NM101 Alzheimer's Disease Phase 3 Topline Readout

November 2023

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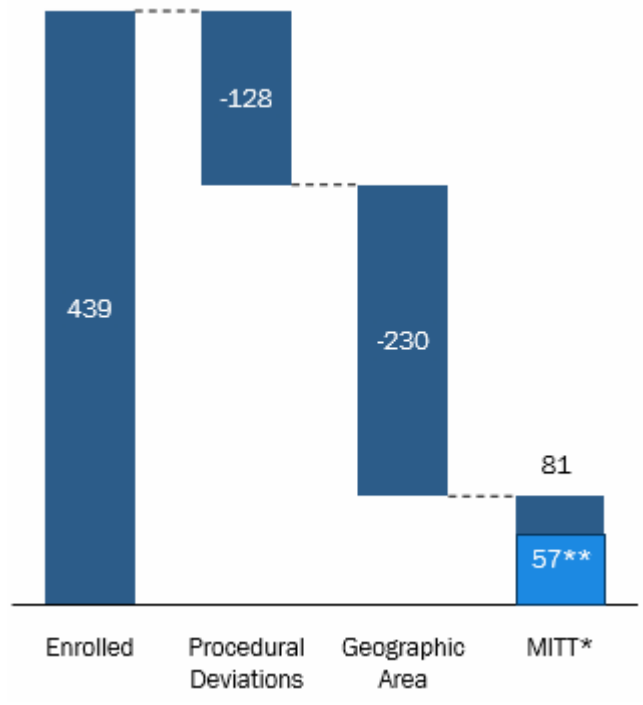
Overview

- NE3107 appears to be biologically active
- Cognitive, functional, biomarker efficacy signal suggest that NE3107:
  - Has a treatment advantage equal to or greater than results reported from clinical trials from approved monoclonal antibody treatments;
  - Associated with a benign safety profile
- Unanticipated exclusion of sites due to deviations led to study being underpowered. Adaptive feature of trial allows the Company to continue enrolling patients to reach statistical significance

Trial Timeline and Enrollment

- The company monitors blinded data to track safety and ensure timely data entry into the EDC
- The Company started noticing unusual data patterns when enough patients completed the trial. Pentara (a leading AD biostatistics firm) reviewed the blinded data and found:
  - Several sites had anomalous data (e.g., inconsistent patterns compared to historical data, large proportions of patients improving compared to baseline, unusual variability patterns)
  - All patients in a particular demographic group enrolled in this trial showed a data pattern not explainable based on disease progression and which substantially deviated from historical data for this demographic in other AD trials
  - Without unblinding and PK data, there was no way to identify the cause. Clear subgroup analyses identified: anomalous sites vs. other sites; identified demographic group vs. all others
- In parallel, BioVie had the first opportunity to start the data review process as sites started to finish patient-facing activities in early summer 2023
  - Noticed deviations from expectations (e.g., data patterns, missing data, copied/pasted MRI results, etc.)
- Retained 2 additional CROs to perform Quality Control (QC) visits and conduct Source Data Verification (SDV) on 100% of records maintained at the site
- CROs identified six sites with numerous and significant procedural deviations, which led us to:
  - Updated SAP to: 1) exclude all patients from affected sites; and 2) pre-specify a series of subgroup analyses
  - Amended our protocol: 1) Finalize CDR-SB and ADAS-Cog12 as primary endpoints based on prior FDA communications; 2) Create “adaptive trial” design
  - Reported the 6 sites to FDA’s Office of Scientific Investigations
- As data was unblinded, anomalous data from the identified demographic group was confirmed to be scientifically improbable. Furthermore, all patients in this demographic were associated with the previously identified anomalous sites, and virtually all of which were concentrated in a single geographic area. Accordingly, these sites were also excluded per our SAP and additionally referred to the FDA

Trial Enrollment patients



* Modified Intent-to-Treat population
** Per Protocol: compliance with protocol with adequate treatment exposure

Safety Profile

	NE3107	Placebo	Total
COVID-19	9.5%	17.6%	13.2%
Urinary tract infection	7.1%	8.8%	7.9%
Blood thyroid stimulating hormone increased	7.1%	2.9%	5.3%
Fall	2.4%	8.8%	5.3%
Headache	9.5%	0.0%	5.3%
Diarrhoea	4.8%	2.9%	3.9%
Dizziness	2.4%	5.9%	3.9%
Hypertension	2.4%	5.9%	3.9%
Nausea	4.8%	2.9%	3.9%
Pneumonia	4.8%	2.9%	3.9%
Vomiting	2.4%	5.9%	3.9%
Blood testosterone decreased	0.0%	5.9%	2.6%
Gastroenteritis viral	0.0%	5.9%	2.6%
Nasopharyngitis	4.8%	0.0%	2.6%
Rash	0.0%	5.9%	2.6%
Thyroxine decreased	2.4%	2.9%	2.6%
Tri-iodothyronine decreased	2.4%	2.9%	2.6%
Abdominal pain	0.0%	2.9%	1.3%
Abdominal pain upper	0.0%	2.9%	1.3%
Accelerated idioventricular rhythm	2.4%	0.0%	1.3%
Agitation	0.0%	2.9%	1.3%
Aortic valve replacement	2.4%	0.0%	1.3%

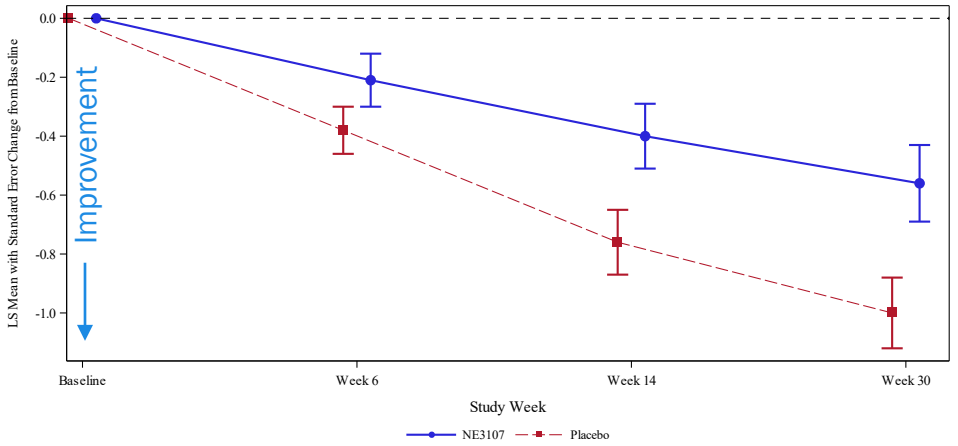
	NE3107	Placebo	Total
Atrioventricular block first degree	2.4%	0.0%	1.3%
Bile duct stone	0.0%	2.9%	1.3%
Blood lactate dehydrogenase abnormal	0.0%	2.9%	1.3%
Blood prolactin decreased	2.4%	0.0%	1.3%
Blood prolactin increased	2.4%	0.0%	1.3%
Blood sodium abnormal	0.0%	2.9%	1.3%
Blood sodium increased	0.0%	2.9%	1.3%
Blood thyroid stimulating hormone decreased	0.0%	2.9%	1.3%
Bronchitis	0.0%	2.9%	1.3%
Calculus bladder	2.4%	0.0%	1.3%
Cholelithiasis	2.4%	0.0%	1.3%
Cough	0.0%	2.9%	1.3%
Delirium	0.0%	2.9%	1.3%
Dementia Alzheimer's type	2.4%	0.0%	1.3%
Dermatitis	2.4%	0.0%	1.3%
Dysphagia	2.4%	0.0%	1.3%
Dysuria	0.0%	2.9%	1.3%
Electrocardiogram abnormal	2.4%	0.0%	1.3%
Eosinophil count increased	2.4%	0.0%	1.3%
Eustachian tube dysfunction	2.4%	0.0%	1.3%
Hordeolum	0.0%	2.9%	1.3%
Hyperkalaemia	2.4%	0.0%	1.3%

	NE3107	Placebo	Total
Hypothyroidism	2.4%	0.0%	1.3%
Hypoxia	0.0%	2.9%	1.3%
Incontinence	0.0%	2.9%	1.3%
Increased appetite	2.4%	0.0%	1.3%
Influenza	0.0%	2.9%	1.3%
Insomnia	2.4%	0.0%	1.3%
International normalised ratio increased	0.0%	2.9%	1.3%
Lethargy	2.4%	0.0%	1.3%
Lipase increased	0.0%	2.9%	1.3%
Muscle spasms	2.4%	0.0%	1.3%
Nephrolithiasis	0.0%	2.9%	1.3%
Nightmare	0.0%	2.9%	1.3%
Obsessive-compulsive disorder	2.4%	0.0%	1.3%
Oesophageal food impaction	0.0%	2.9%	1.3%
Optic ischaemic neuropathy	2.4%	0.0%	1.3%
Orthostatic hypotension	2.4%	0.0%	1.3%
Papilloedema	2.4%	0.0%	1.3%
Paranasal sinus discomfort	0.0%	2.9%	1.3%
Patient elopement	0.0%	2.9%	1.3%
Pelvic fracture	0.0%	2.9%	1.3%
Pharyngitis streptococcal	2.4%	0.0%	1.3%

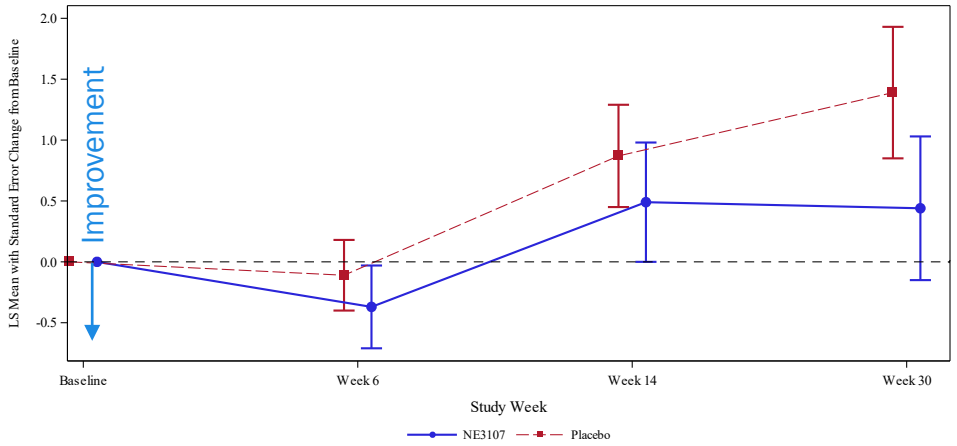
Data From All Sites In One Geographic Area Had Data Unlike All Other Sites

CDR-SB

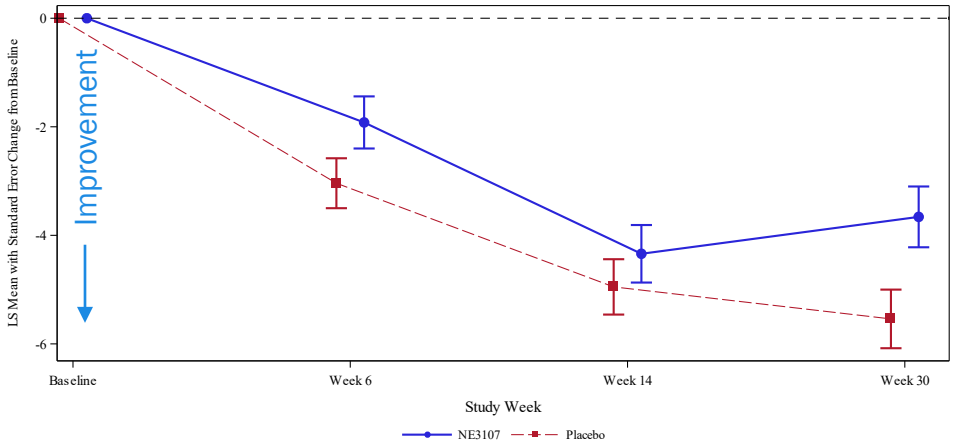
All Sites In Affected Geographic Area

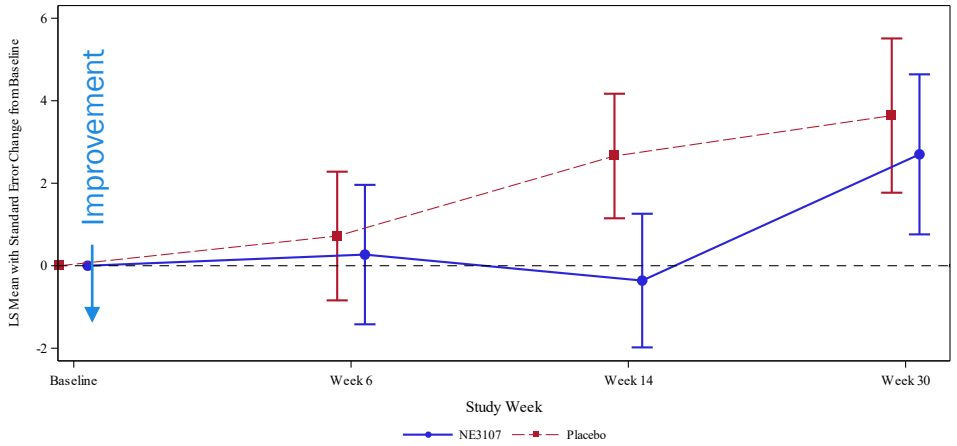


All Sites Oustide Affected Geographic Area



ADAS-Cog12





Baseline Characteristics of Per-Protocol Population

	NE3107	Placebo
N	24	33
Age – Mean years (Standard Deviation)	75.1 (6.4)	74.9 (5.9)
<70 years	25.0%	24.2%
>=70	75.0%	75.8@
Gender		
Male	37.5%	51.5%
Female	62.5%	48.5%
Race		
Asian	0%	9.1%
Black/African American	8.3%	3.0%
Caucasian	91.7%	84.8%
Mot Reported	0%	3.0%
CDR-SB – Mean (SD)	6.58 (2.5)	7.15 (2.3)
ADAS-Cog12 – Mean (SD)	31.0 (7.6)	34.4 (11.8)
MMSE – Mean (SD)	20.4 (2.6)	19.5 (3.0)
ADCS-ADL – Mean (SD)	58.8 (12.4)	56.0 (14.1)
ADCOMS – Mean (SD)	0.81 (0.2)	0.88 (0.3)

Week 30 Suggest NE3107 Advantage vs. Placebo is Comparable to or Better than Results Reported from Clinical Trials by Approved Medications

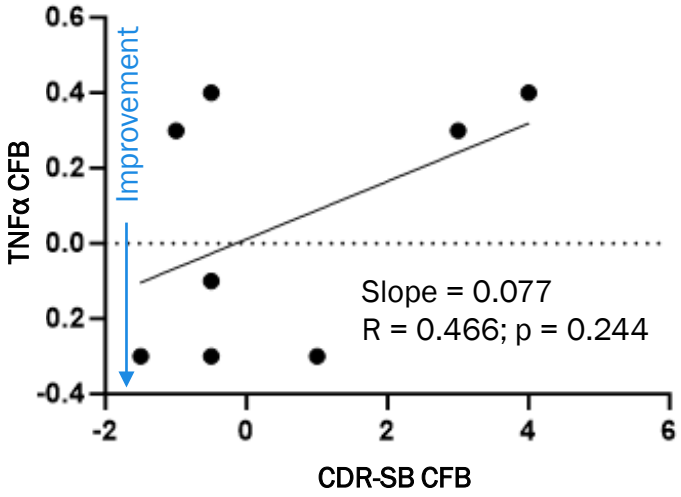
Change from baseline

	Placebo Decline	NE3107	NE3107 vs. Placebo	Comparator (18 mos)
CDR-SB (lower is improvement)	+1.39 (p=0.0125; n=26)	+0.44 (p=0.4522; n=24)	-0.95 (68%) (p=0.2278)	-0.45 (27%)[1] -0.39 (22%)[2]
ADAS-Cog12 (lower is improvement)	+3.64 (p=0.0545; n=23)	+2.70 (p=0.1618; n=24)	-0.94 (26%) (p=0.7212)	-1.44 (25%)[1] -1.40 (27%)[2]
MMSE (higher is improvement)	-2.54 (p=0.0007; n=26)	-1.52 (p=0.0547; n=24)	+1.02 (40%) (p=0.3181)	+0.6 (18%)[2]
ADCS-ADL (higher is improvement)	-6.54 (p<0.0001; n=27)	-3.46 (p=0.0435; n=24)	+3.08 (47%) (p=0.1620)	+2.0 (36%)[1]
ADCS-CGIC (lower is improvement)	+0.31 (p=0.2733; n=26)	-0.12 (p=0.6951; n=24)	-0.43 (139%) (p=0.2866)	
ADCOMS (lower is improvement)	+0.11 (p=0.0358; n=22)	+0.09 (p=0.1094; n=24)	-0.03 (27%) (p=0.7063)	-0.05 (23%)[1]

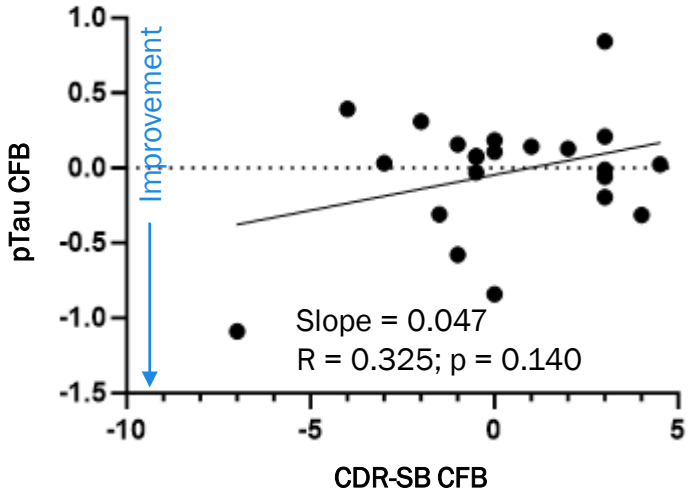
[1] Lecanamab after 18 months; van Dyck et al. *N Engl J Med* 2023;388:9-2
[2] Aducunumab after 18 months; Haeberlein et al. *J Prev Alz Dis* 2022;2(9):197-210

NE3107-treated Patients' Changes in CDR-SB Appears Correlated with Key Biomarkers

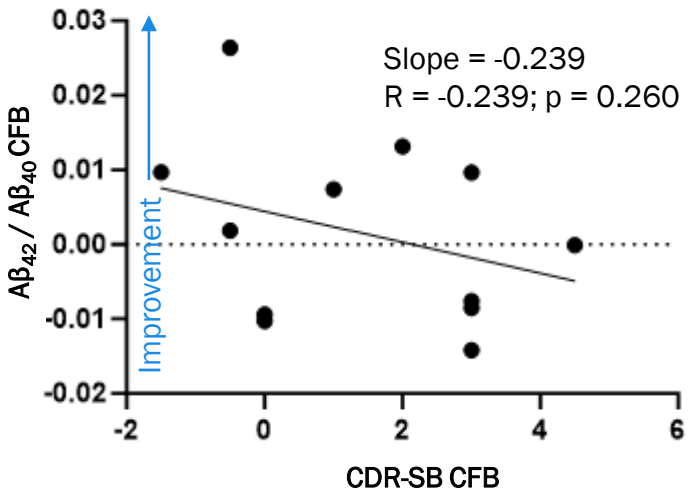
TNFα



Phospho-Tau



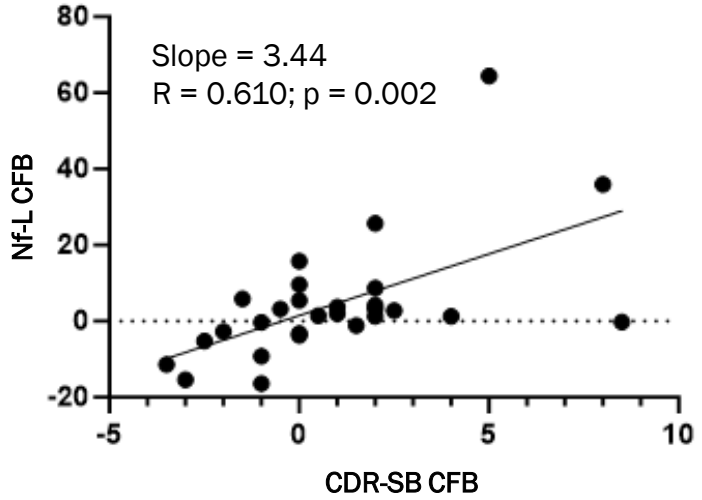
$A\beta_{42}$ / $A\beta_{40}$



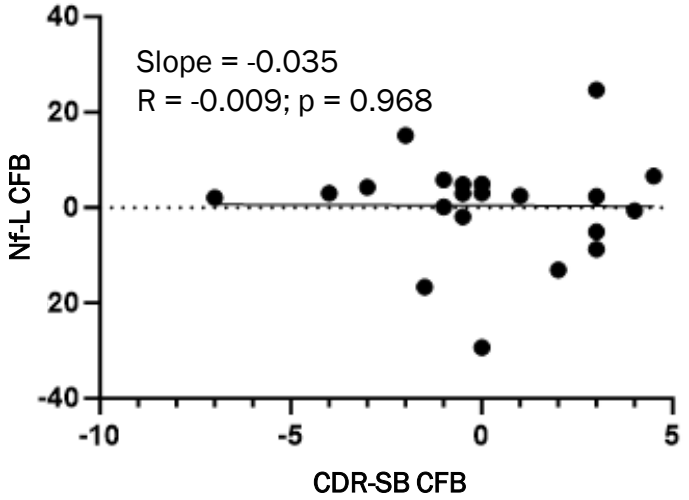
NE3107 Appears to Decrease the Neuroinflammatory Processes that Link Nf-L and GFAP to Cognitive Decline

Nf-L

Placebo

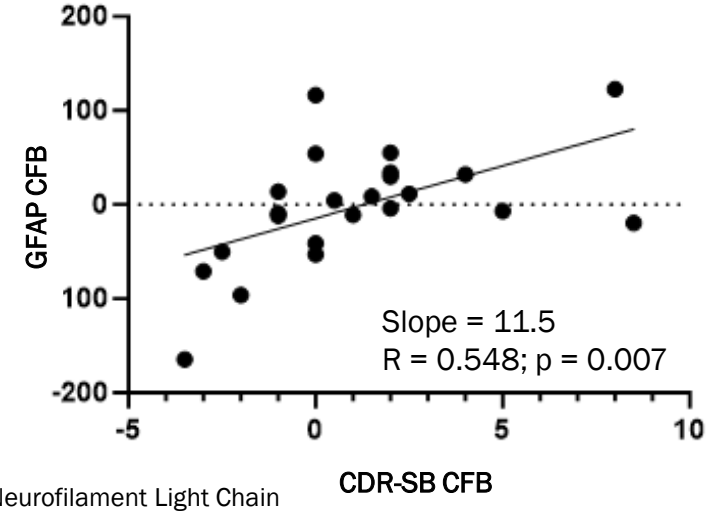


NE3107

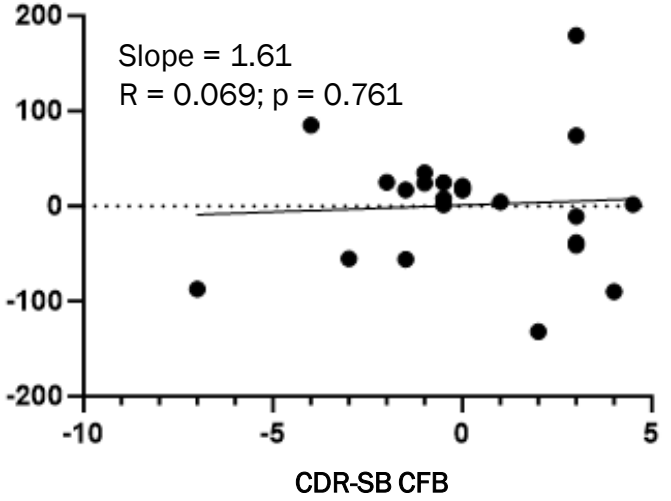


GFAP

Placebo



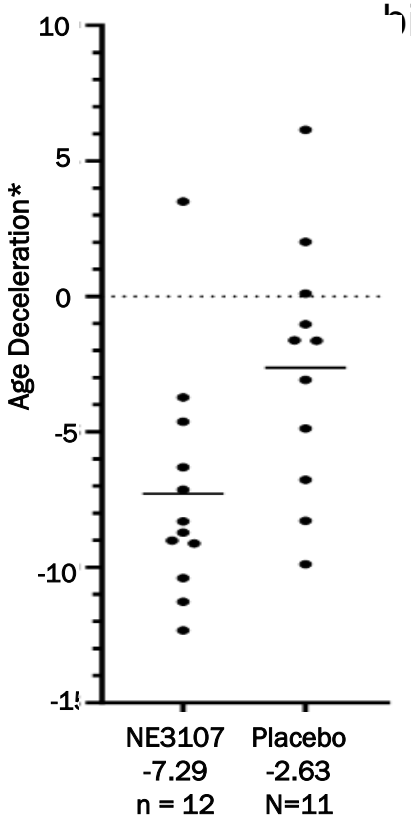
NE3107



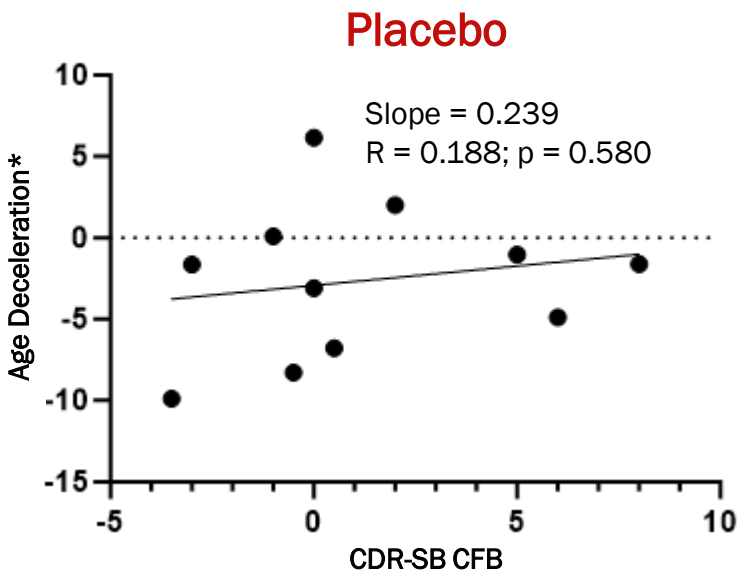
Nf-L = Neurofilament Light Chain
GFAP = Glial fibrillary acidic protein

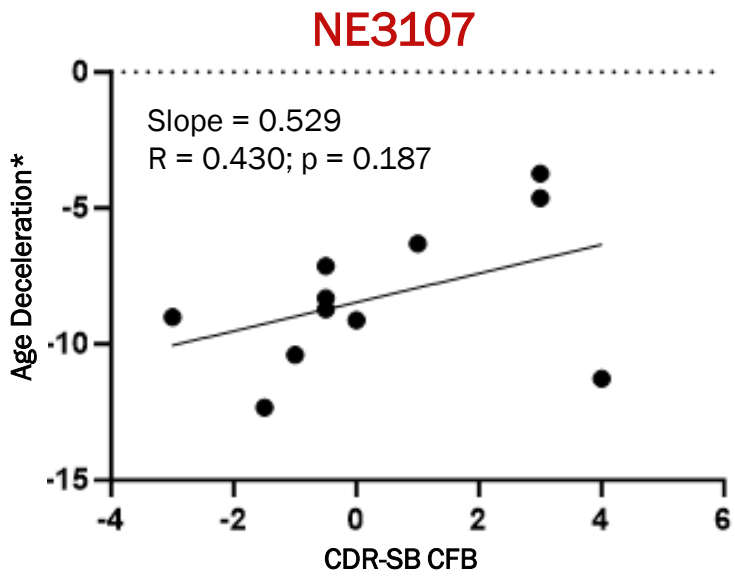
NE3107-treated Patients Experienced Significant "Age Deceleration" in a Manner Correlated to Cognitive and Functional Improvements

Age Deceleration[1] is used by longevity researchers[2] to measure the difference between a person's biological age and the actual chronological age.



Difference = -4.66 years
p = 0.020





NOTE: The Company is still awaiting roughly one-half of the DNA methylation data

[1] DNA Methylation Skin Blood Clock Age – Chronological Age
[2] Yusupov et al. *Neuropsychopharmacology* vol 48, 1409–1417 (2023)

Recap

- NE3107 appears to be biologically active
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Thank You