Evidence for A Survival Benefit with CNM-Au8 Treatment: Interim Results from the RESCUE-ALS Trial Long-Term Open Label Extension

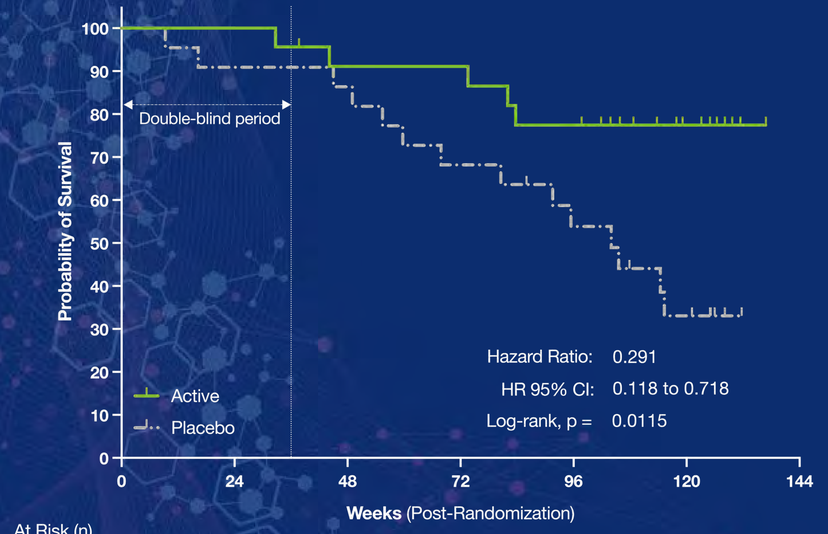
RESCUEALS
Long-Term OLE

Steve Vucic PhD, DSc, FRACP, FAHMS[1], Parvathi Menon PhD, FRACP[1], William Huynh PhD, FRACP[2], Colin Mahoney, PhD, MB, MRCPI[2], Karen S. Ho, PhD MSc[3], Austin Rynders, RN[3], Jacob Evan[3], Jeremy Evan, PA-C[3], Robert Glanzman, MD FAAN[3], Michael T. Hotchkin[3], Matthew C. Kiernan PhD, DSc, MBBS, FRACP, FAHMS
[1]Concord Repatriation General Hospital, University of Sydney, Australia; [2]Brain and Mind Centre, University of Sydney, Australia; [3]Clene Nanomedicine, Salt Lake City, UT, USA

CONCLUSION: CNM-Au8 treatment improved long-term survival with decreased mortality risk >70% vs. original placebo randomization, and compared to ENCALS predicted median survival

Long Term Survival
All Randomized | Active vs. Placebo
Original Treatment vs. No OLE or OLE Delayed Start

Long-Term Survival: Originally Randomized Active vs. Placebo
Interim Analysis (31-Aug-2022), ITT Population, All Subjects from Randomization
(Long-term vital status including all study withdrawals)

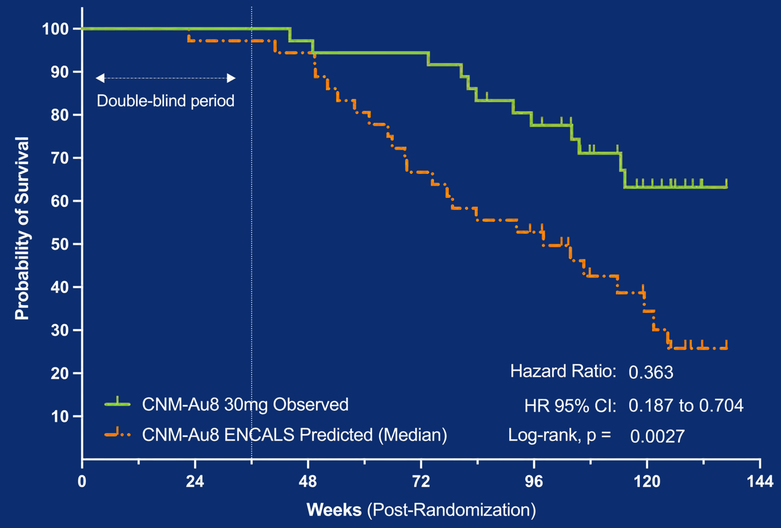


At Risk (n)

CMM-Au8:	23	23	20	20	17	9
Placebo:	22	20	19	15	10	6

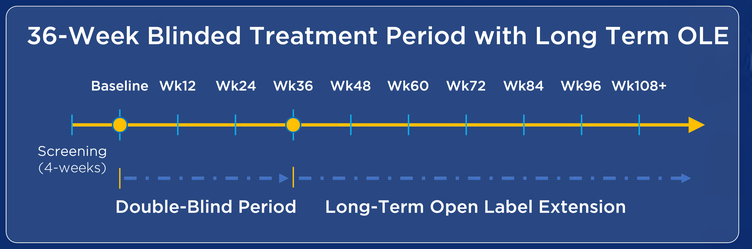
All OLE Participants | Survival
Observed Survival vs.
ENCALS Predicted Median Survival

All Open-Label Participants Long-Term Observed Survival vs. ENCALS Predicted Median Survival
All CNM-Au8 + Placebo Subjects Entering OLE
Survival from Randomization, ITT Population Subset



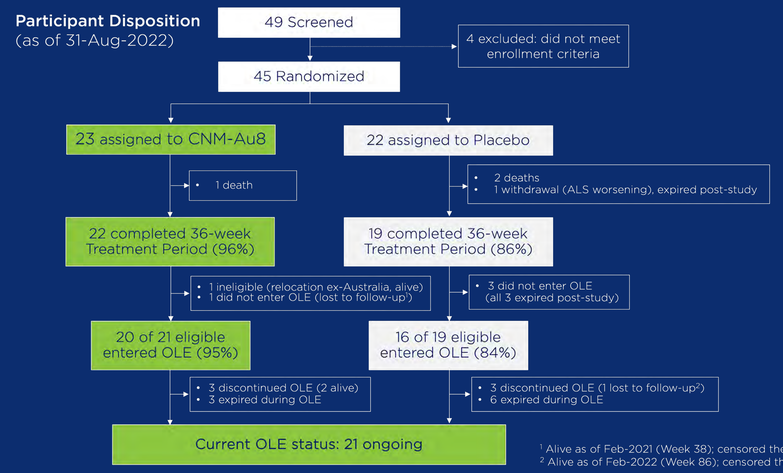
At Risk (n): 36 36 35 34 27 14

Study Design Scheme



- Early symptomatic ALS (within 2-years onset or 1-year diagnosis)
- Randomized (1:1, CNM-Au8 30 mg or placebo)

Participant Vital Status by Treatment Group



[1] Alive as of Feb-2021 (Week 38); censored thereafter
[2] Alive as of Feb-2022 (Week 86); censored thereafter

Notes: Time to all-cause mortality amongst participants originally randomized to CNM-Au8 compared to participants originally randomized to placebo through 31-Aug-2022. Vital status and date of death (as applicable) were captured for all subjects withdrawn from the study. Lost-to-follow-up (active, n=1; placebo, n=1) censored as of the date of last study contact (Active: Feb-2021; Placebo: Feb-2022). All OLE ex-placebo CNM-Au8 transitioned participants within the placebo group. All alive subjects are right censored as of 31-Aug-2022. **Acknowledgements:** We thank the ALS study patients and their families for their support and willingness to engage in clinical research. We thank the site investigators for their research excellence and dedication to patients. We thank FightMND of Australia for substantially funding the RESCUE-ALS trial.

CLene NANOMEDICINE