2026 ASCO® ANNUAL MEETING

CONVERGE-01: Phase 2 Study of Ac-225 Rosopatamab Tetraxetan (CONV01-α)

Lu-PSMA-pretreated metastatic androgen pathway modulator-resistant (APMR) prostate cancer

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Key Takeaway Points

1

CONV01-α is safe for patients with prior exposure to Lu-177-PSMA radioligand therapy (Lu-PSMA)

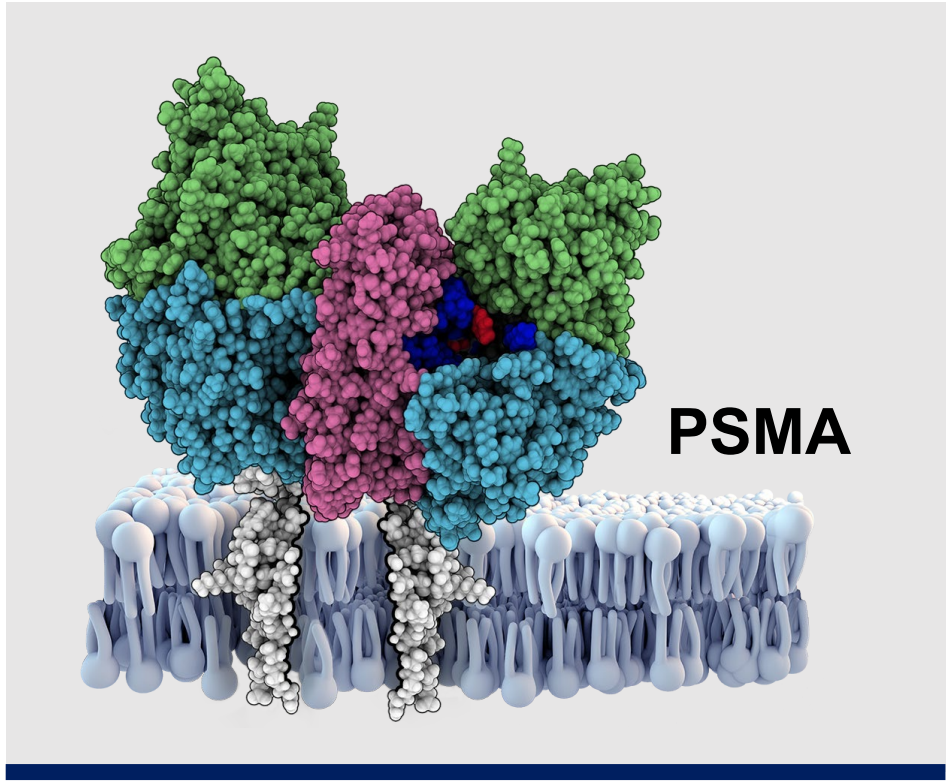
2

Clinically-manageable hematologic toxicity. No nephrotoxicity or high-grade xerostomia

3

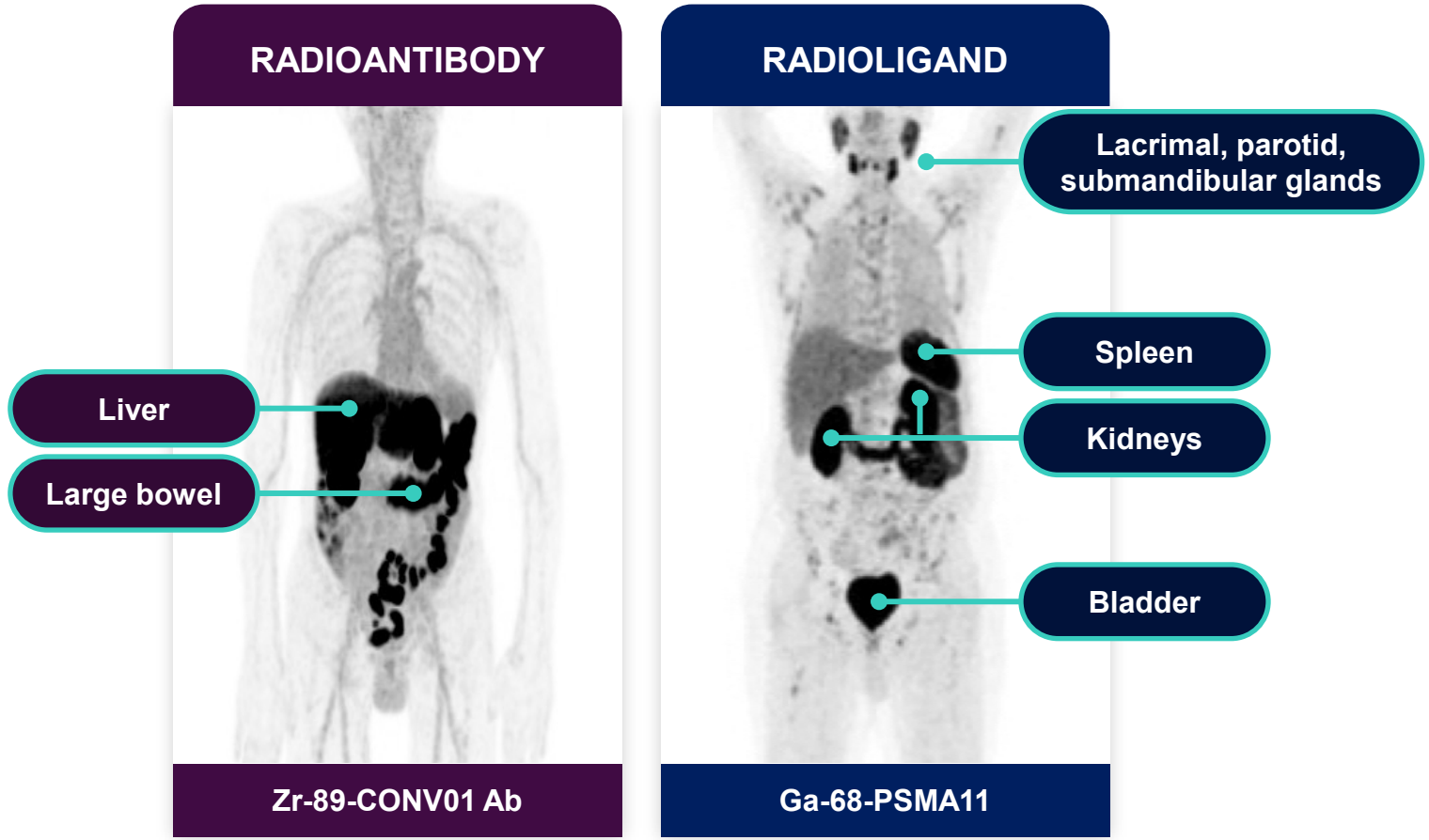
CONV01-α has promising activity and durability in patients previously treated with Lu-PSMA

Next Generation PSMA-directed Radiopharmaceuticals Have Emerged



Biodistribution of Antibodies versus Small Molecules

- Reduced uptake in salivary glands and kidneys
- Uptake in liver without clinical impact
- Longer elimination half-life with a potential hematologic impact
- Superior uptake and retention in tumor cells



Tagawa S, Bander N et al. *Weill Cornell Medicine (Data on File).*

Advantages of Ac-225 as an Alpha-emitting Payload

10-day half-life well-complements the antibody targeting moiety

No need for restrictive lifestyle modification
Decay daughters (Bi-213, Fr-221) are rapidly cleared without toxicity

Accelerator-derived production facilitates adequate supply of radioisotope

High purity production methodology eliminates complicated waste disposal/handling, long-term decay concerns

CONV01-α Combines an Alpha-emitting Isotope (Ac-225) with the PSMA-directed Antibody (rosopatamab)

Background of Dosing Regimen

- Over 100 patients treated with Ac-225 rosopatamab tetraxetan at Weill Cornell Medicine[1,2]
  - Total administered activity was fractionated across two doses, administered on Day 1 and Day 15
  - This regimen demonstrated safety and efficacy and proved to be superior to the other dosing schedules evaluated
  - Activity demonstrated in Lu-PSMA-exposed population

[1]Tagawa ST, *et al*. *JCO* 2023; [2]Nauseef JT, *et al*. *AACR* 2023.

CONVERGE-01 is Evaluating Safety and Efficacy of CONV01-α in a Lu-PSMA-exposed Population

Key eligibility

- Progressive mAPMR
- ≥1 PSMA PET (+) metastatic lesion and no PSMA PET (-) lesions
- Prior ≥1 ARPI
- ≤1 prior taxane chemotherapy regimen
- Prior Lu-PSMA (1-6 doses of Pluvicto or Lu-177-PSMA-I&T)
- No prior PARPi, Ra-223, or platinum chemotherapy

Biodistribution Lead-in

In-111-CONV01
148 ± 37 MBq on Day 1

Lu-PSMA-exposed Dose Escalation & Expansion

CONV01-α on Days 1 & 15 at 45 kBq/kg and 55 kBq/kg
BOIN design

Study Objectives

Safety and efficacy

Establish Target Dose in Lu-PSMA-exposed

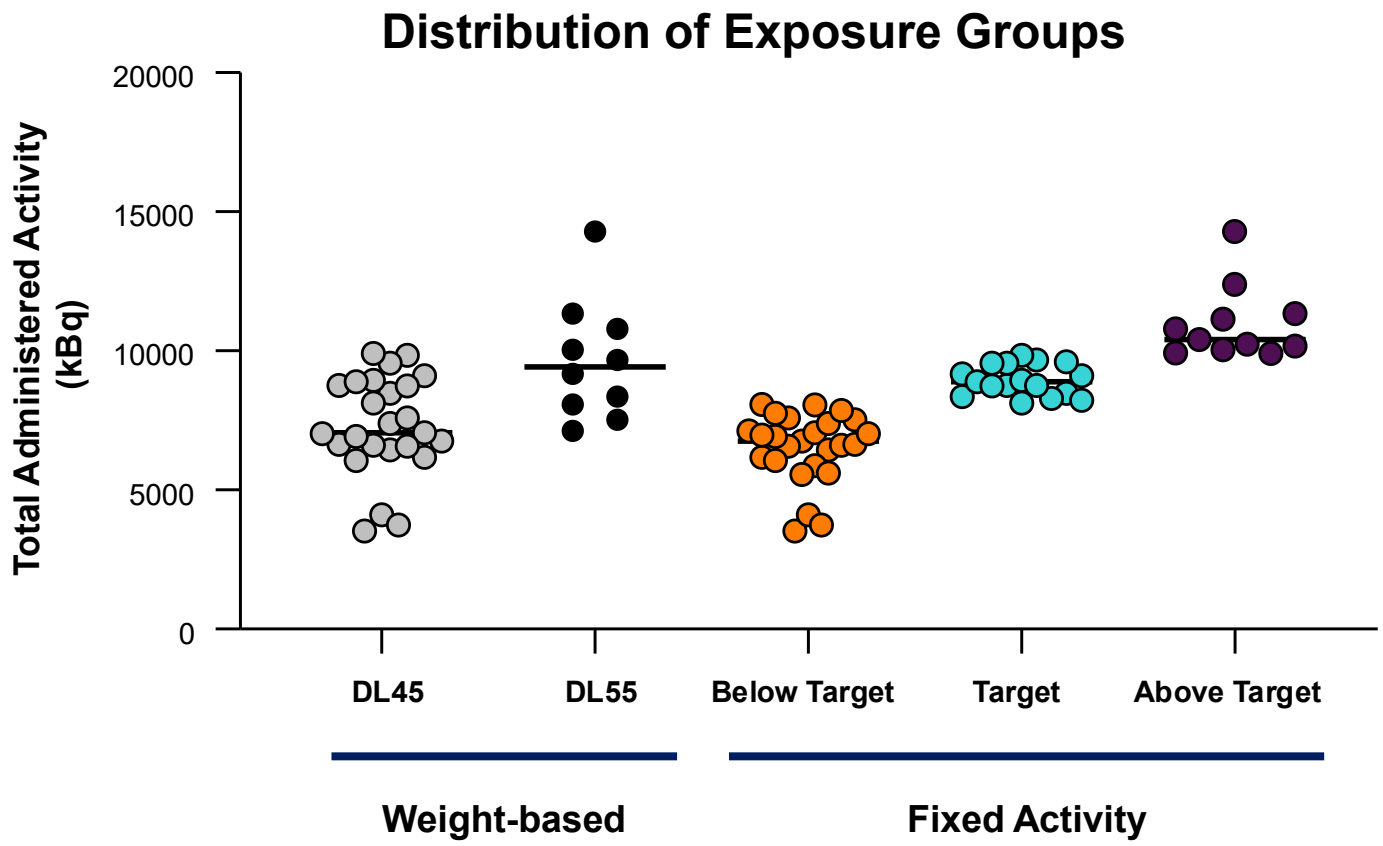
BOIN = Bayesian optimal interval, DLs = dose levels, PARPi = PARP inhibitor

Weight-based Administration in CONVERGE-01 Facilitated Fixed Activity Dose Selection

All patients treated by weight-based dosing in CONVERGE-01 were regrouped by total administered activity for analysis

Total Administered Activity

- Above Target
- On Target (9.0 MBq)
- Below Target



CONVERGE-01: Baseline Characteristics

Baseline Characteristics	n=35
Age, median (range)	72 (58, 83)
ECOG status, n (%)	
0	19 (54%)
1	16 (46%)
Sites of disease, n (%)	
Bone	31 (89%)
Lymph Node – Regional	11 (31%)
Lymph Node – Distant	11 (31%)
Lung	2 (6%)
Liver	1 (3%)
Other	2 (6%)
PSA – ng/mL	
C1D1, median (range)	40.12 (4.16, 1910)
PSADT, median (range) - months	1.77 (-6.85, 17.36)
LDH – U/L	
<260	26 (74%)
≥260	6 (17%)
Not Done	3 (9%)

Baseline Characteristics	n=35
Platelet Count – 1000/uL	
C1D1, median (range)	230 (103, 453)
Hemoglobin - g/dL	
C1D1, median (range)	11.5 (9.1, 14.8)
History of xerostomia[#]	48.6%

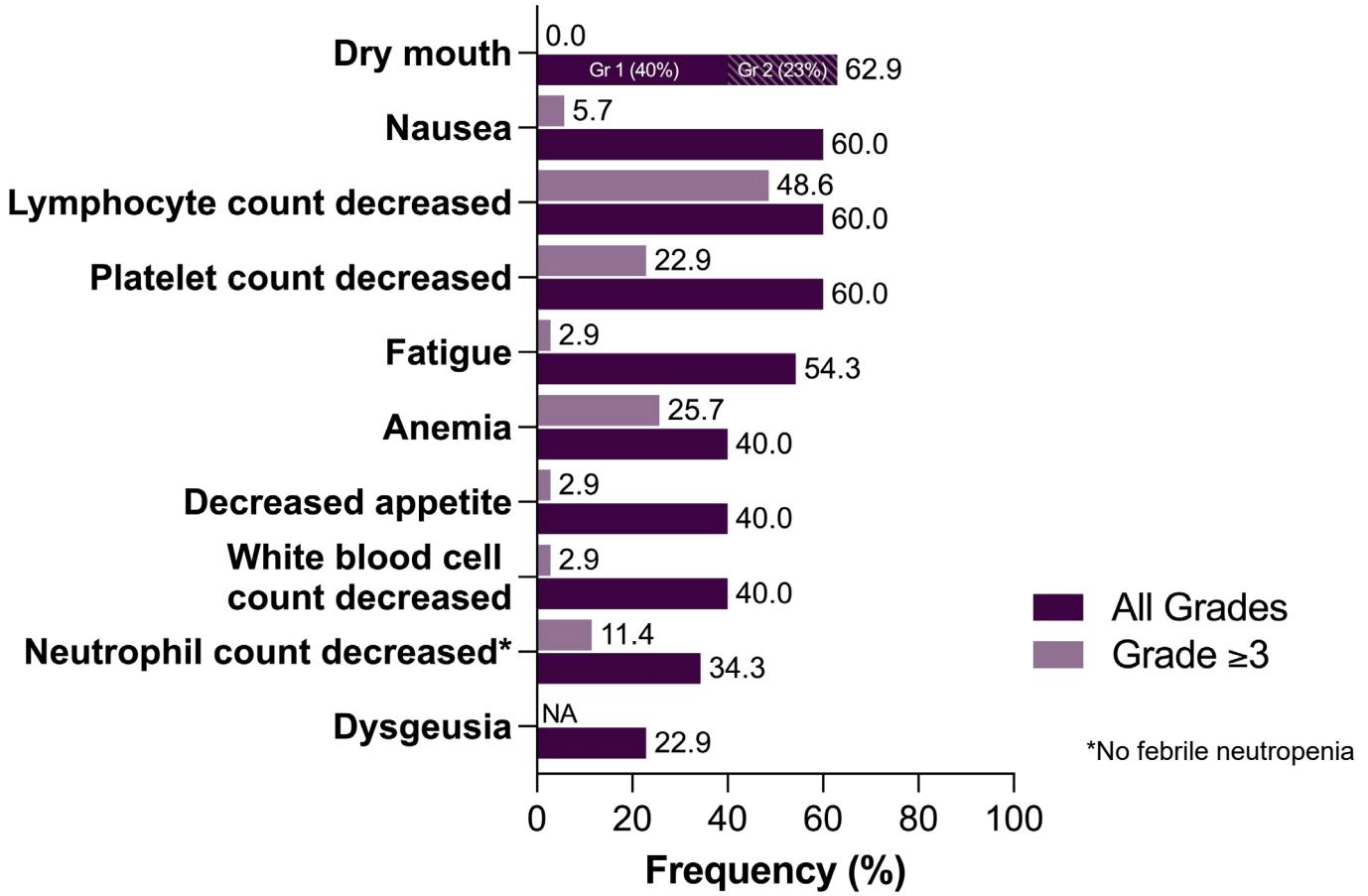
Prior Therapies	n=35
ARPI Exposure, n (%)	35 (100%)
1	14 (40%)
2	19 (54%)
>2	2 (6%)
Taxane Exposure*	28 (80%)
Docetaxel	27 (77%)
Cabazitaxel	2 (6%)
None	7 (20%)
Lu-PSMA cycles, median (range)	6 (2-6)
<4	n=8 (23%)
≥4	n=27 (77%)

[#]Patient report of xerostomia with Lu-PSMA and/or active xerostomia during screening.
*One participant's medical history included exposure to two taxanes due to switching to cabazitaxel after experiencing toxicity on docetaxel.

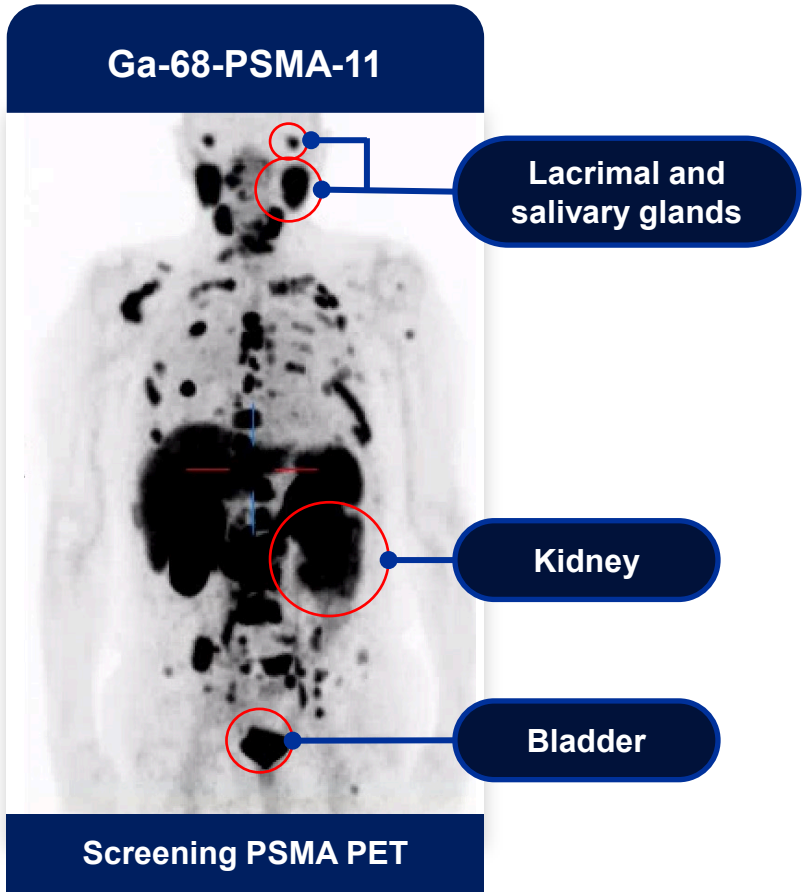
CONV01-α was Well-tolerated with No Dose Limiting Toxicities

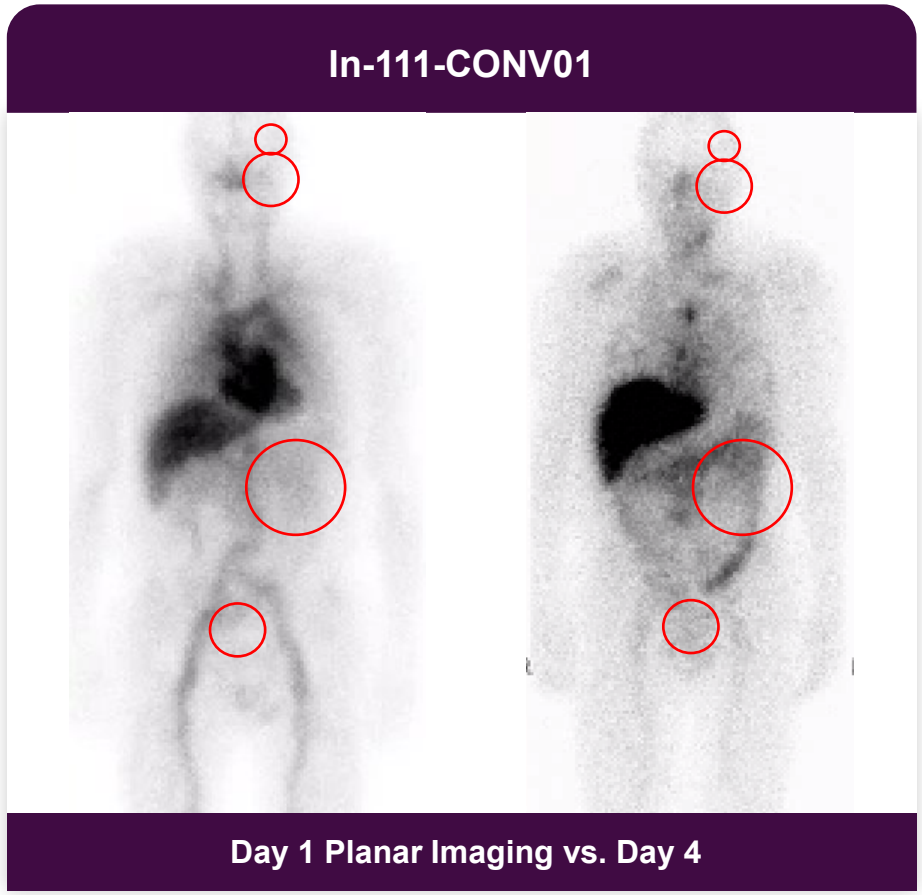
- Most common treatment-emergent adverse events (TEAEs) are hematologic, digestive, and constitutional events
- Grade ≥3 TEAEs are clinically-manageable, generally transient
- No treatment-related events led to treatment discontinuation
- 48.6% of patients had xerostomia with Lu-PSMA or at screening
- All high-grade anemia was Gr 3, no transfusion-dependence

Treatment-Emergent Adverse Events – *10 Most Common*



CONV01 is Not Visualized in the Salivary Glands or Urinary System



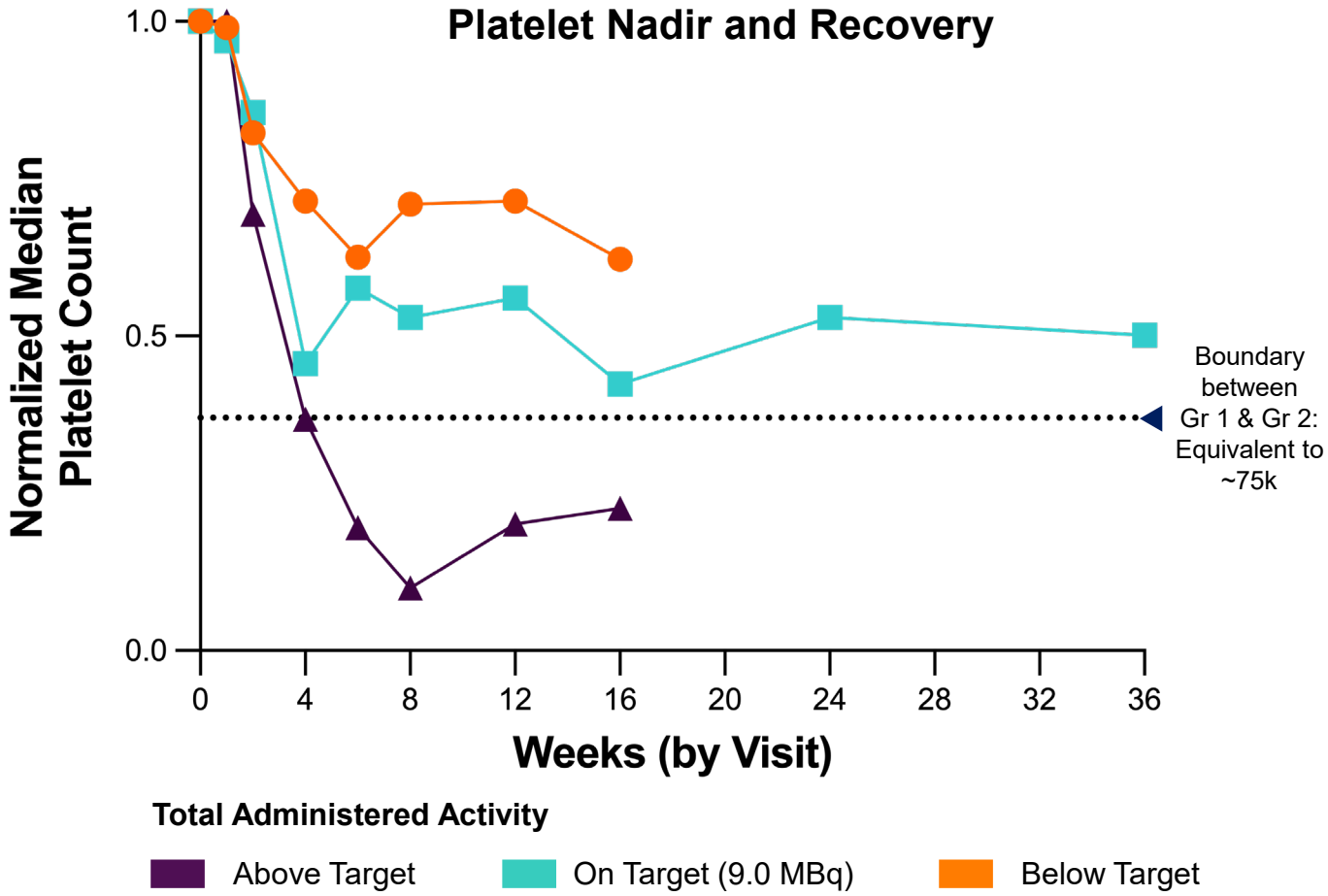


Thrombocytopenia is Predictable, Dose-related, and Clinically-Manageable

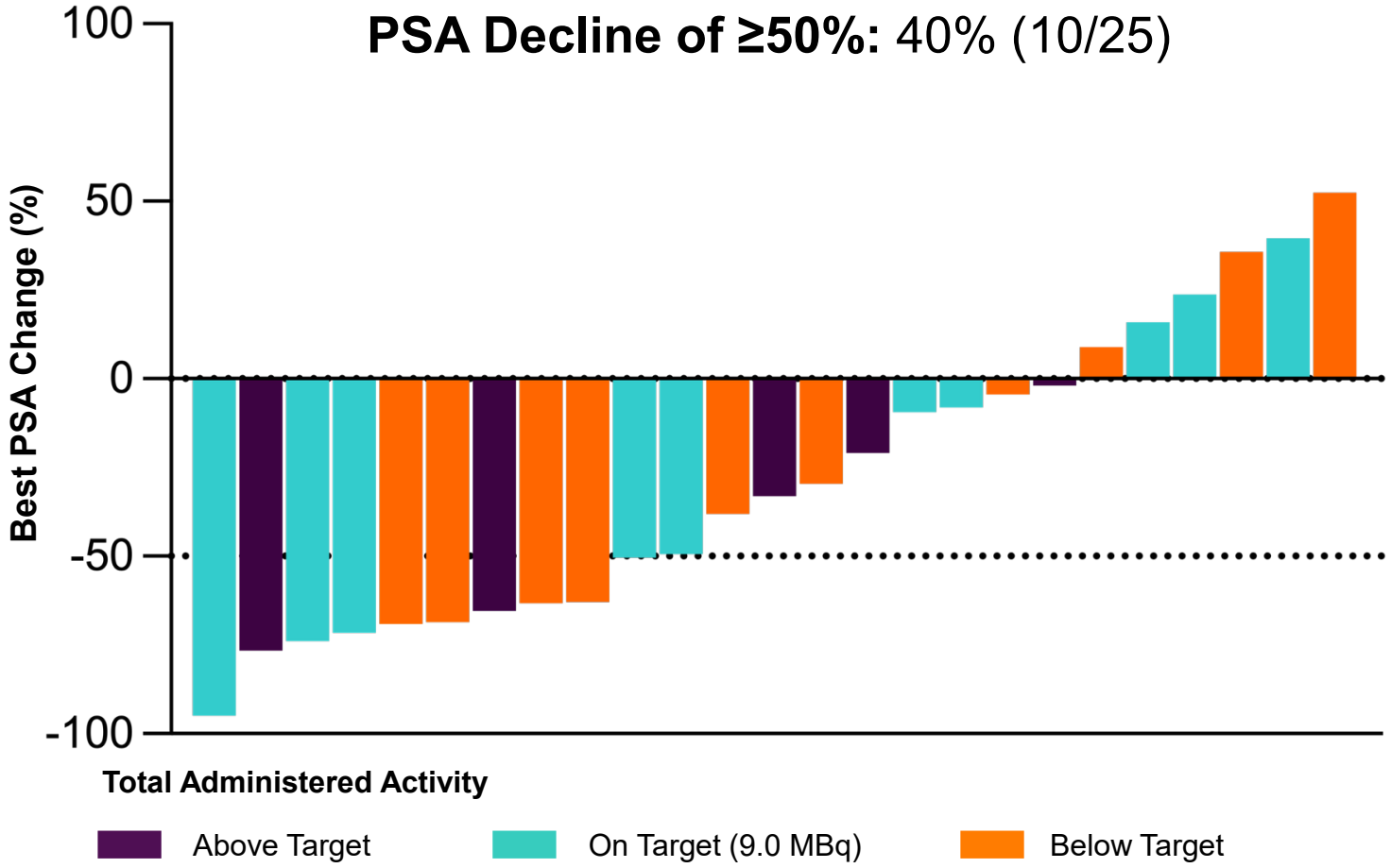
Across exposure groups, the populations:

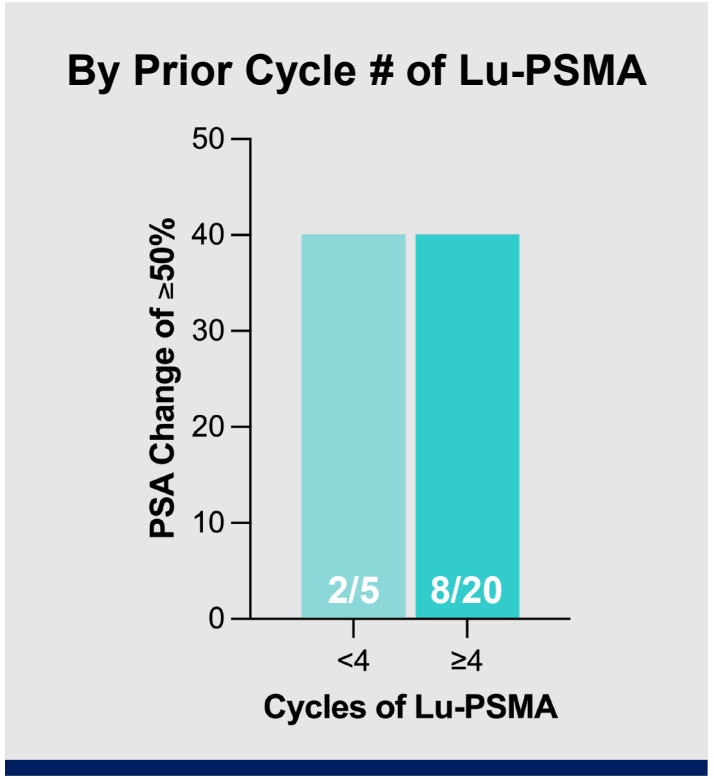
- Experience an early nadir
- Evidence of recovery
- Little evidence of clinical risk
- Support for Target Dose range

Patients evaluable in each group: Above Target (n=5), On Target (n=12), Below Target (n=17)



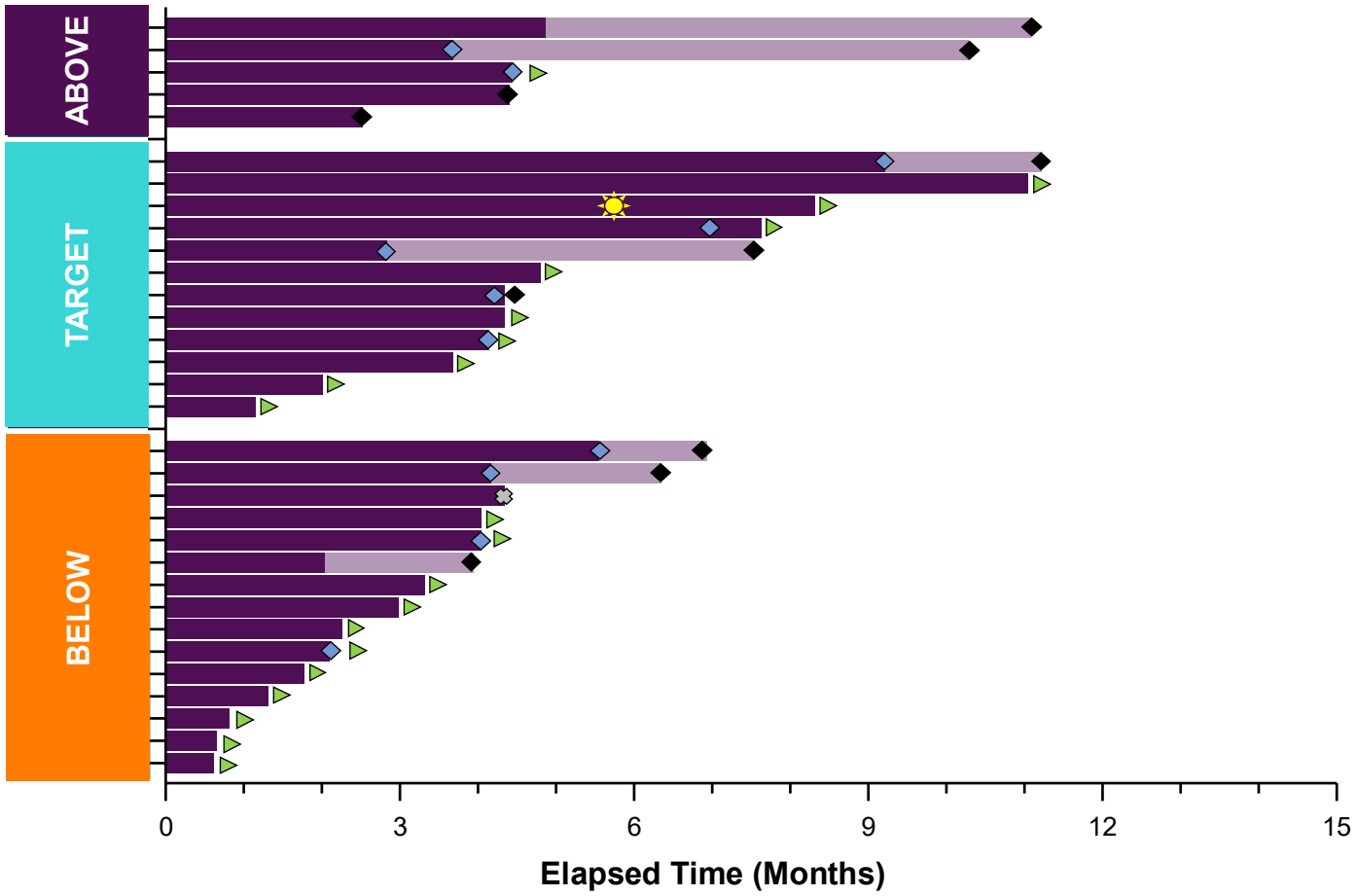
CONV01-α Demonstrates Promising Activity in Lu-PSMA-exposed Patients





**Participants were considered evaluable if they had ≥12 weeks of follow up, clinical/radiographic progression before 12 weeks, or PSA decline of ≥50% at any time.*

PSA50 Rates are Similar Across Dose Groups, the Target Dose Group Demonstrates Greater Durability



Short-term Follow-up*
Long-term Follow-up
Remains on Study
Withdrawn
Radiographic PR
Radiographic PD
Death

Total Administered Activity

- Above Target
- On Target (9.0 MBq)
- Below Target

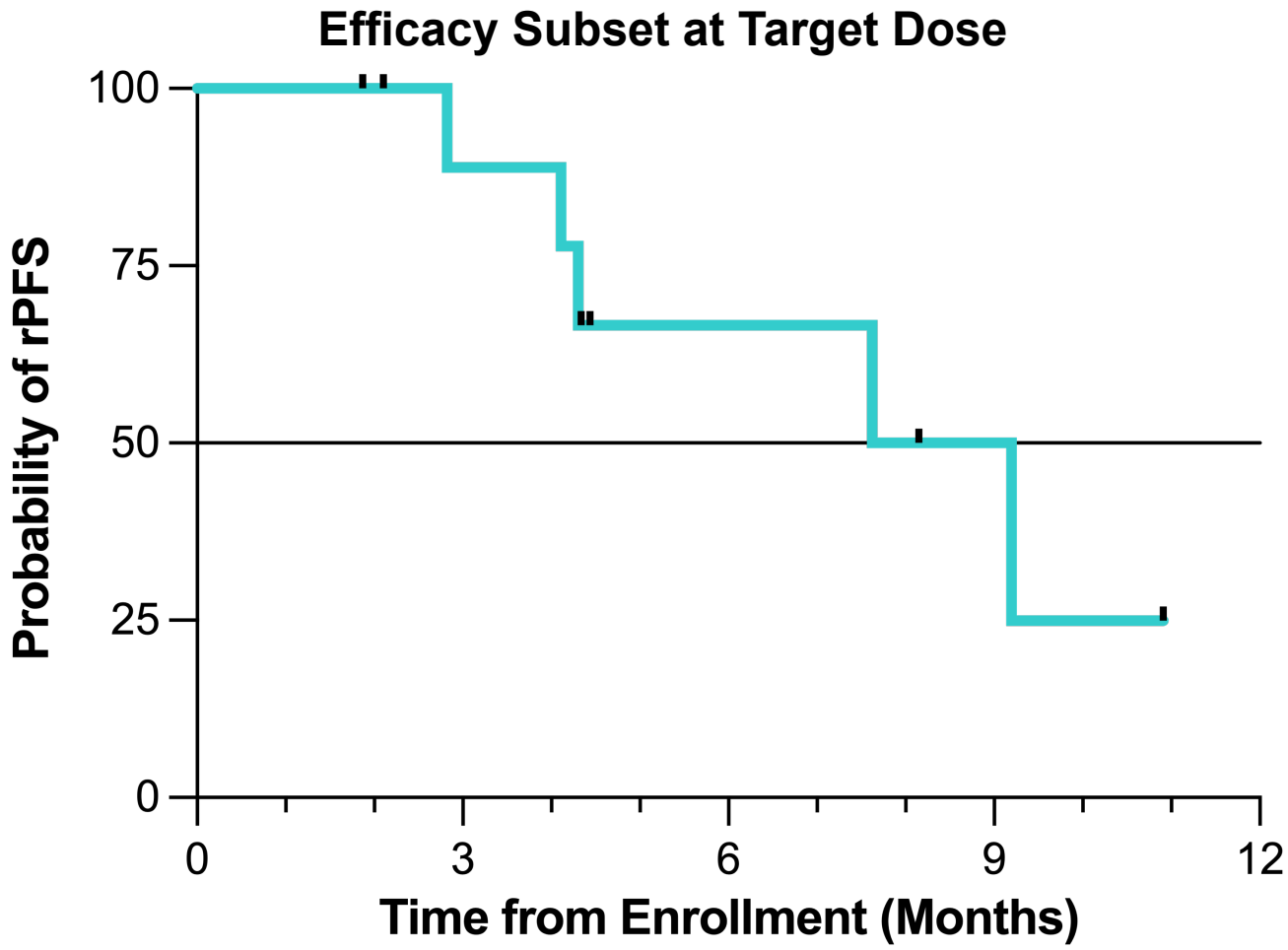
**Following completion of treatment, patients enter short-term follow-up and are monitored until disease progression per RECIST v1.1 and/or PCWG3, initiation of new therapy, unacceptable toxicity, or withdrawal. After progression, patients enter long-term follow-up to be monitored for survival*

Preliminary Radiographic PFS (rPFS) Supports Clinical Benefit in a High Unmet Need Population

- **Median rPFS is 8.41 months** (95% CI 2.83-inf) among 11 participants in the Target dose range (9.0 MBq)
- Median follow-up 8.14 months (2.10-inf)

Total Administered Activity

On Target (9.0 MBq)



Key Takeaway Points

1	2	3
CONV01-α is safe for patients with prior exposure to Lu-177-PSMA radioligand therapy (Lu-PSMA)	Clinically-manageable hematologic toxicity. No nephrotoxicity or high-grade xerostomia	CONV01-α has promising activity and durability in patients previously treated with Lu-PSMA

- *CONVERGE-01 continues in taxane- and Lu-PSMA-naïve patients*
- *A pivotal phase 3 study is in preparation in Lu-PSMA-exposed patients*

Acknowledgements

- Deep gratitude to the patients and their families for their participation in CONVERGE-01
- Thank you to the Investigators and their staff at all trial sites

Backup Slides

Alpha (α) particles are significantly more potent and precise than beta (β) particles

α (Ac-225)		β (Lu-177)
7,300	**Relative particle mass**	1
50 μm	**Max range in tissue**	1,700 μm
100 keV/μm	**Linear energy transfer**	0.2 keV/mm
Double strand breaks	**Type of DNA damage generated**	Single strand breaks
1	**DNA hits required for cell death**	1,000

1. Henriksen G et al. *J Nucl Med*. 2003;44(2):252-259. 2. Kozempel J et al. *Molecules*. 2018;23(3):581. 3. Hosono M et al. *Ann Nucl Med*. 2018;32(3):217-235. 4. Kassis A. *Semin Nucl Med*. 2008;38:358-366. 5. Nayak T et al. *Cancer Biother Radiopharm*. 2005;20(1):52-57. 6. Wadas TJ et al. *AJR Am J Roentgenol*. 2014;203(2):253-260.