

Cutting edge research into Frontotemporal Dementia and Motor Neurodegenerative Syndromes



Randomized, Double-Blind, Placebo-Controlled Study in Early Symptomatic Amyotrophic Lateral Sclerosis Patients on Stable Background Therapy to Assess Bioenergetic Catalysis with CNM-Au8 to Slow Disease Progression in ALS

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Disclosures & Acknowledgements

 MCK and the University of Sydney have received research funding from Clene to undertake Rescue-ALS

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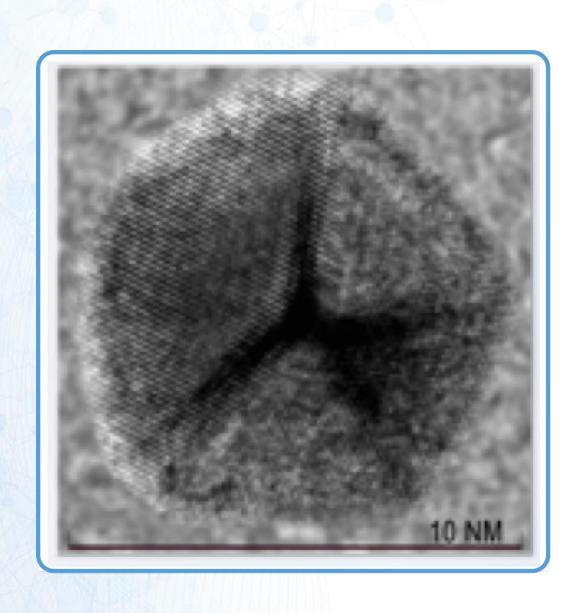


 We thank the study participants and their families for their willingness to support clinical research



CNM-Au8® | Catalytically Active Au Nanocrystals Improve Cellular Energy Production

CNM-Au8®
Nanocrystal



Clean Surfaced, Highly Faceted
Shape Enhances Catalytic
Activity

Electrons (e-)
Move Freely Across
Nanocrystal Surface

Vertices, Edges, & Facets
Key to Catalytic Activity

Mechanistic Effects









Increased Energy Production & Utilization





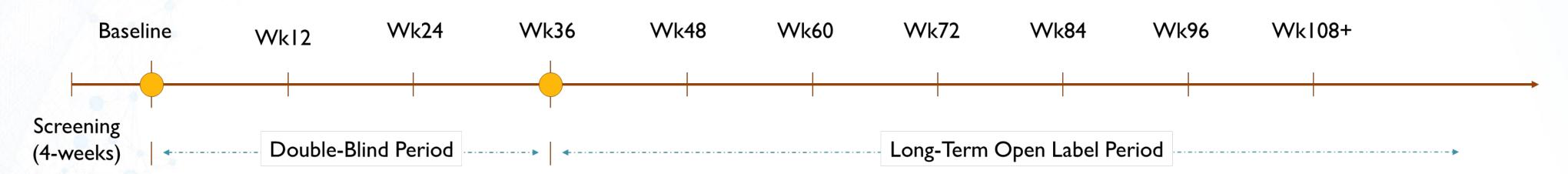






Design & Baseline Characteristics

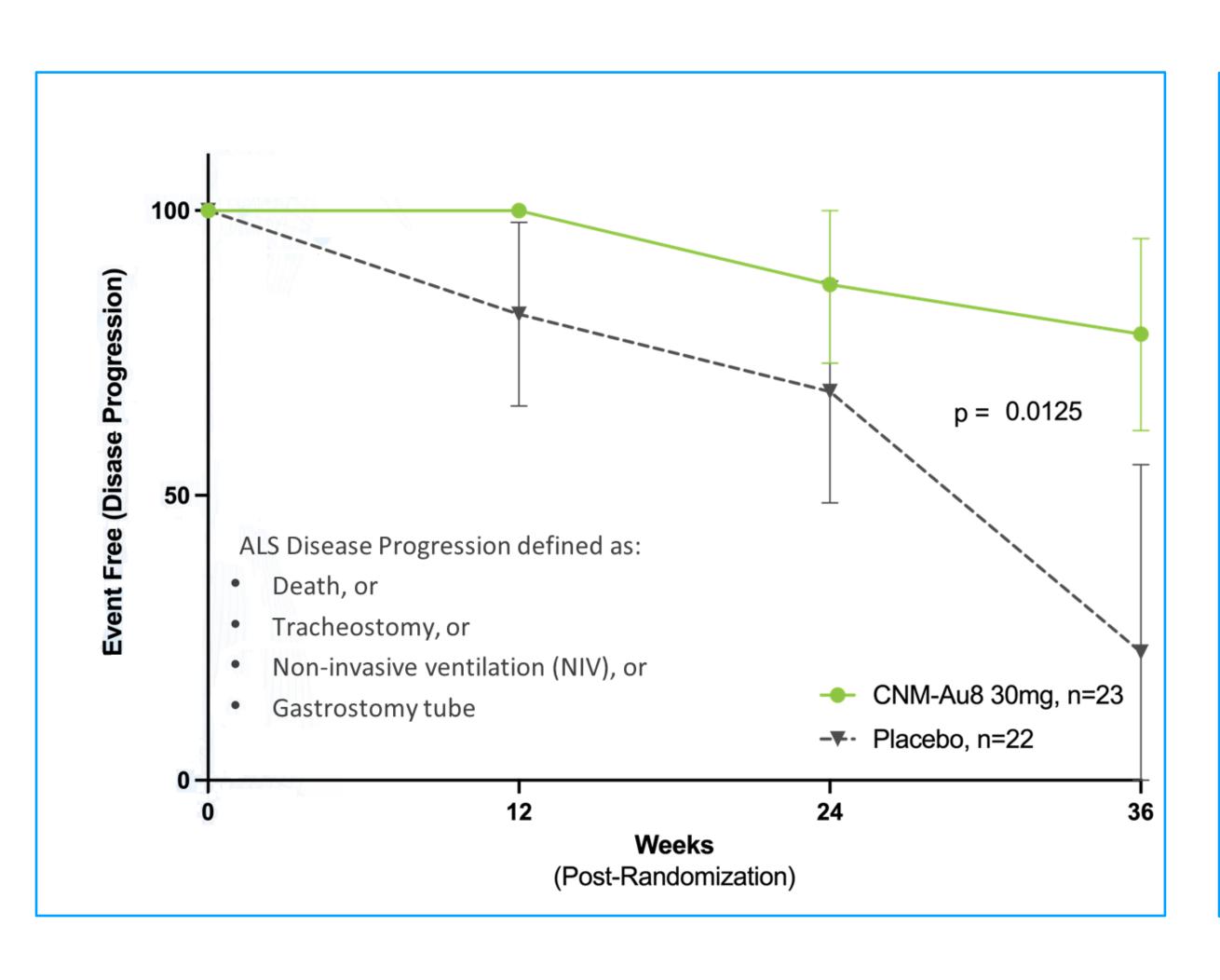
36-Week Treatment Blinded Treatment with Long-Term Open-Label Follow-Up

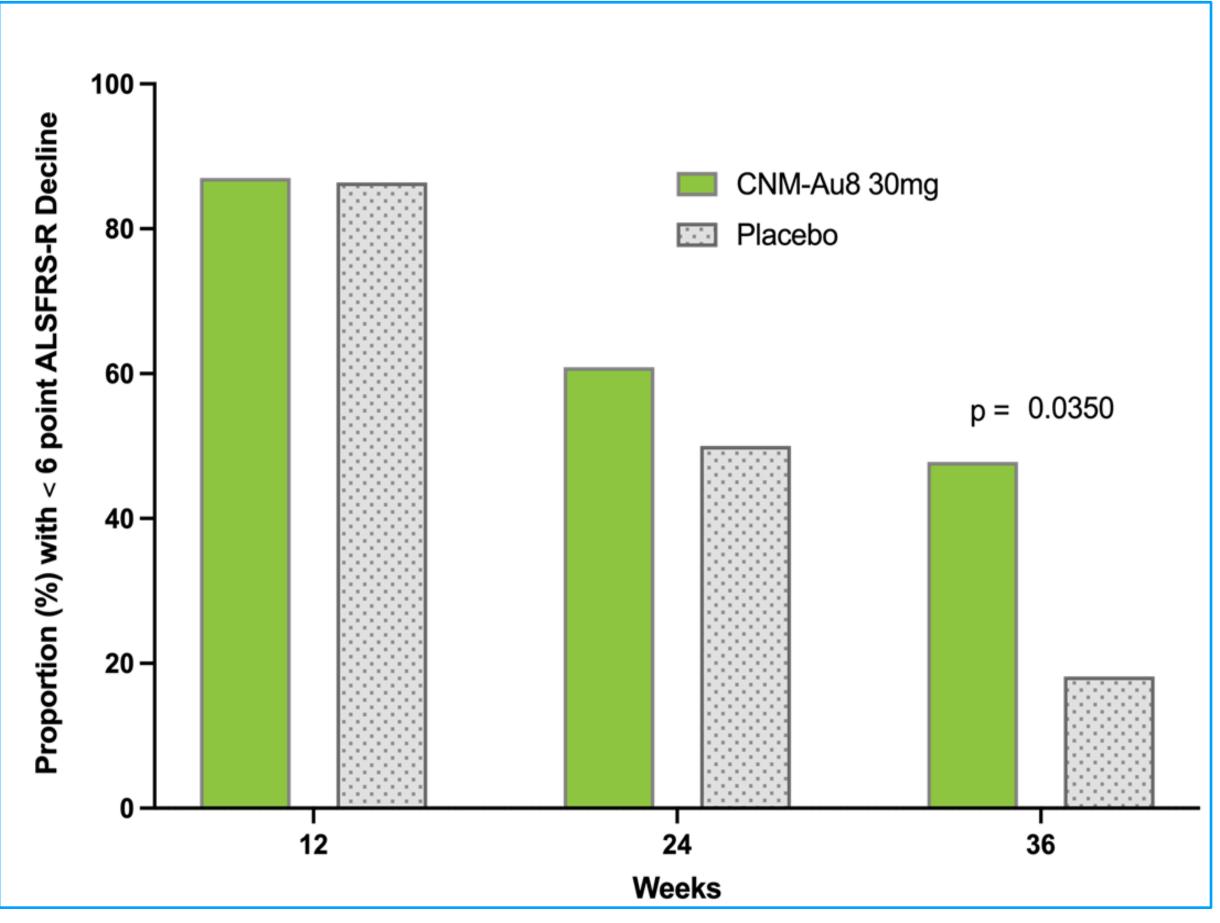


Baseline Value mean (sd)	Age (yrs)	Sex n, (%) Male Female	Onset Site n, (%) Limb Bulbar	Months from Onset	FVC (% pred.)	ALSFRS-R Score	ENCALS Risk Score	MUNIX Sum
All (n=45)	59.1	M: 26 (58%)	L: 33 (73%)	15.8	81.5	38.7	-4.4	378.2
	(12.3)	F: 19 (42%)	B: 12 (27%)	(9.3)	(16.7)	(6.0)	(1.8)	(175.3)
CNM-Au8 30mg (n=23)	57.0 (13.3)	M: 13 (57%) F: 10 (43%)	L: 16 (70%) B: 7 (30%)	15.5 (7.6)	84.5 (18.3)	38.6 (6.6)	-4.6 (1.7)	380.2 (198.0)
Placebo	61.3	M: 13 (59%)	L: 17 (77%)	16.1	78.2	38.8	-4.2	376.2
(n=22)	(10.9)	F: 9 (41%)	B: 5 (23%)	(10.9)	(14.5)	(5.4)	(1.8)	(152.7)

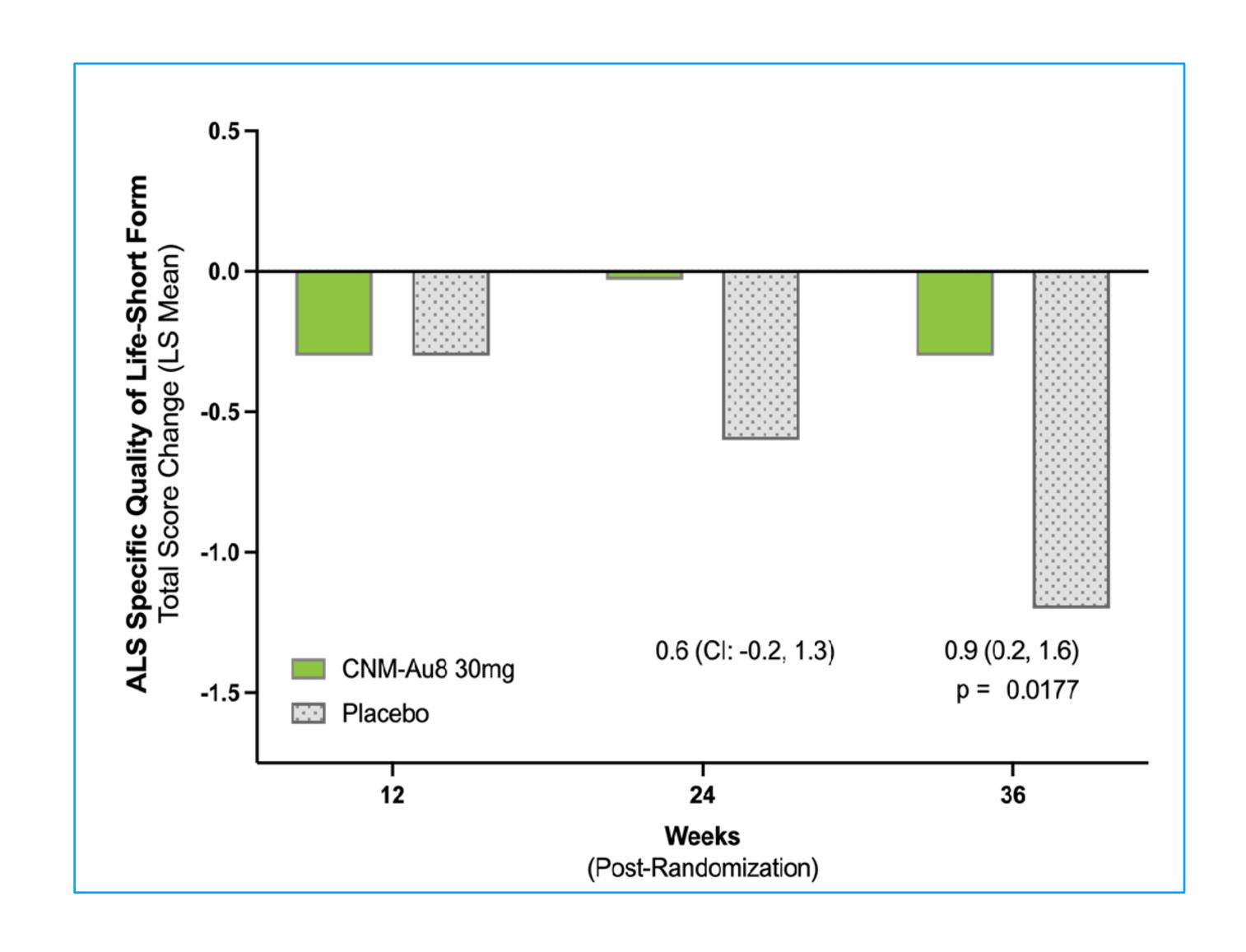


Significant slowing in disease progression & ALSFRS-R 6-point decline

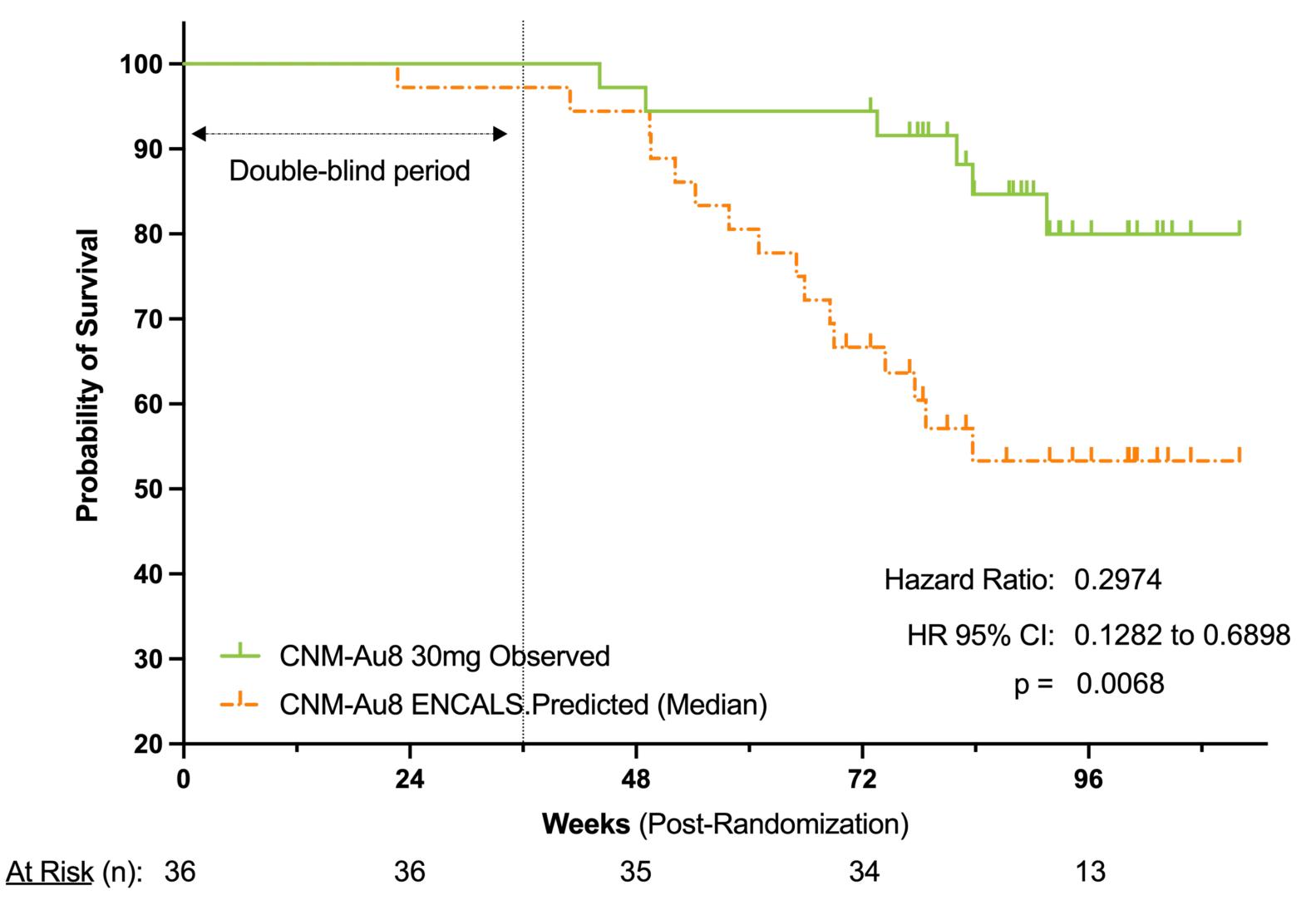




Significant improvement in quality of life

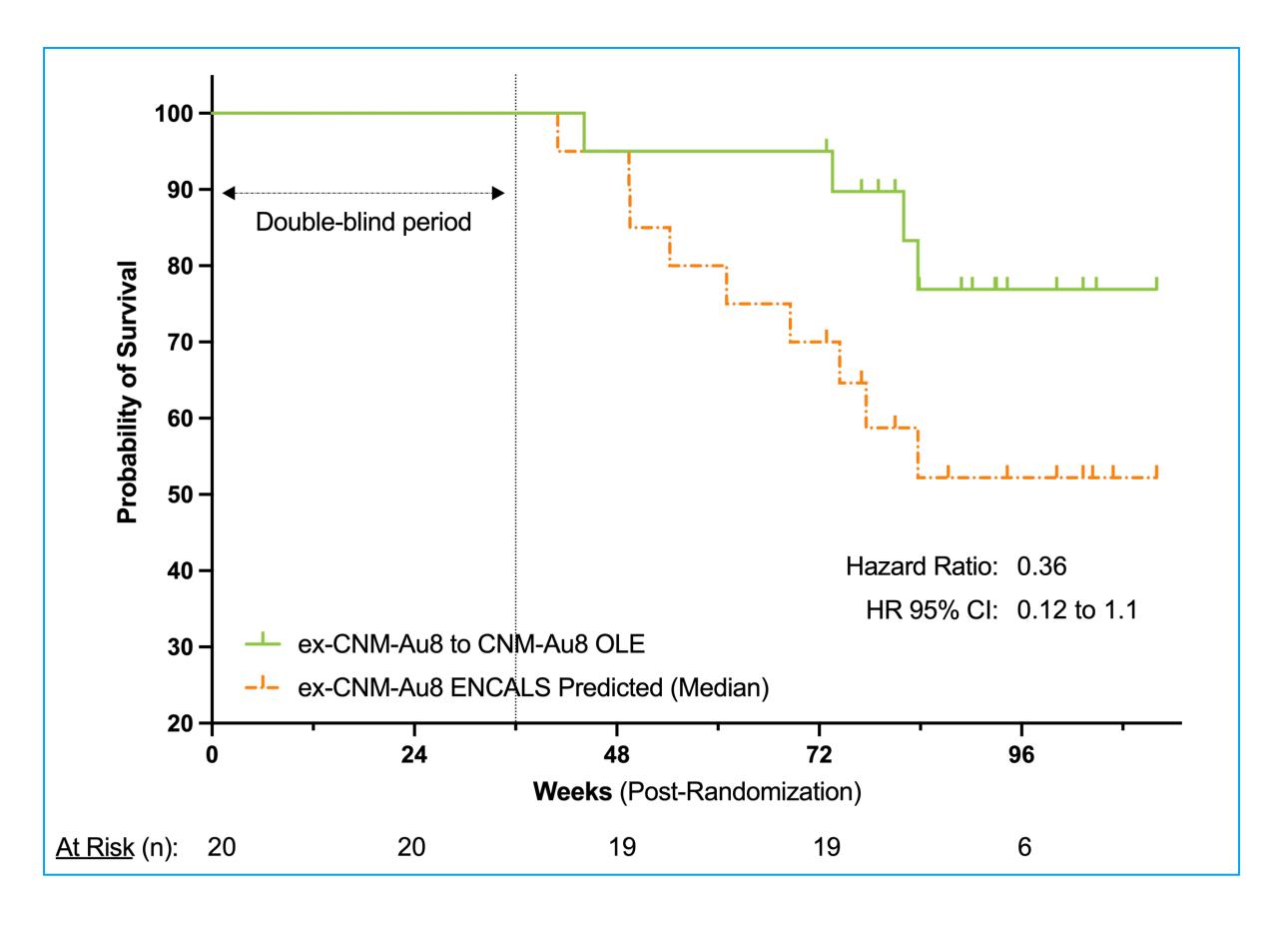


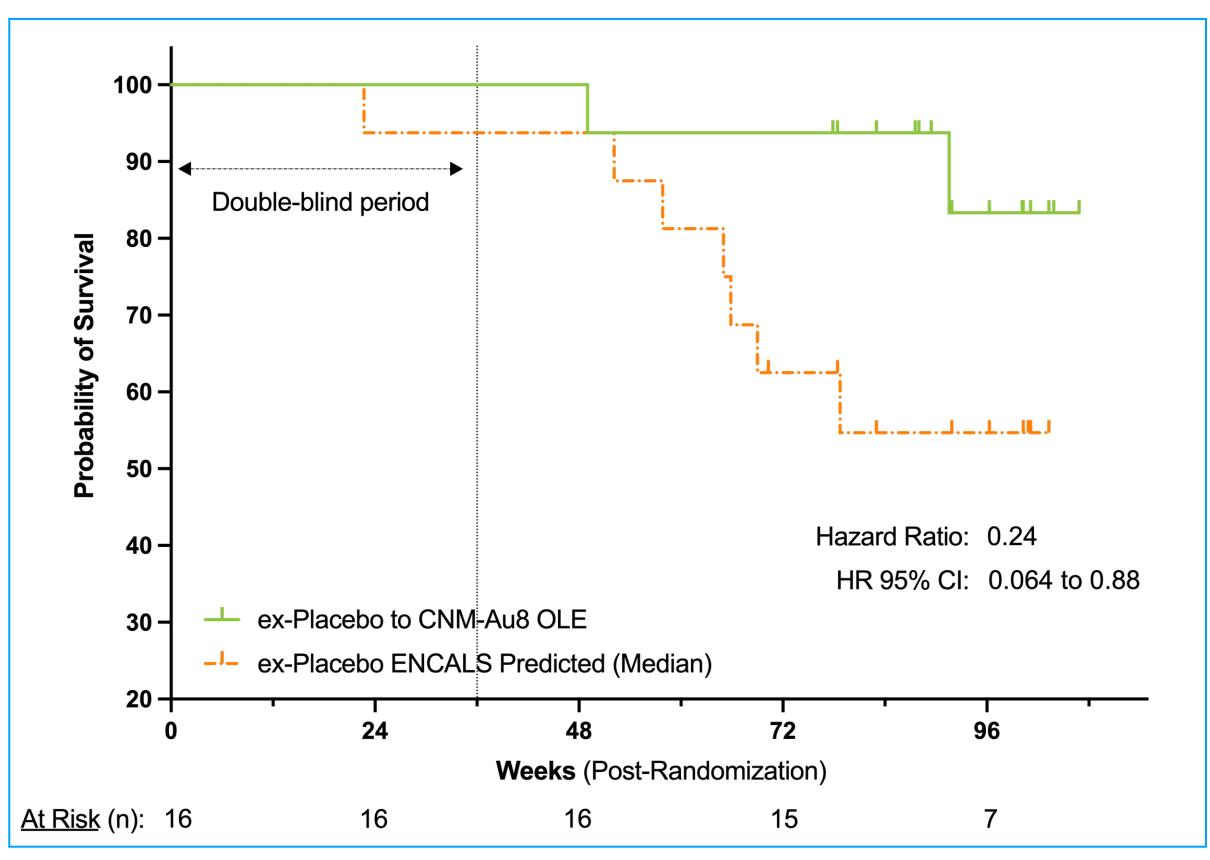
Long-Term Survival in OLE Participants: 70% Improvement vs. Predicted Survival



• All OLE participants. Data censored as of 10-March-2022. Vital status and date of death (as applicable) captured for all subjects withdrawn from the study. ENCALS median survival estimate from baseline characteristics.

Consistent Survival Effect in ex-Placebo Participants





• All OLE participants. Data censored as of 10-March-2022. Vital status and date of death (as applicable) captured for all subjects withdrawn from the study. ENCALS median survival estimate from baseline characteristics.

Conclusions

- Well tolerated and safe in ALS
- Evidence of CNM-Au8 therapeutic activity:
 - Evidence for improved survival
 - > Significant reduction in functional decline
 - Significant slowing in disease progression
 - > Improvement in quality of life

