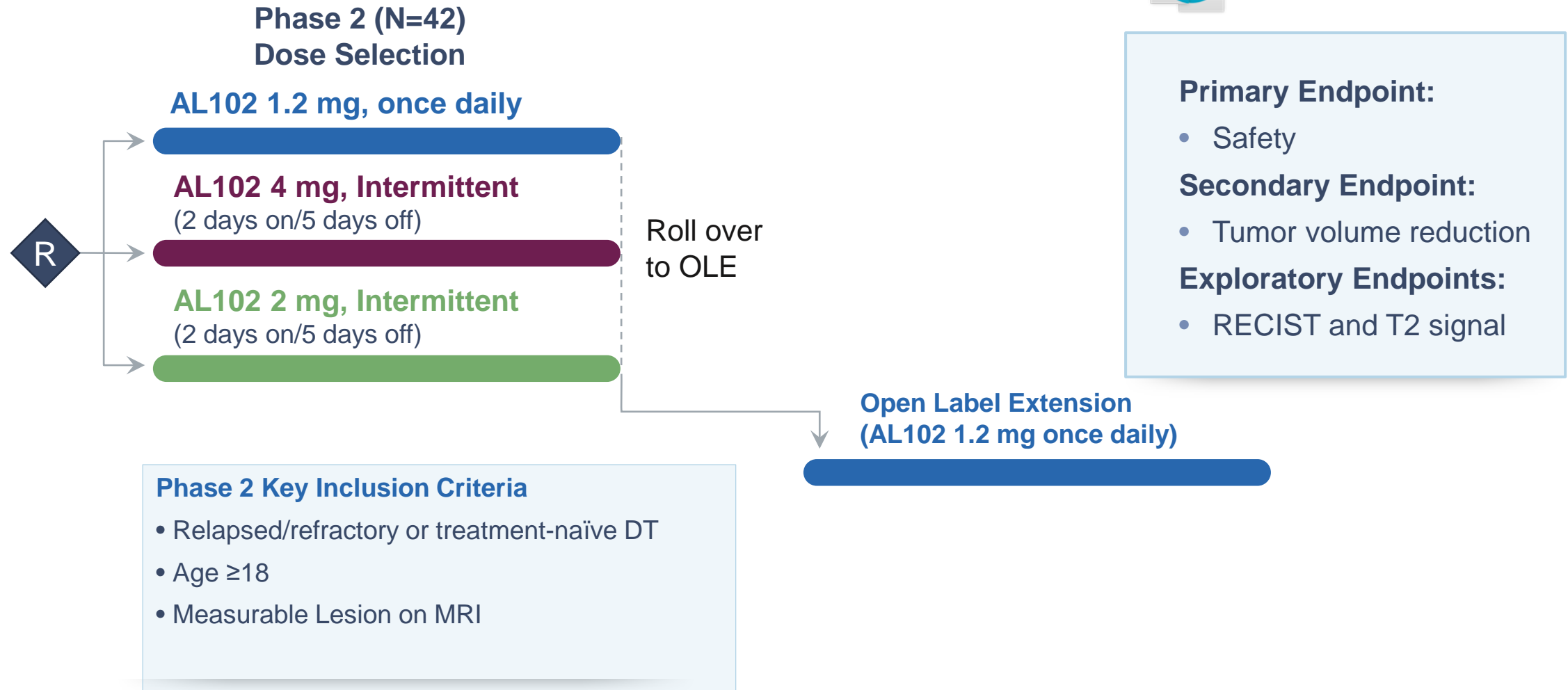
# Desmoid Tumor Pathophysiology is Driven by Wnt Pathway

- Desmoid tumors (DT) are driven by CTNNB1 (somatic) mutations (~85%) or APC (germline) mutations (10-15%)—both result in activation of the Wnt Pathway<sup>1</sup>
- There is overlap as well as direct cross talk between Notch target gene activation and Wnt Pathway<sup>2</sup>
- GSIs are potent modulators of Notch, providing a mechanistic rationale for GSI therapy with AL102 in DT<sup>2</sup>
- The genomic landscape supports the use of AL102 in other tumor types (e.g., hepatocellular, endometrial and ovarian cancer)



# RINGSIDE Phase 2 Evaluated Three Dose Levels and Treatment Schedules

Phase 2 completed, patients on OLE



## Phase 2: Patient Population – Representative for Patients with DTs

Baseline characteristics were generally balanced across treatment groups

Baseline Patient and Disease Characteristics	Total (N=42) n (%)
Age (years), Median (range)	38.5 (19-72)
Gender	
Female	31 (73.8)
Male	11 (26.2)
Location of Tumor at Initial Diagnosis	
Intra Abdominal	11 (26.2)
Extra Abdominal	31 (73.8)
Size of Tumor, Measured (n)	39
Median in mm (min, max)	61.0 (0, 169)
Prior Desmoid Cancer Therapies	29 (69.0)
Prior Desmoid Cancer Surgeries	20 (47.6)
Prior Desmoid Radiation Therapies	4 ( 9.5)

# Efficacy Measure #1: Best Overall Response Rate (ORR) by RECIST1 Substantial Reductions in Tumor Size

## AL102 Phase 2 interim results

Population	1.2 mg QD		4 mg BIW		2 mg BIW		ALL	
	Evaluable	ITT	Evaluable	ITT	Evaluable	ITT	Evaluable	ITT
	(n=12)	(n=14)	(n=13)	(n=14)	(n=11)	(n=14)	(n=36)	(n=42)
<b>Objective Response Rate<sup>1</sup> (CR + PR), n (%)</b>	<b>9 (75%)</b>	<b>9 (64%)</b>	<b>8 (62%)<sup>2</sup></b>	<b>8 (57%)<sup>2</sup></b>	<b>5 (45%)</b>	<b>5 (36%)</b>	<b>22 (61%)</b>	<b>22 (52%)</b>
<b>Best Overall Response</b>								
Complete Response (CR)	0	0	0	0	1 (9%)	1 (7%)	1 (3%)	1 (2%)
Partial Response (PR)	<b>9 (75%)</b>	<b>9 (64%)</b>	<b>8 (62%)<sup>2</sup></b>	<b>8 (57%)<sup>2</sup></b>	<b>4 (36%)</b>	<b>4 (29%)</b>	<b>21 (58%)</b>	<b>21 (50%)</b>
Stable Disease (SD)	3 (25%)	3 (21%)	5 (38%)	5 (36%)	5 (45%)	5 (36%)	13 (36%)	13 (31%)
Progressive Disease (PD)	0	0	0	0	1 (9%)	1 (7%)	1 (3%)	1 (2%)
Disease Control Rate (DCR)	12 (100%)	12 (86%)	13 (100%)	13 (93%)	10 (91%)	10 (71%)	35 (97%)	35 (83%)
<b>Time to objective response, median (range), months</b>	6.8 (3.8, 15)		12 (9, 18)		9.2 (6.4, 9.2)		9.3 (3.8, 18)	

Kasper, B. et al., ESMO Congress 2023\_1929P with updates to ORR and time to response based on additional analyses in Jan 2024

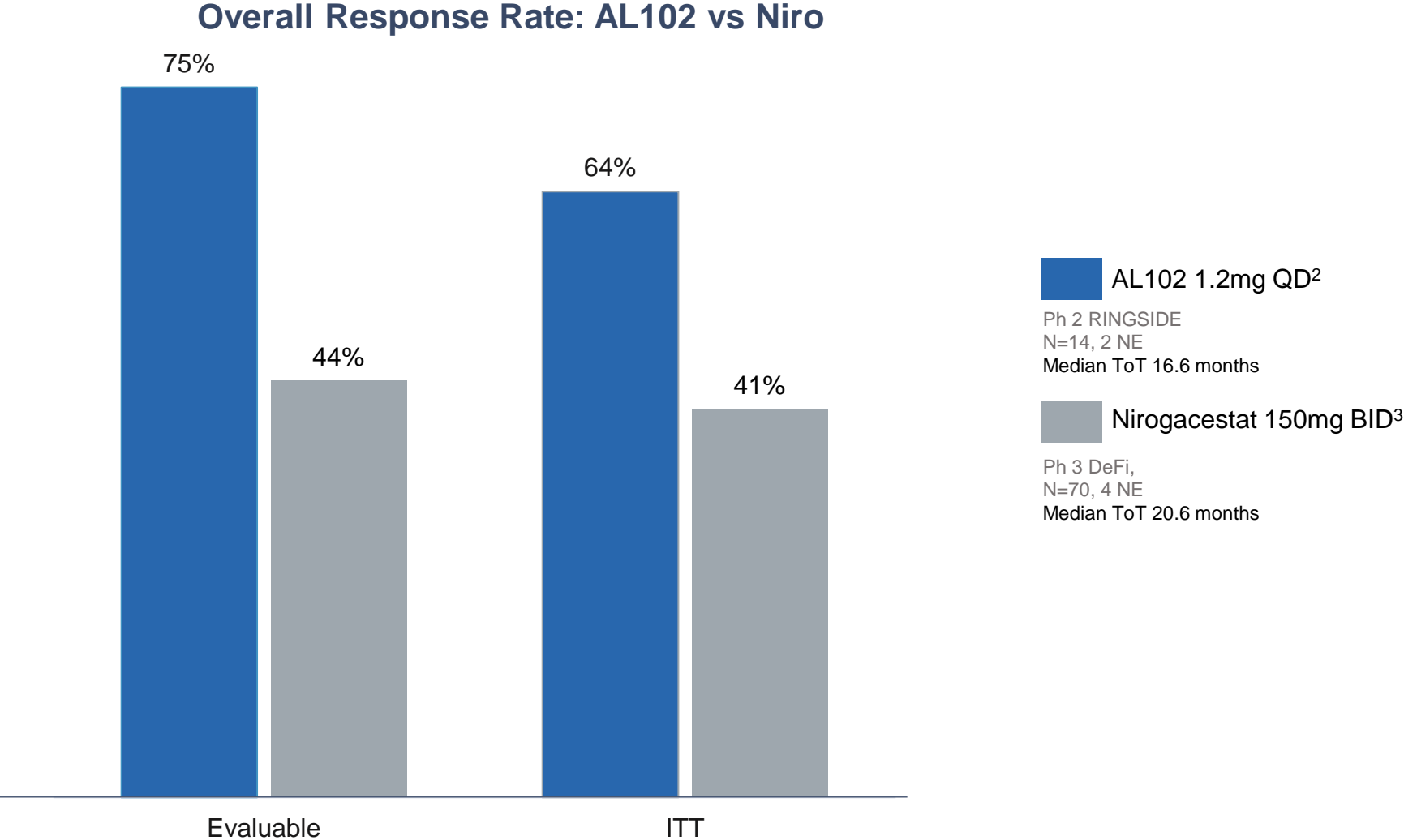
Evaluable, population with baseline and follow-up scan; ITT, Intention-to-Treat; NE, not evaluable

<sup>1</sup> Change from baseline in tumor shrinkage as measured on MRI by Blinded independent Central Review (BICR)

<sup>2</sup> Three of the eight responses in this arm occurred after rollover to OLE

# Efficacy Measure #1: Best Overall Response Rate by RECIST<sup>1</sup>

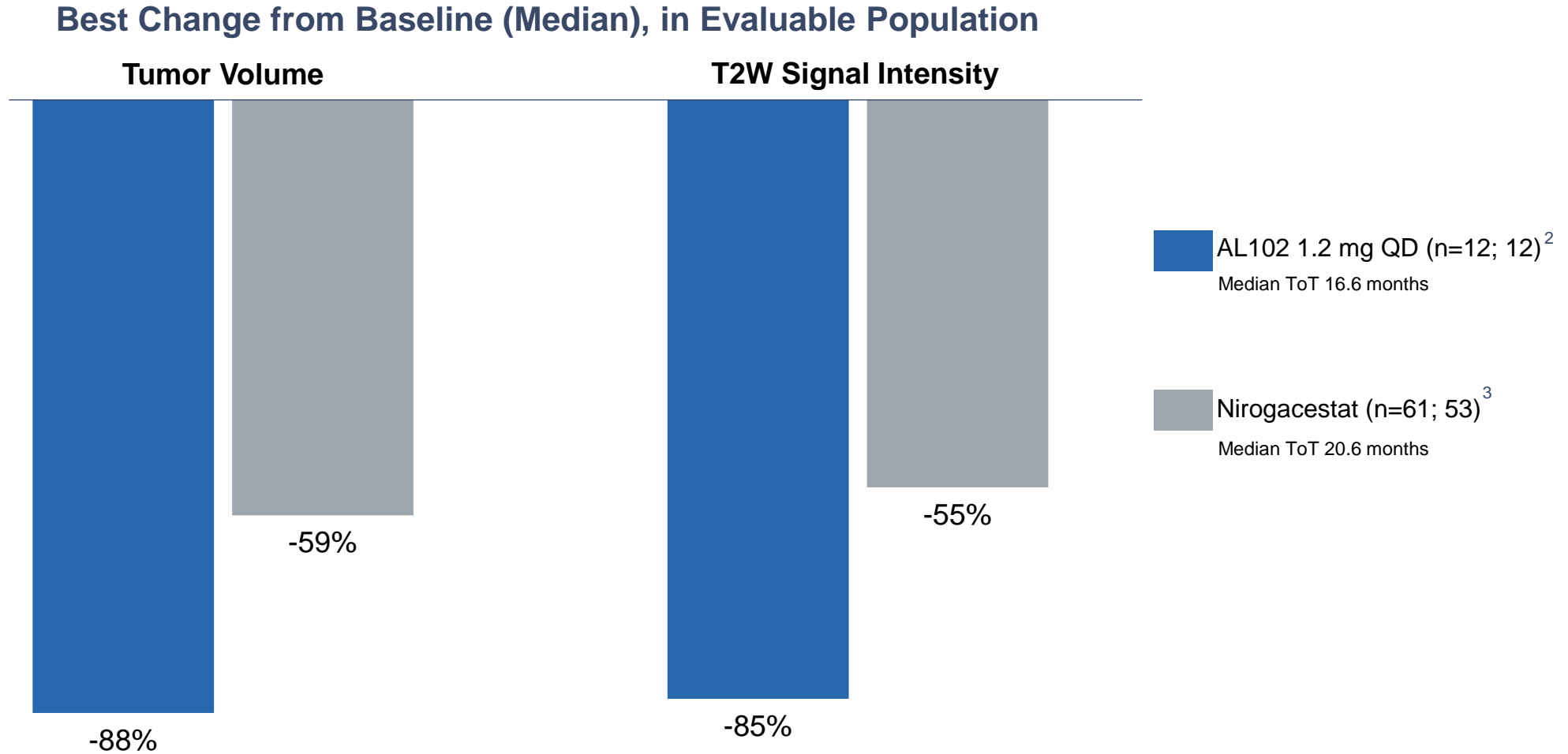
## Potential Superior Efficacy



<sup>1</sup> Change from baseline in tumor shrinkage as measured on MRI by Blinded independent Central Review (BICR)  
<sup>2</sup> Kasper B et al., ESMO Congress 2023\_1929P with updates to Overall Response Rate based on additional analyses in Jan 2024  
<sup>3</sup> Gounder M et al., NEJM 2023, 388:898  
ITT, Intention-to-Treat; NE, not evaluable

# Efficacy Measures #2 & 3: Change to Tumor Volume & T2 Signal<sup>1</sup>

## Potential Superior Efficacy



<sup>1</sup> As measured on MRI by Blinded independent Central Review (BICR) in RINGSIDE and DeFi Studies

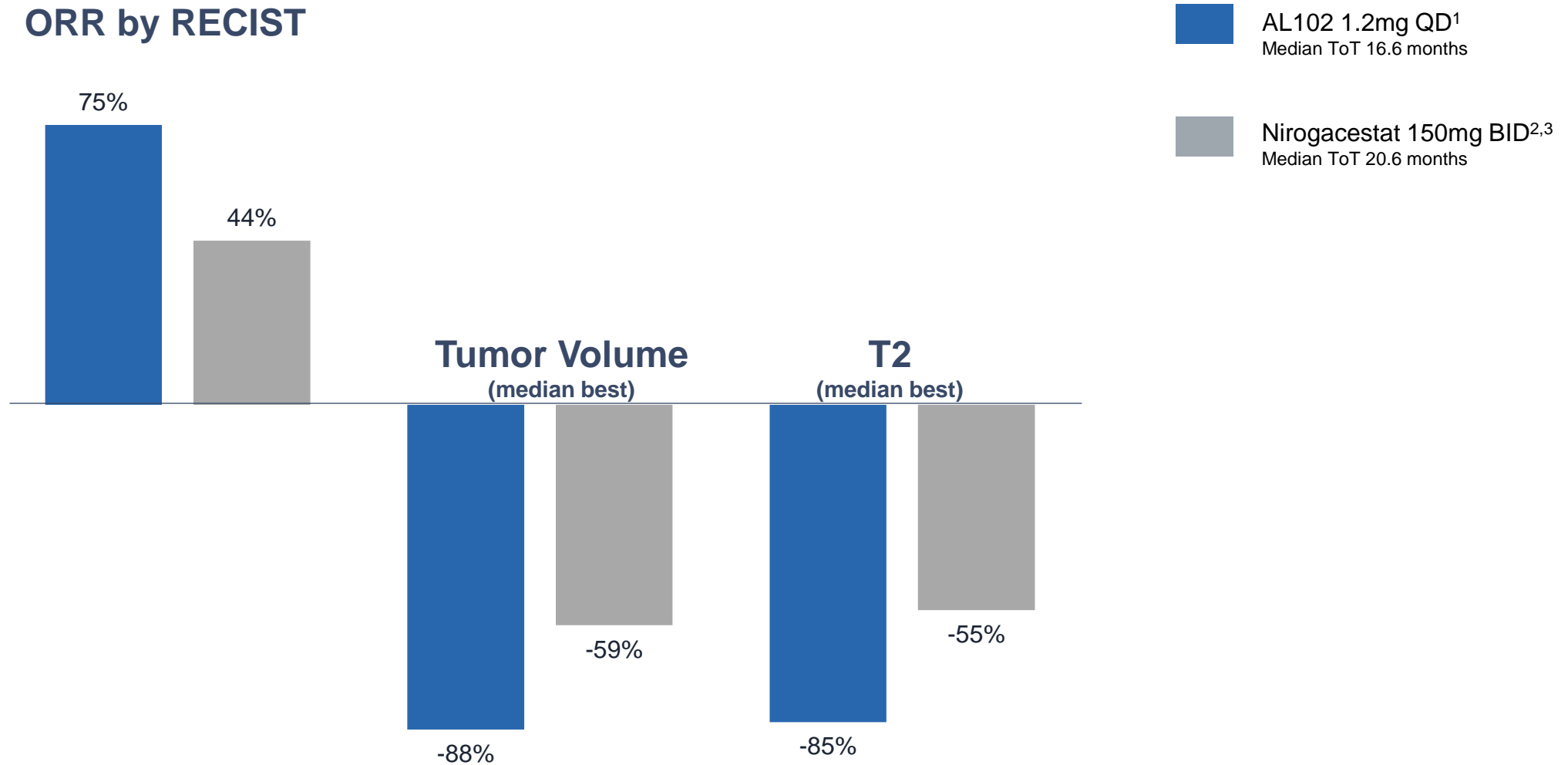
<sup>2</sup> Kasper B et al., ESMO Congress 2023\_1929P

<sup>3</sup> Alcindor T., et al., ASCO Annual Meeting 2023, Abstract #11514

ToT, time on treatment

# Summary

## Potential Superior Efficacy of AL102 across Three Efficacy Measures



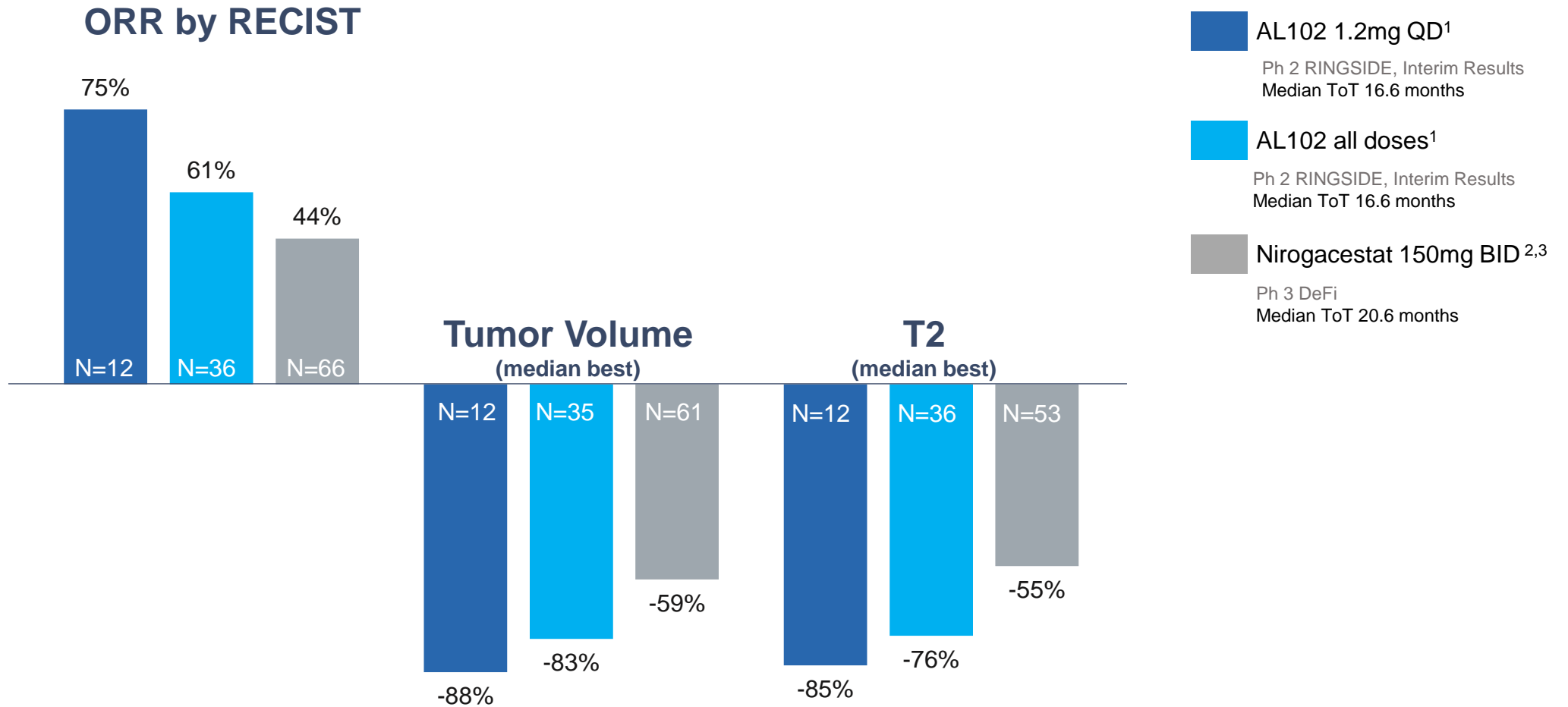
1 Kasper B et al., ESMO Congress 2023\_1929P with updates to ORR based on additional analyses in Jan 2024

2 Gounder M et al., NEJM 2023, 388:898

3 Alcindor T., et al., ASCO Annual Meeting 2023, Abstract #11514  
Evaluable Population

# Summary

## Superior Efficacy of AL102 across Three Efficacy Measures



1 Kasper B et al., ESMO Congress 2023\_1929P with updates to ORR based on additional analyses in Jan 2024

2 Gounder M et al., NEJM 2023, 388:898

3 Alcindor T., et al., ASCO Annual Meeting 2023, Abstract #11514  
Evaluable Population



# Safety Profile in 1.2 mg Once-Daily Cohort Consistent with GSI Class

AL102 had lower incidence of Grade  $\geq 3$  and Serious TEAEs in comparison to nirogacestat

Safety Population, n (%)	AL102 mg QD (n=14)		Nirogacestat 150 mg BID (n= 69)	
	Any Grade	Grade $\geq 3$	Any Grade	Grade $\geq 3$
No. of pts with one or more TEAE	14 (100)	<b>5 (35.7)</b>	69 (100)	<b>38 (55)</b>
TEAEs leading to discontinuation	4 (28.6)		14 (20)	
Any serious TEAE	1 (7.1)		14 (20)	
Treatment-related serious TEAEs	0		9 (13)	
TEAEs leading to death	0		0	
Months on the study (mean range), months	16.6 (1-21.6)		20.6 (0.3 - 33.6)	

# Safety Profile in 1.2 mg Once-Daily Cohort Consistent with GSI Class

TEAEs reported in ≥25% of pts in AL102 1.2 mg QD arm

Study Population, n(%)	AL102, 1.2mg QD (n=14)		Nirogacestat 150mg BID (n=69)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Diarrhoea	13 (92.8)	2 (14.3)	58 (84)	11 (16)
Nausea	8 (57.1)	-	37 (54)	1 (1)
Fatigue	7 (50)	-	35 (51)	2 (3)
Alopecia	7 (50)	-	13 (19)	-
Dry skin	7 (50)	-	11 (16)	-
Stomatitis	7 (50)	1 (7.1)	20 (29)	3 (4)
Dermatitis acneiform	6 (42.9)	-	15 (22)	-
Dry mouth	6 (42.9)	-	NR	NR
Hypophosphatemia	6 (42.9)	-	29 (42)	2 (3)
Rash maculo-papular	5 (35.7)	-	22 (32)	4 (6)
Aspartate aminotransferase increased	4 (28.6)	-	11 (16)	-
<b>Months on the study (mean range), months</b>	16.6 (1-21.6)		20.6 (0.3 - 33.6)	

Ovarian dysfunction\* in pre-menopausal women: 5/9 (55.6%) with AL102 in 1.2 mg QD arm versus 27/36 (75.0%) in Niro DeFi Study

Kasper B et.al. ESMO Congress 2023\_1929P

Nirogacestat reported TEAEs in Gounder M et al., NEJM 2023, 388:898 | Gounder, CTOS 2022

\* Ovarian dysfunction defined as premature menopause, menopause, ovarian failure, amenorrhea, and irregular menstruation; 6/8 (75%) with AL102 4 mg twice weekly and 3/6 (50%) with AL102 2 mg twice weekly

# RINGSIDE Phase 3 Pivotal Study in DT Initiated on Strength of Positive Phase 2 Results

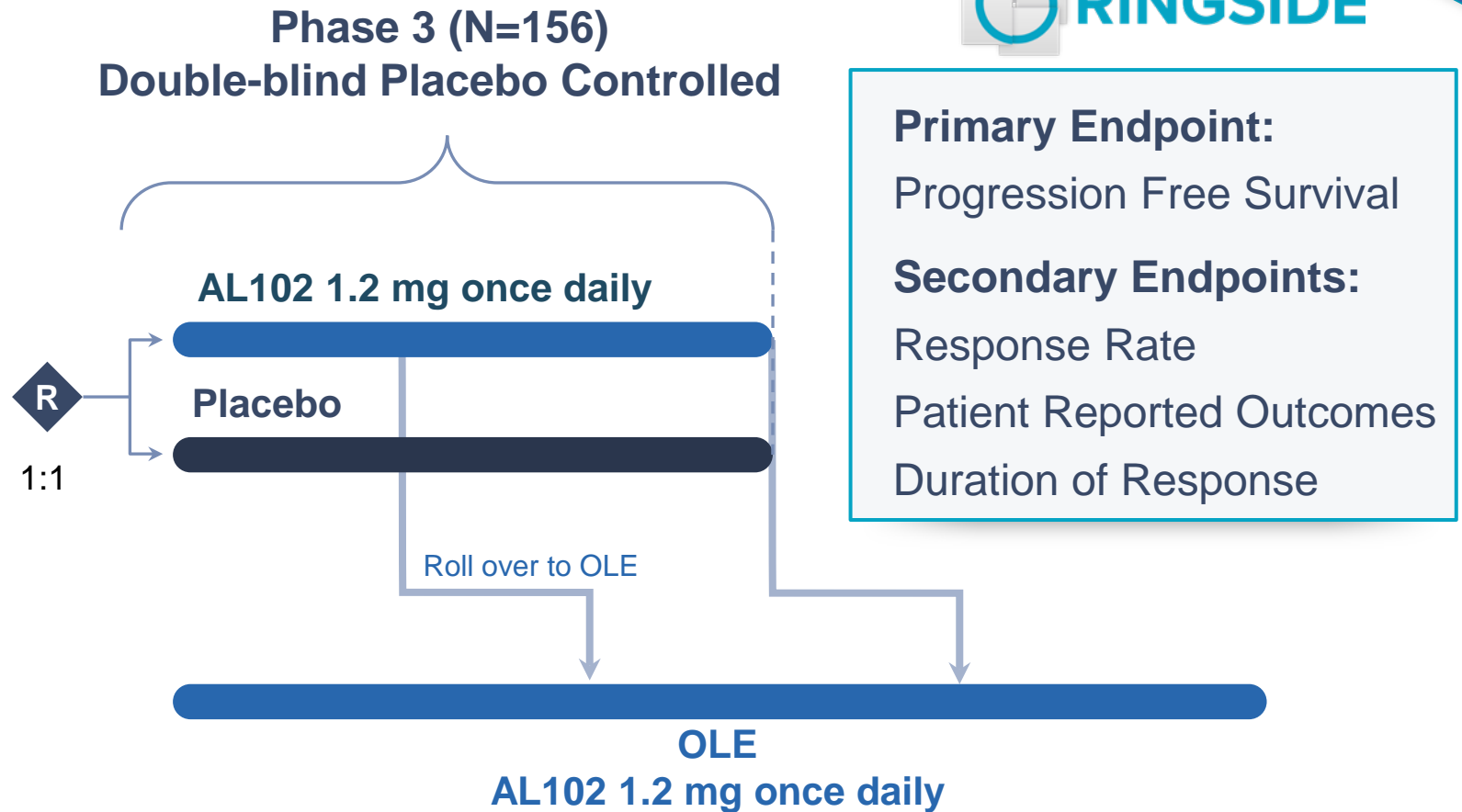
Randomized, double-blind placebo-controlled study evaluating 1.2mg once-daily dose

FDA  
Fast Track  
Designation



## Phase 3 Key Inclusion Criteria

- Relapsed/Refractory or
- Treatment Naïve DT
- Age ≥12



# RINGSIDE Phase 3 Enrolling Globally



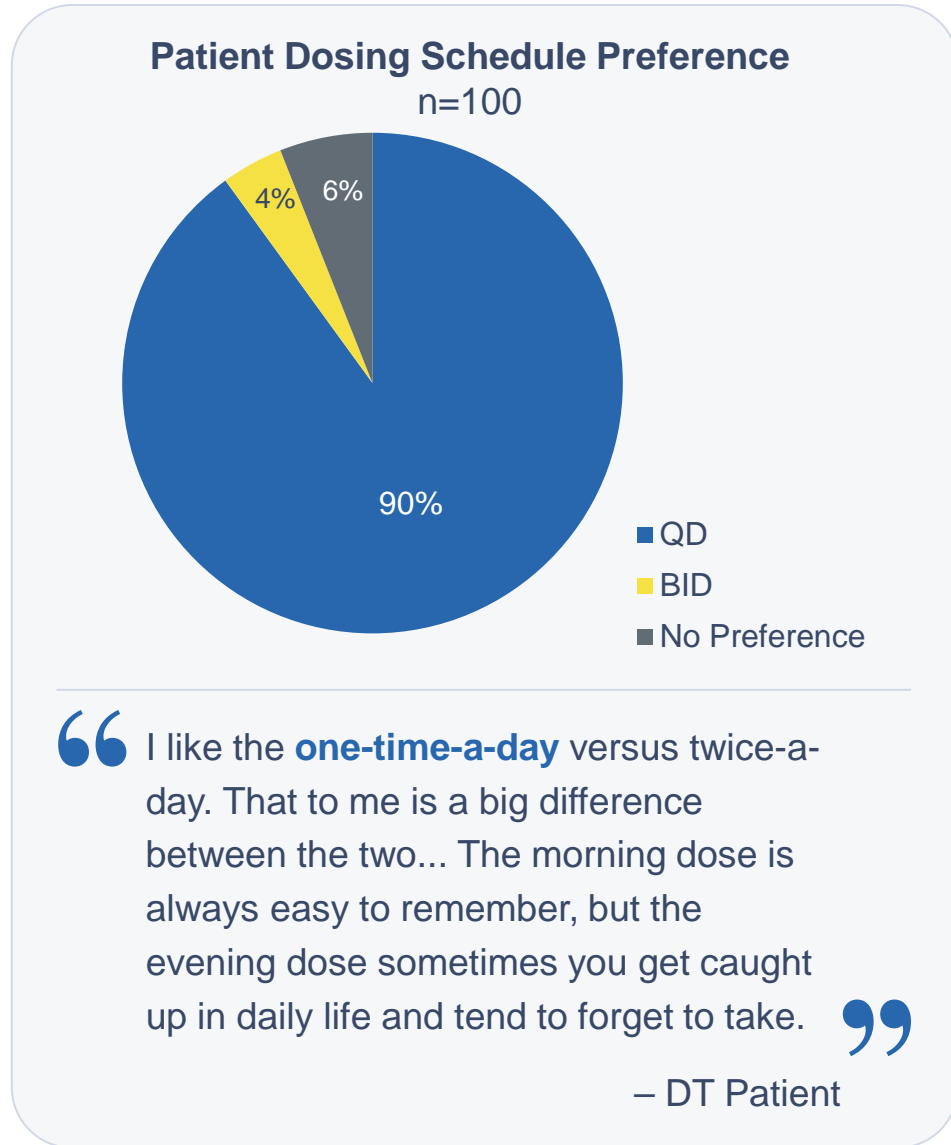
> 70% of patients enrolled

## Study running in:

- USA
- Australia
- Belgium
- Germany
- Israel
- Italy
- Netherlands
- Poland
- Spain
- South Korea
- UK

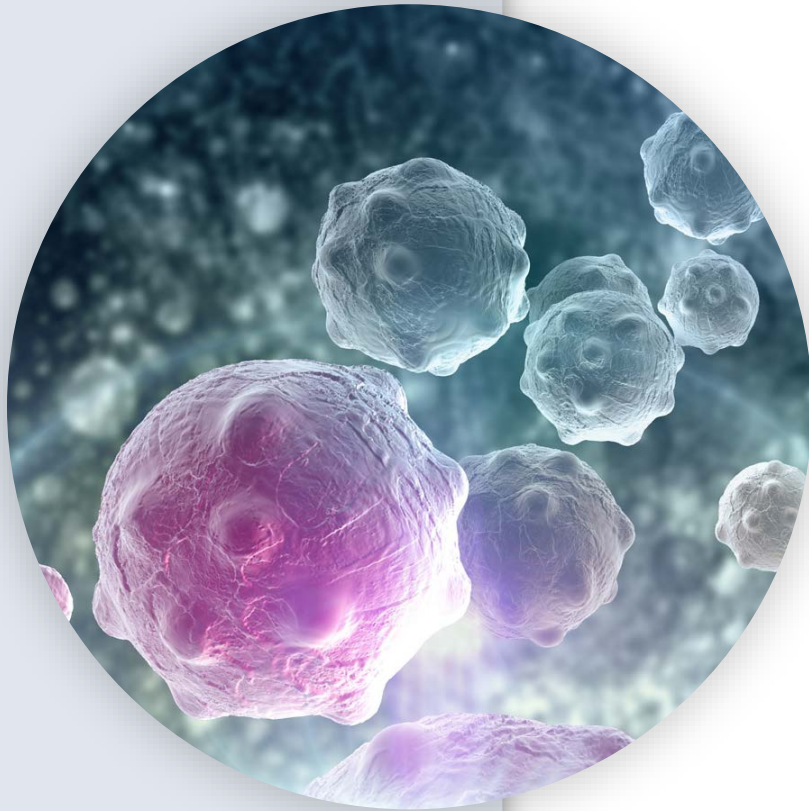


# Patients Prefer Once-Daily Option



Patient market research reveals that most patients prefer once-daily (QD) dosing regimen vs. twice-daily (BID)<sup>1</sup>

- Patients see once-daily dosing as a key competitive advantage for AL102 (assuming efficacy is at least comparable)<sup>2</sup>
  - Enhanced adherence
  - Less intrusive
  - Better fit to schedule and active life-style



**Aspacytarabine (BST-236),  
a Potential New Backbone for  
Combination Therapy in Acute Myeloid  
Leukemia**

# Aspacytarbine: Clinical-Stage Asset with Significant Commercial Potential



## Potential new backbone for AML combination regimens

- Aspa, a novel anti-metabolite with reduced toxicity
- Enables delivery of high doses of cytarabine to unfit AML patients with prospect of improved survival<sup>1</sup>



## High Unmet Need<sup>2</sup>

- Intensive cytarabine-based chemotherapy is the gold standard for fit AML patients, delivering high complete remission rates and median overall survival of ~24 months<sup>3</sup>
- Half of patients diagnosed with AML are medically unfit for this therapy<sup>2,4</sup>
- Current treatment options for unfit patients deliver inferior outcomes with median overall survival of 14.1 months<sup>5</sup>



## Clinical proof of concept as monotherapy (Phase 2) and in combination<sup>6-7</sup>

- Initial data in combination with venetoclax suggest potential for improved outcomes in first line, unfit AML patients

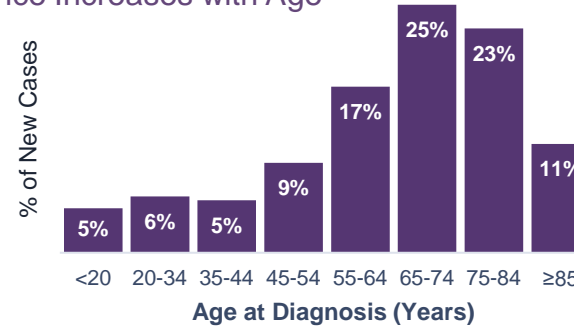
# AML is a Large and Growing Market Predominantly Affecting the Elderly Population

## Age at Diagnosis

Median age at diagnosis:

**68-75 years**

Incidence Increases with Age<sup>1,2</sup>



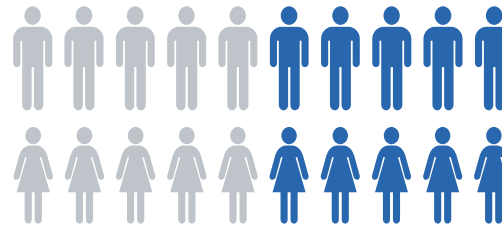
## Disease Incidence

Survival Rate in Patients  
≥ 70 years old:<sup>3</sup>

**1-year 9-26%**

**5-year 2-5%**

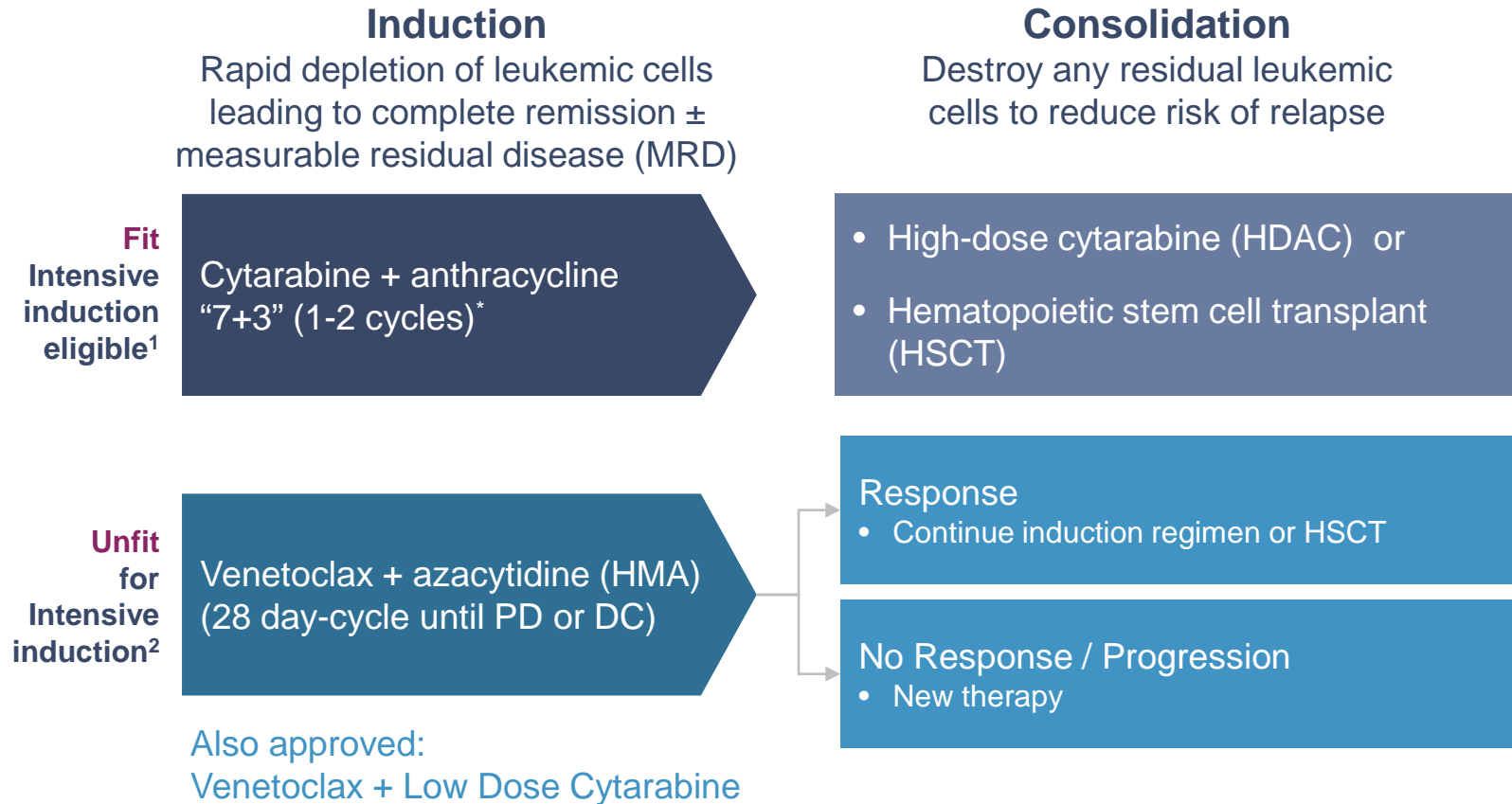
Half of the patients are **unfit** for SOC  
chemotherapy<sup>3,4</sup>



**9K new unfit AML patients annually in the US<sup>1</sup>**

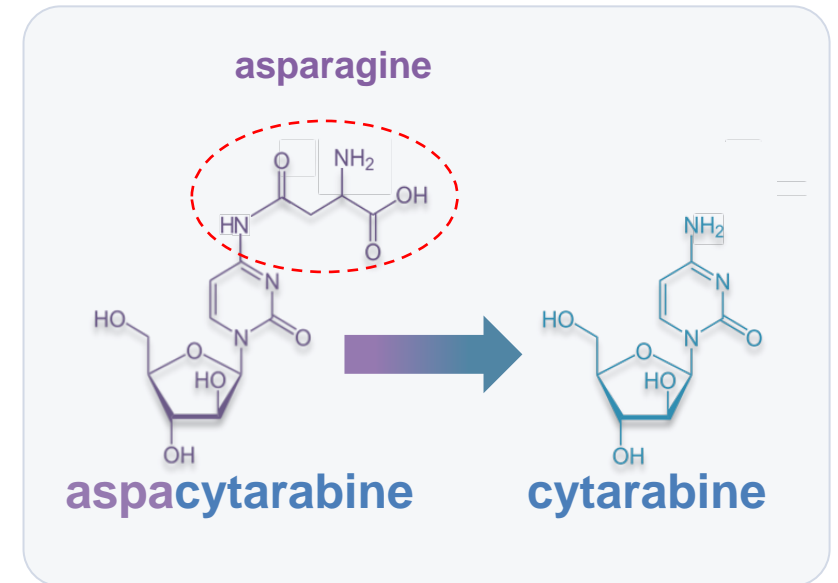


# Standard of Care for AML Fit & Unfit Patients



# Aspacytarabine Delivers High-Dose Cytarabine with Less Toxicity

- Aspa is a designed prodrug with unique pharmacokinetics
- Aspa gradually releases cytarabine over ~8 hours, reducing systemic exposure to free cytarabine<sup>1</sup>
  - Enables high-dose cytarabine treatment with relative sparing of normal tissue
  - 1-hour intravenous infusion of 4.5 g/m<sup>2</sup>/day of aspa provides the equivalent of 3 g/m<sup>2</sup>/day cytarabine infused over 3 hours<sup>2</sup>



Dose	4.5 g/m <sup>2</sup> /day
Administration	6-day cycles, IV
Regimen	1 - 2 inductions 1 - 3 consolidations

# Aspa Monotherapy Is Clinically Active with a Safety Profile Suitable for Combination Studies

- >140 patients treated to-date (studies 001 to 004)

Study	Phase	Status	Indications
001	Ph1/2a	Completed	AML, ALL
002	Ph2b	Completed	1L unfit AML
003	Ph2 IIS	Ongoing	R/R unfit AML R/R HR unfit MDS
004	Ph2	Ongoing	R/R unfit AML R/R HR unfit MDS

# Aspa Ph2b Results Show Strong Clinical Activity and Tolerability in Frontline Unfit AML Patients<sup>1</sup>

- Single-agent activity at 4.5 g/m<sup>2</sup>/day in 6-day cycles (n=66)
  - CR = 37% (all with complete recovery of blood cells)
  - CR MRD- = 52%
  - mOS = 9 months (range 6.0-16)
  - 4 patients able to proceed to potentially curative HSCT
- Aspa was well tolerated in older and unfit patients—a profile acceptable for future combination therapies
  - Mainly “on-target” adverse events; no ≥ Grade 3 cerebellar toxicity or severe mucositis as seen with high-dose cytarabine
  - Rapid recovery of blood cell counts in 21-28 days
  - Low 30-day all cause mortality of 12.5%

<sup>1</sup> BST-236 CSR V1.0\_25 April 2023

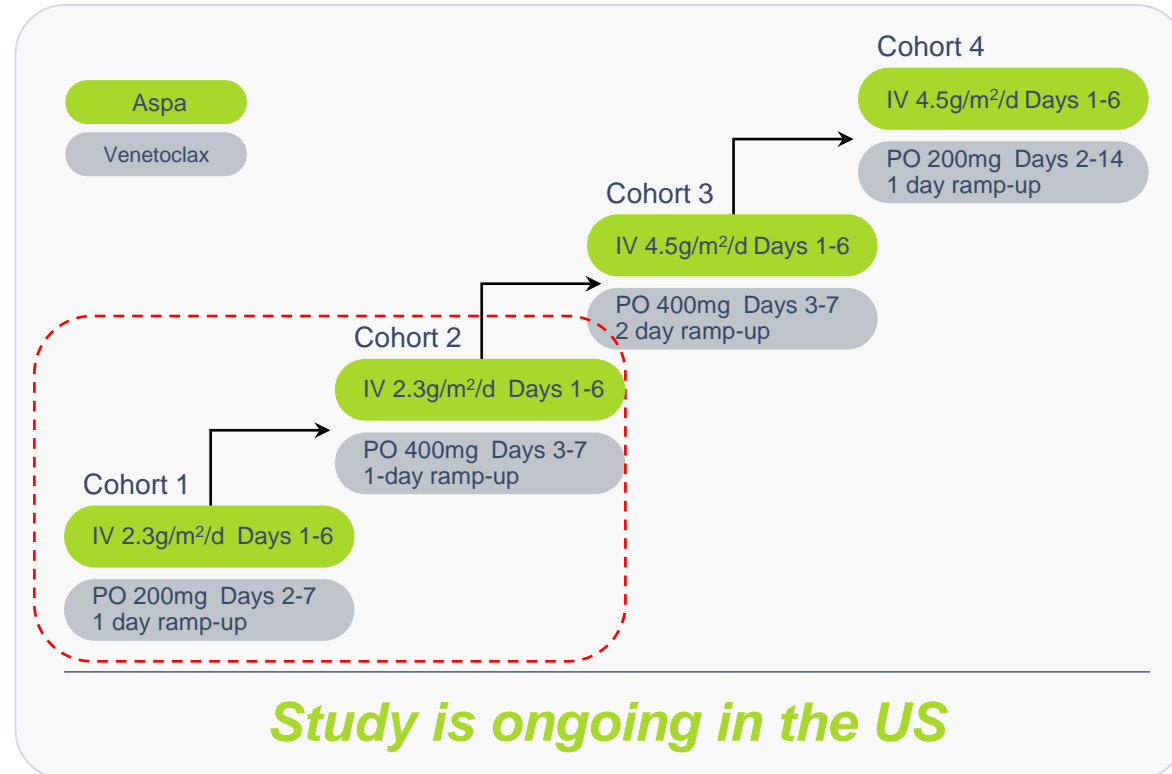
R/R, relapsed refractory; ALL, acute leukoblastic leukemia; HR MDS. Higher-risk myelodysplastic syndrome; CR, complete remission; mOS, median overall survival; IIS, Investigator Initiated Study

MRD-, measurable residual disease negative; HSCT, hematopoietic stem cell transplant

# Study 005 – Phase 1/2 Aspacytarabine Combo with Venetoclax

<b>Status</b>	Phase 1 ongoing in US sites Cohort 1 & 2 fully enrolled
<b>Study Population</b>	Newly-diagnosed AML patients, unfit for standard induction therapy
<b>Primary Endpoints</b>	DLT
<b>Treatment Regimen</b>	Induction: BST-236 + venetoclax – up to 2 cycles Consolidation: up to 3 cycles with aspa
<b>NCT</b>	NCT05503355

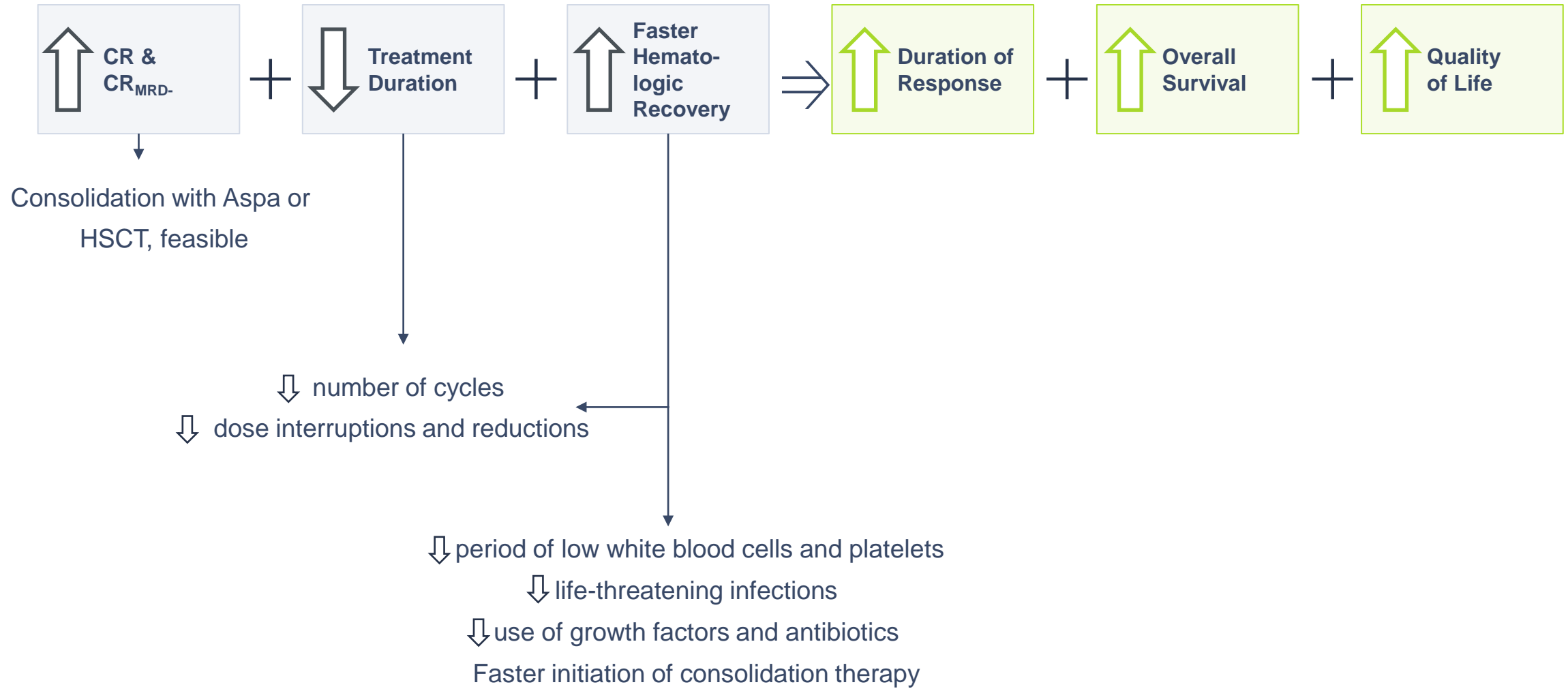
## Phase 1 Dose Escalation



## Objectives

- Safety profile
- MTD (Maximum Tolerated Dose)
- RP2D (Recommended Phase 2 Dose )

# Frontline Aspa + Venetoclax has Potential Advantages for Unfit AML Patients vs Ven + Aza or Ven + LDAC



# Frontline Aspa + Venetoclax in Unfit AML Patients – Next Steps

- Initial data in combination with venetoclax suggest potential for improved CR and MRD- rates in frontline, unfit AML patients
  - Phase 1 study to be completed to define safety, tolerability, clinical activity and Recommended Phase 2 Dose (RP2D)
- A future single-arm, Phase 2 study could lead to a potential accelerated approval if the safety/efficacy ratio in unfit AML patients is compelling

# Investment Highlights

- ▶ Recently announced entering into an agreement with Immunome (Nasdaq: IMNM) for the sale of all assets relating to AL102 and AL101
  - ▶ Asset purchase agreement signed February 5, 2024. Closing subject to Ayala shareholder approval and other customary conditions
  - ▶ Immunome will pay Ayala \$20 million in cash and ~2.175M shares of IMNM stock plus up to \$37.5 million in development and commercial milestone payments for the assets
- ▶ Aspacytarabine, or aspa, (BST-236) in acute myeloid leukemia (AML)
  - ▶ Phase 1 of Aspa + venetoclax (AbbVie) in first-line unfit AML patients
- ▶ Management with deep experience in oncology and rare diseases with track record of bringing drugs through clinical development to approval
  - ▶ Combined company leadership Ken Berlin (CEO), Roy Golan (CFO), Andres Gutierrez (EVP CMO), Dana Gelbaum (General Manager & CBO)



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