

# Unlocking the science of longevity to develop transformative therapies

Corporate Presentation • March 2024

## Forward-looking statements

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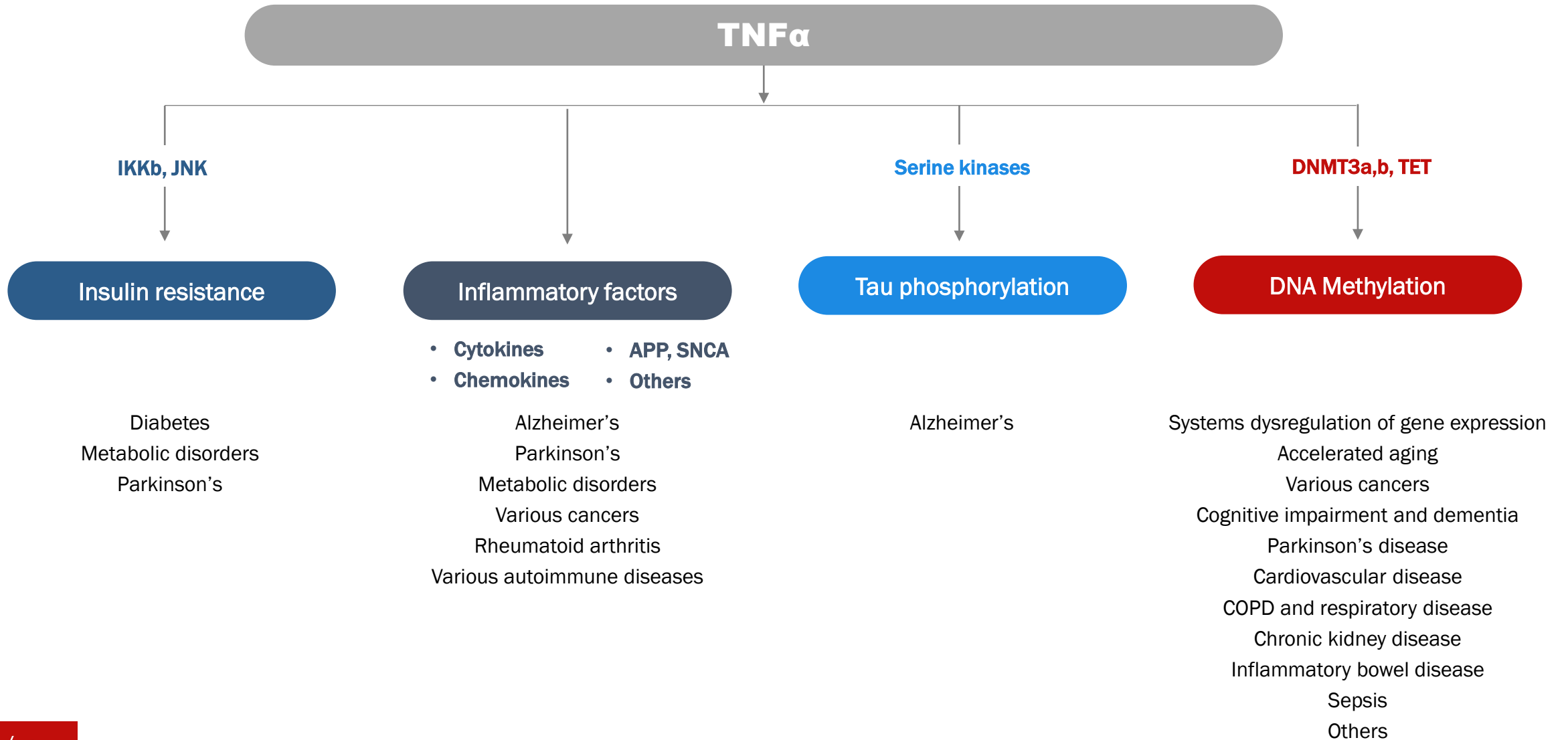
# Overview

Our lead asset NE3107 modulates the production of TNF $\alpha$ . In clinical trials, many patients treated with NE3107 experienced:

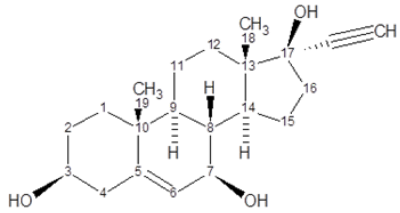
- Reduced inflammation and the associated insulin resistance
- Improved cognition and function, lowered amyloid  $\beta$  and p-tau levels, and improved brain imaging scans in Alzheimer's Disease (AD)
- Improved motor control and “morning on” symptoms in Parkinson's disease (PD)
- Lowered DNA methylation levels

BIV201 reduces fluid build up and has the potential to become the first therapeutic for ascites, a condition with 50% mortality rate within 12 months

# Far-reaching impact of TNF $\alpha$ -mediated chronic low-grade inflammation



# NE3107's mechanism of action

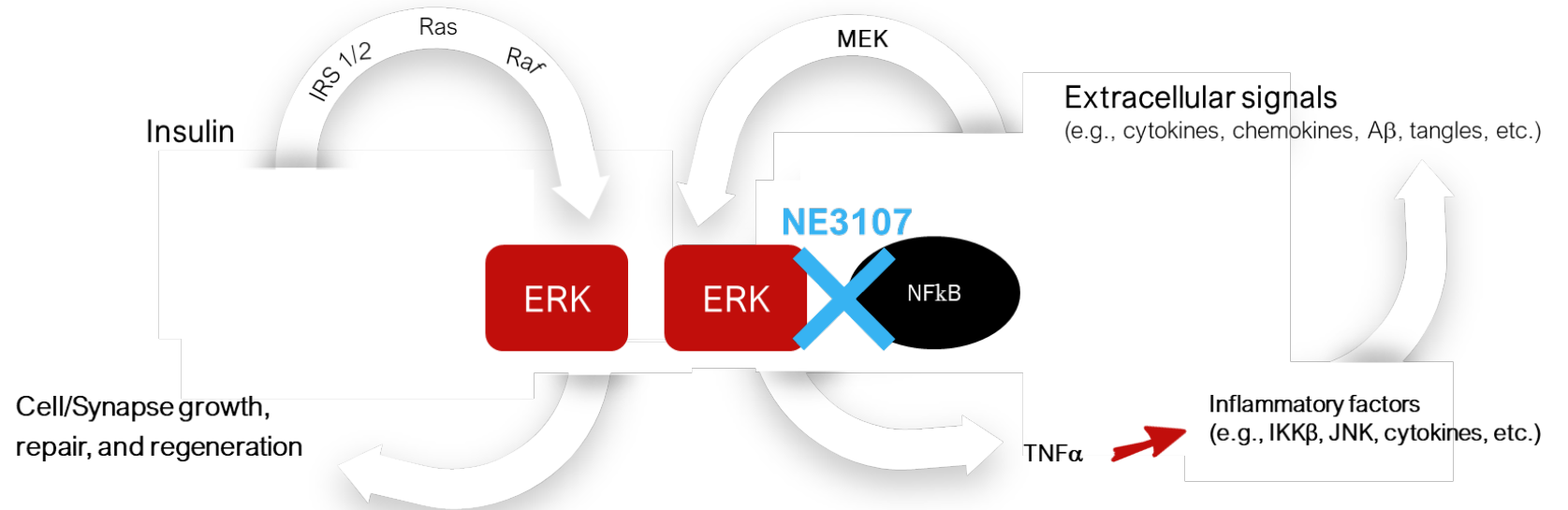


First-in-class molecule with desirable characteristics

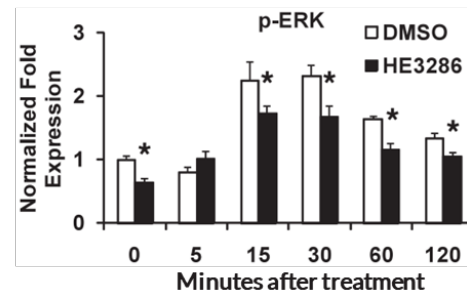
Small molecule; orally bioavailable

Crosses blood-brain barrier, thus CNS and peripheral applications

No safety issues identified to date in pre-clinical and clinical trials (up to Phase 2)

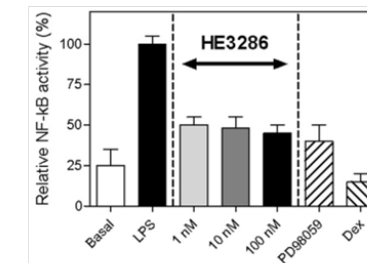


NE3107 Reduces ERK Activation



Lu 2010 Am J Physiol Endocrinol Metab 298 E1036

NE3107 Reduces NFkB Activity

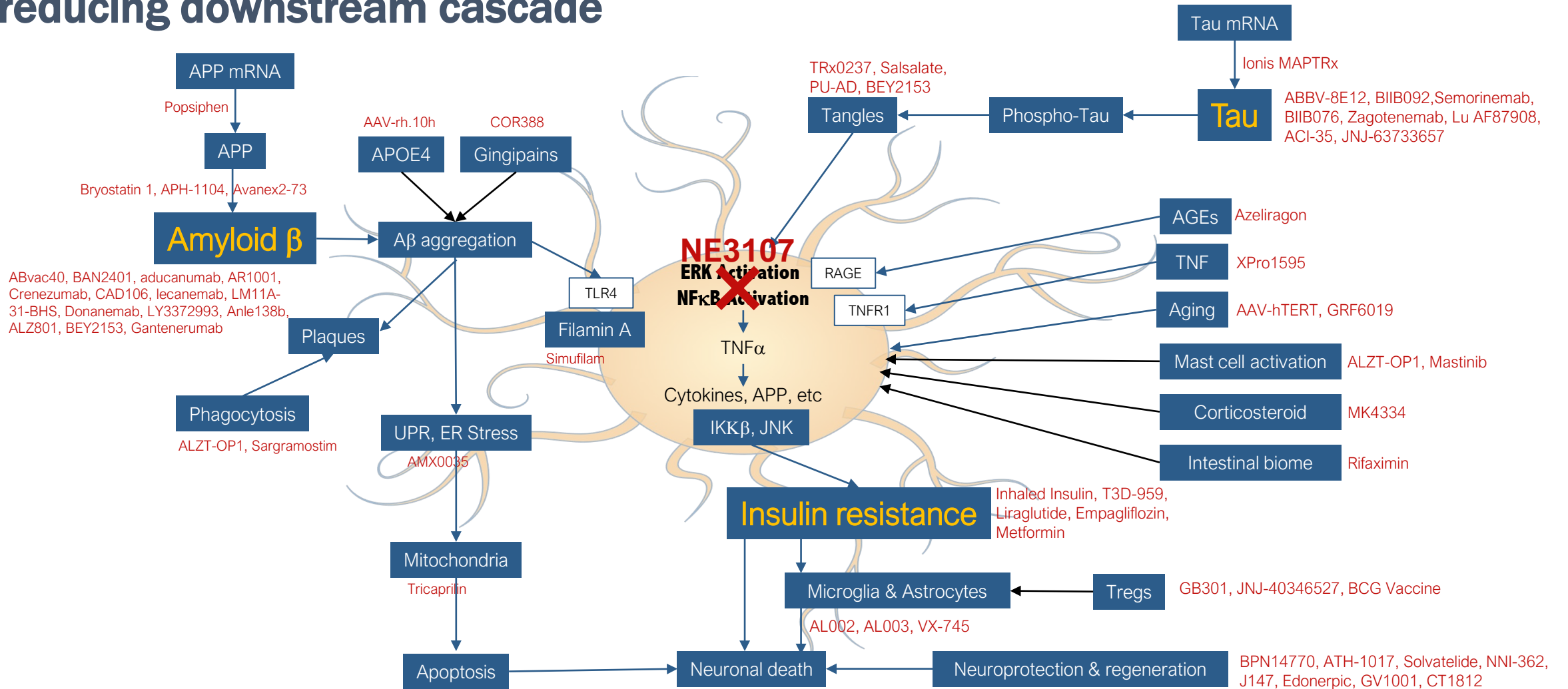


Wang 2010 J Pharmacol Exp Ther 333 70



# NE3107 in Alzheimer's Disease

# NE3107 modulates inflammation at the central hub, thereby potentially reducing downstream cascade



# NM101 Phase 3 trial in Mild to Moderate Alzheimer's

A Phase 3, Double-blind, Randomized, Placebo-controlled, Parallel Group, Multicenter Study of NE3107. Enrolled 439 Patients who have Mild to Moderate AD

- Pivotal study for Alzheimer's disease. Two weeks each of 5 mg and 10 mg BID dose titration followed by 26 weeks of 20 mg twice daily vs. placebo; 1:1 randomization; 80% power
- Diagnosed with probable AD and without evidence of a vascular contribution. Mild to moderate disease. CDR 1-2. MMSE 14-24.
- 60-85 years old, males and females
- Randomization stratified by MMSE and Homeostatic Model Assessment 2 Insulin Resistance (HOMA2)
- **Co-primary endpoints**
  - Mean change from Baseline to Week 30 in Dementia Rating-Sum of Boxes (CDR-SB) comparing the NE3107 group to the placebo group
  - Mean change from Baseline to Week 30 in the twelve-question form of the Alzheimer's Disease Assessment Scale-Cognitive (ADAS-Cog 12) comparing the NE3107 group to the placebo group
- **Secondary endpoints**
  - ADCS-ADL (functional), Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (ADCS-CGIC), ADCOMS (4 Alzheimer's Disease Assessment Scale-cognitive subscale items, 2 Mini-Mental State Examination items, and all 6 Clinical Dementia Rating-Sum of Boxes items), NPI-12 (care-giver rating of behavioral changes), MMSE, CDR
  - Glycemic control: HOMA2, Mean Amplitude of Glycemic Excursion (MAGE) using continuous glucose monitoring, fructosamine levels, post-prandial glucose and fasting blood glucose vs time.
  - MRI total hippocampus volume change, baseline to end of treatment in a subset of active and placebo subjects
  - Target engagement assessed in a small subset of active and placebo subjects using PET to quantify cortical glucose utilization



# Trial Summary

- 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 258 patients from 15 sites due to deviations led to study being underpowered

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

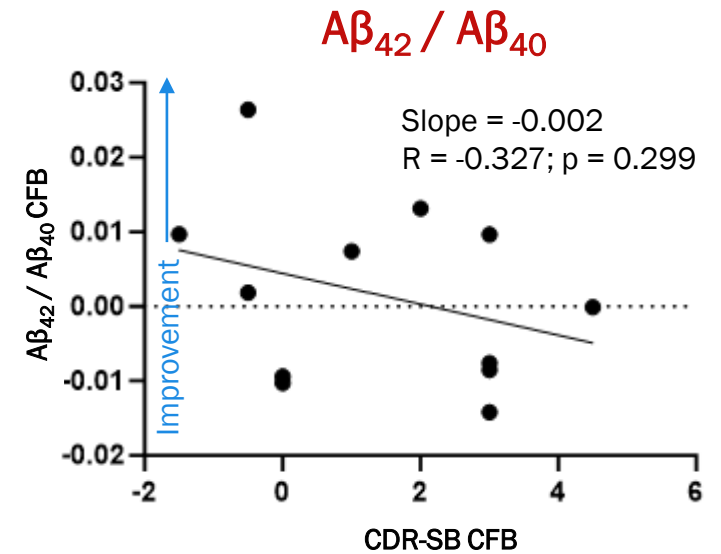
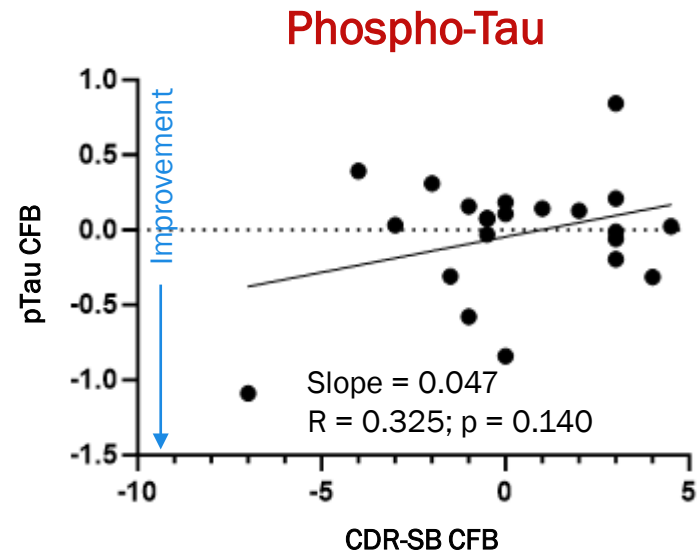
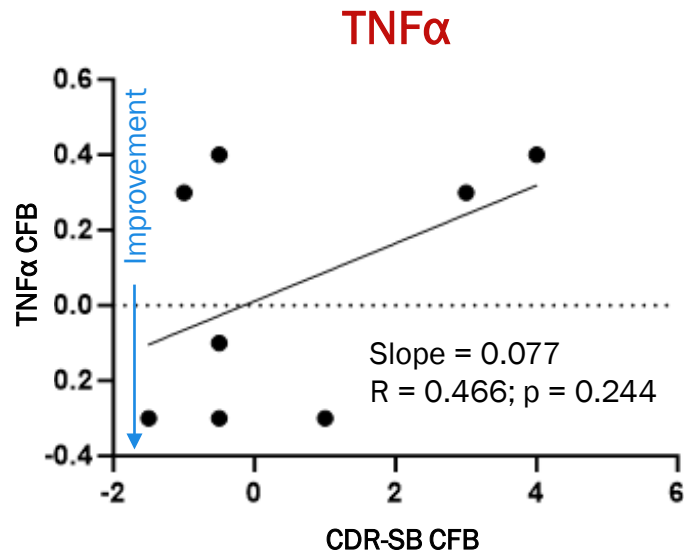
## Change from baseline

	Placebo Decline	NE3107	NE3107 vs. Placebo	Comparator (18 mos)
<b>CDR-SB</b> (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%) <sup>1</sup> -0.39 (22%) <sup>2</sup>
<b>ADAS-Cog12</b> (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%) <sup>1</sup> -1.40 (27%) <sup>2</sup>
<b>MMSE</b> (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%) <sup>2</sup>
<b>ADCS-ADL</b> (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%) <sup>1</sup>
<b>ADCS-CGIC</b> (lower is improvement)	+0.31 (p=0.2733; n=26)	-0.12 (p=0.6951; n=24)	-0.43 (139%) (p=0.2866)	
<b>ADCOMS</b> (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%) <sup>1</sup>

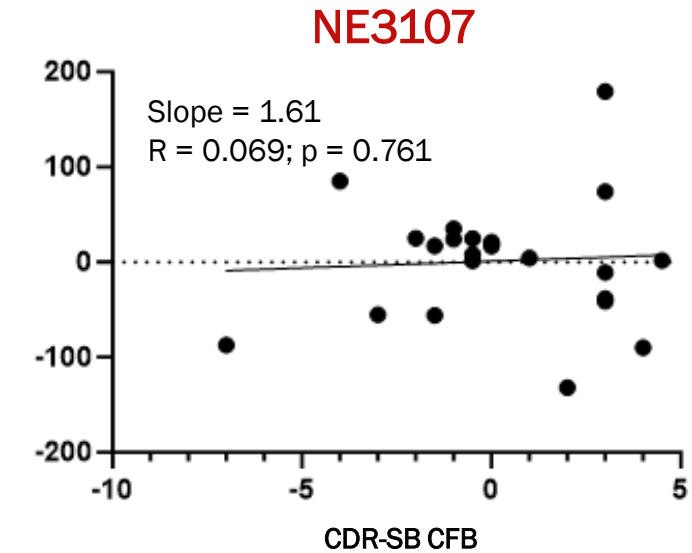
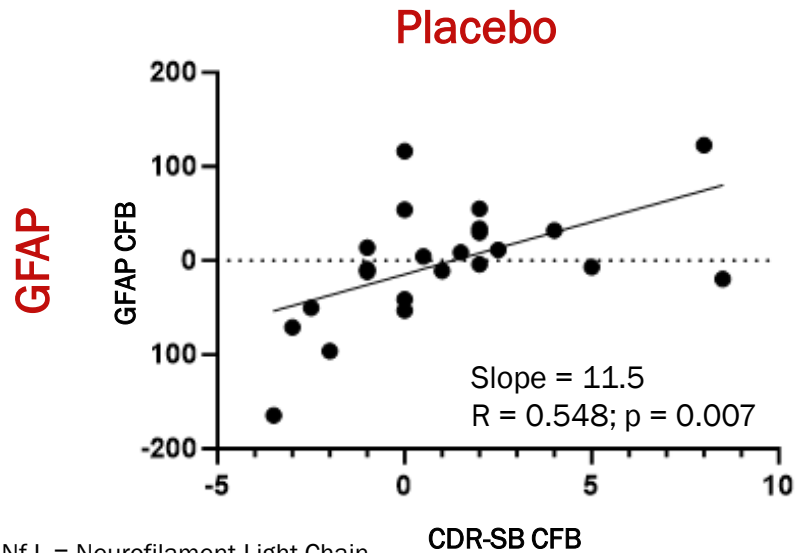
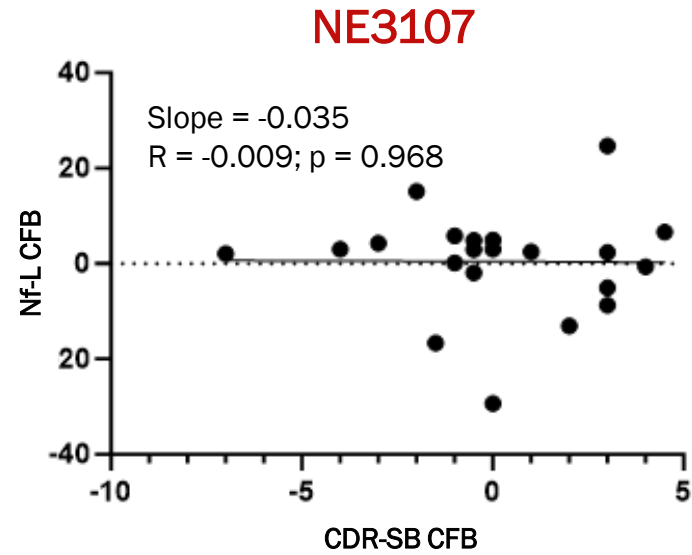
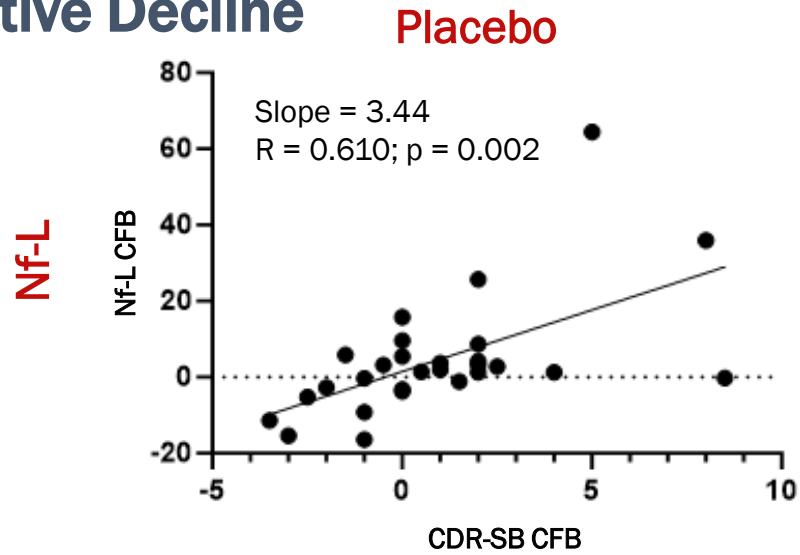
<sup>1</sup> Lecanamab after 18 months; van Dyck et al. *N Engl J Med* 2023;388:9-2

<sup>2</sup> Aducunumab after 18 months; Haerberlein et al. *J Prev Alz Dis* 2022;2(9):197-210

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



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



# 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%

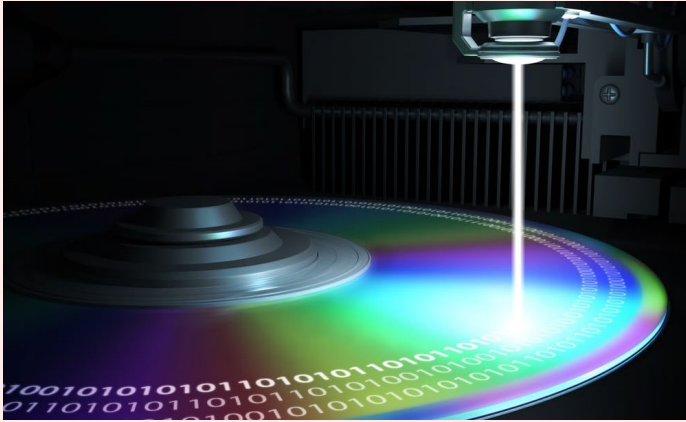


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The text "NE3107 in Longevity" is positioned in the bottom left corner of the slide. It is written in a white, bold, sans-serif font. The background behind the text features a blue gradient with abstract, wavy lines and faint, light-colored circuitry patterns, including gears and a large eye-like shape.

Clean DVD leads to clear picture and sound



Scratches & smudges lead to skips and blurs



## Impact of wear & tear on a laser's ability to decode DVDs

Quality of picture is dependent on the laser's ability to clearly decode the disk ...

The same thing happens in our body



# DNA methylation

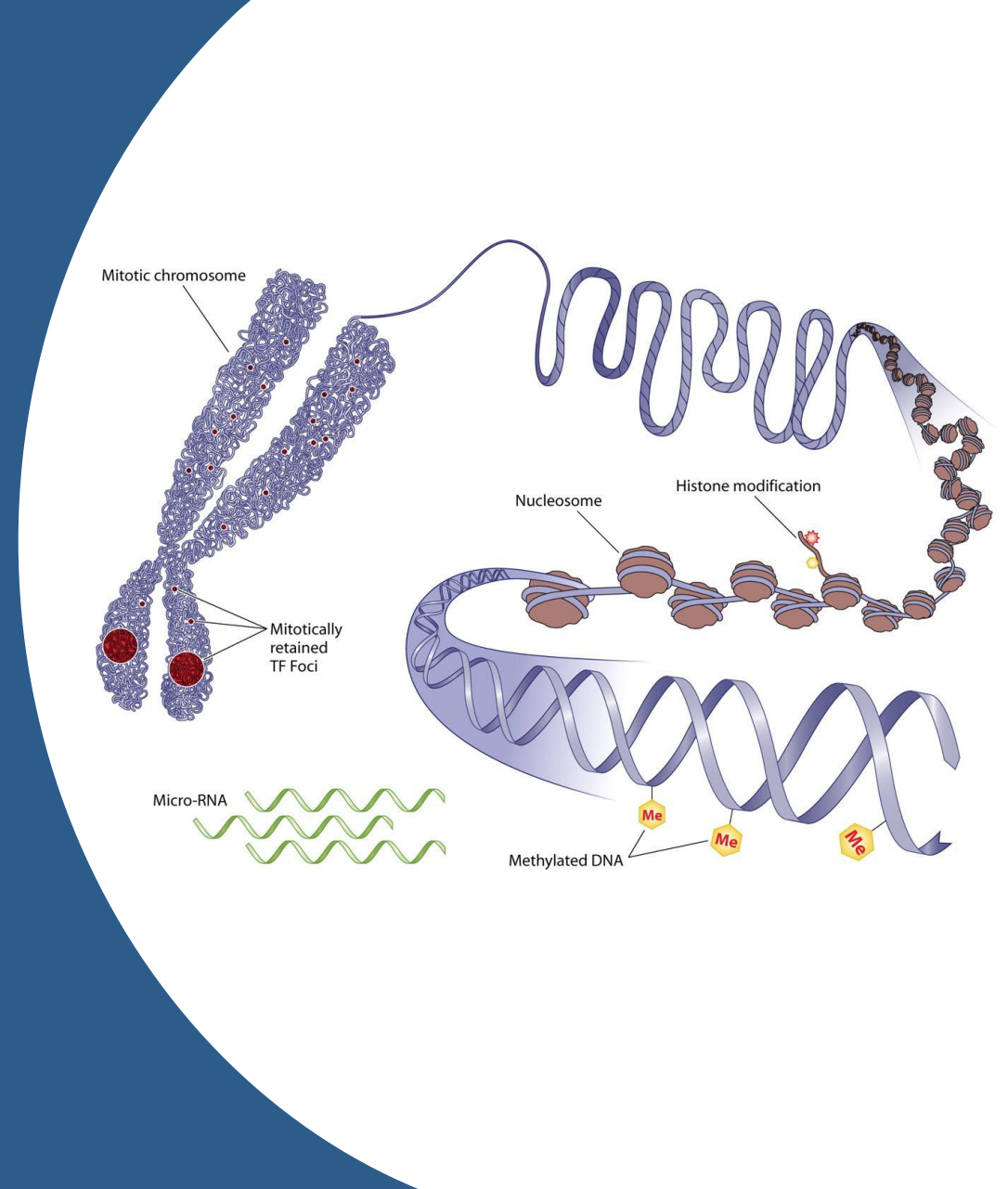
DNA methylation happens when methyl groups are added to our DNA

- DNA methyltransferases add methyl groups to DNA
- Functionally the equivalent of scratches and smudges on a DVD surface
- The methyl groups interfere with RNA polymerase's ability to decode DNA

DNA methylation may happen where a cytosine is positioned next to guanine and is separated by a phosphate group (CpG)

- 28 million CpGs in genome

Hypermethylation of DNA is associated with many disease conditions



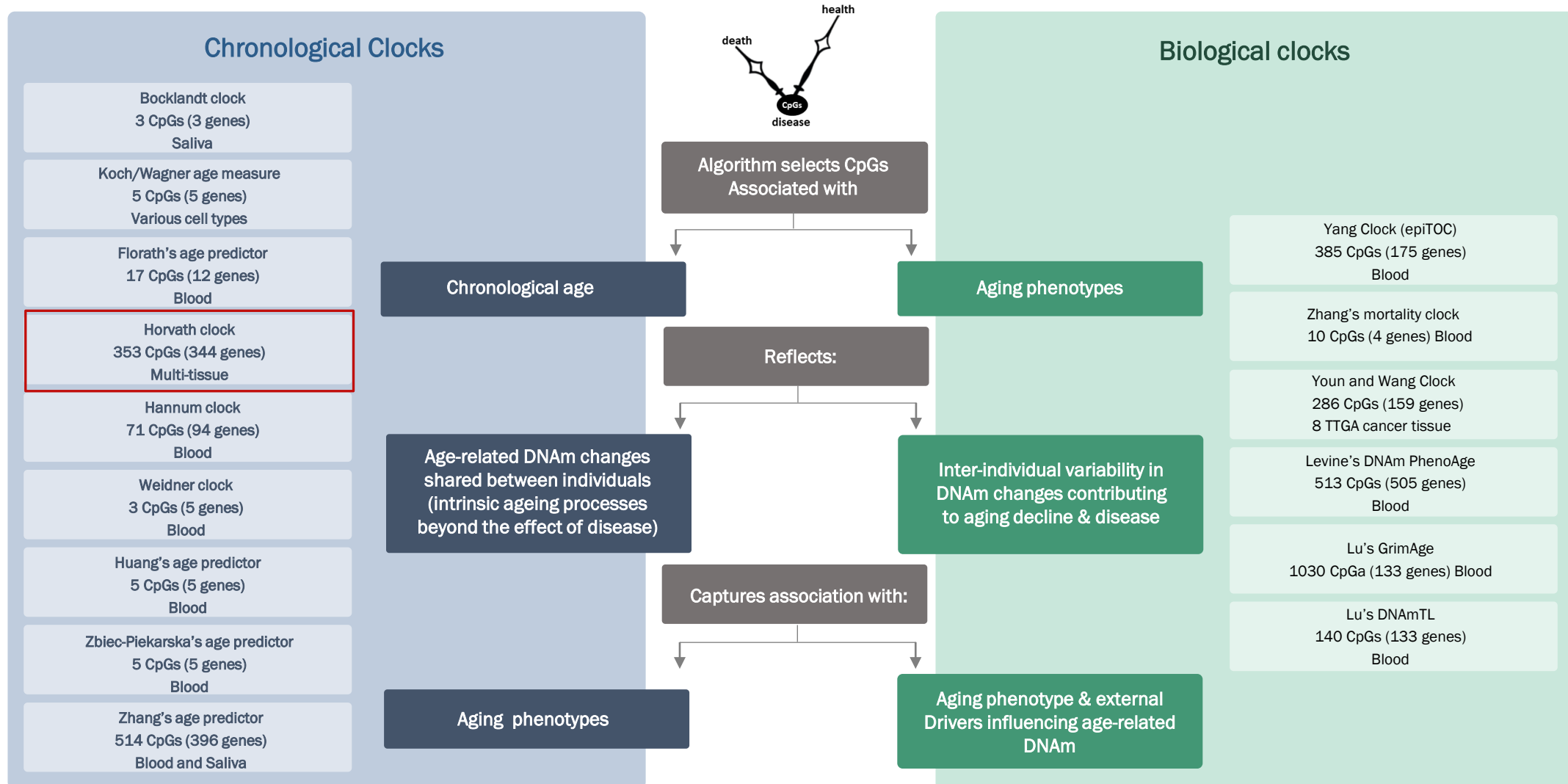
# Observations about DNA methylation

- DNA methylation increases as we age
- DNA methylation can be affected by behavioral (diet, exercise) and environmental factors
- DNA hypermethylation is associated with a large number of disease conditions, including various forms of cancers, age-related cognitive impairment and dementia, Parkinson's disease, cardiovascular disease, COPD and respiratory disease, chronic kidney disease, inflammatory bowel disease, sepsis, and many others\*
- Inflammation has been shown to be a driver of hypermethylation of DNA\*\*
- Extent of DNA methylation can be measured by various “clocks”

\* Wang Z Nucleic Acids Research, 2020, Vol. 48, No. 5; Sugden K Neurology 2022;99:e1402-e1413; Tang X DOI: 10.1002/mds.29157; Tabaeia S Artificial Cells, Nanomedicine, and Biotechnology, 47:1, 2031-2041; Qiu W Am J Respir Crit Care Med Vol 185, Iss. 4, pp 373–381, Feb 15, 2012; Rysz C Int. J. Mol. Sci. 2022, 23(13), 7108; Kraicy J Mucosal Immunology volume 9, pages 647–658 (2016); Rump K Sci Rep 9, 18511 (2019)

\*\* Stenvinkel P doi: 10.1111/j.1365-2796.2007.01777.x

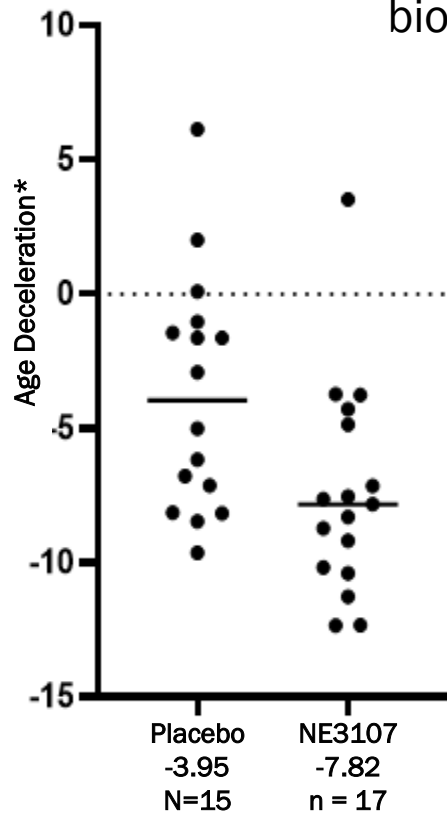
# DNA methylation “clocks” measure extent of aging and biological function



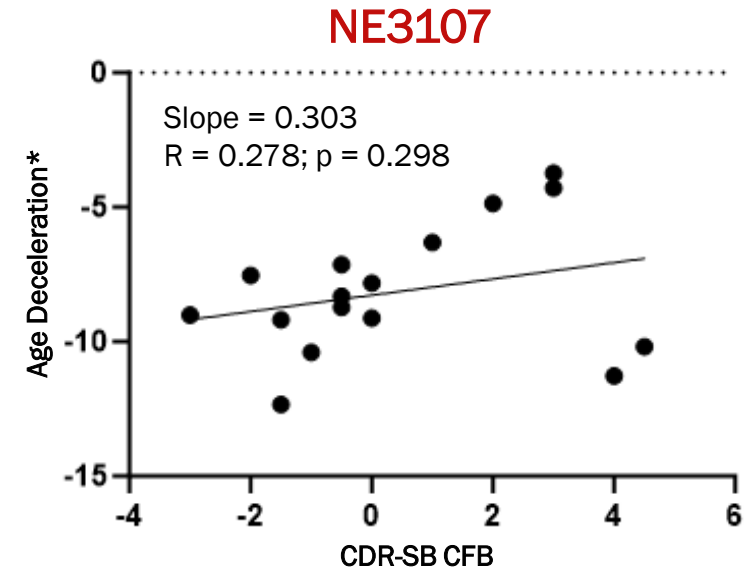
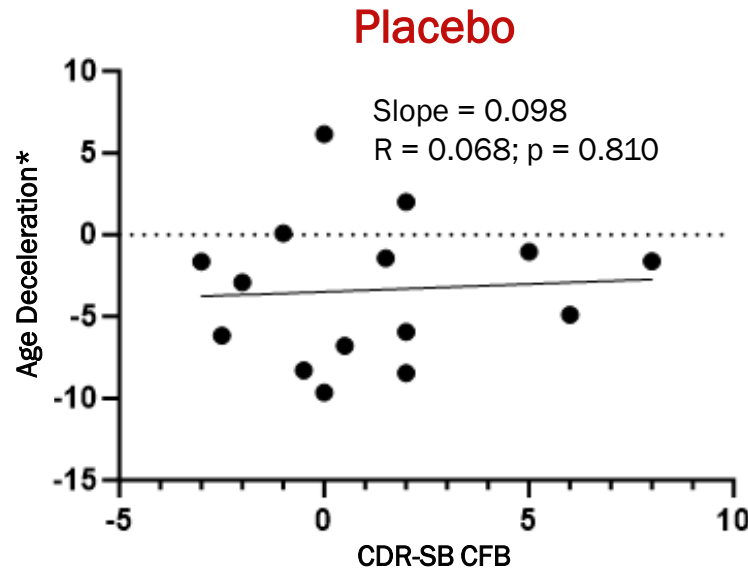


# NE3107-treated patients experienced significant “age deceleration” in a manner correlated to cognitive and functional improvements

**Age Deceleration**<sup>1</sup> is used by longevity researchers<sup>2</sup> to measure the difference between a person’s biological age and the actual chronological age.



**Difference = -3,87 years**  
 $p = 0.012$



# NE3107 in Parkinson's Disease

# Parkinson's Disease Clinical Development Program

## NM201 Phase 2

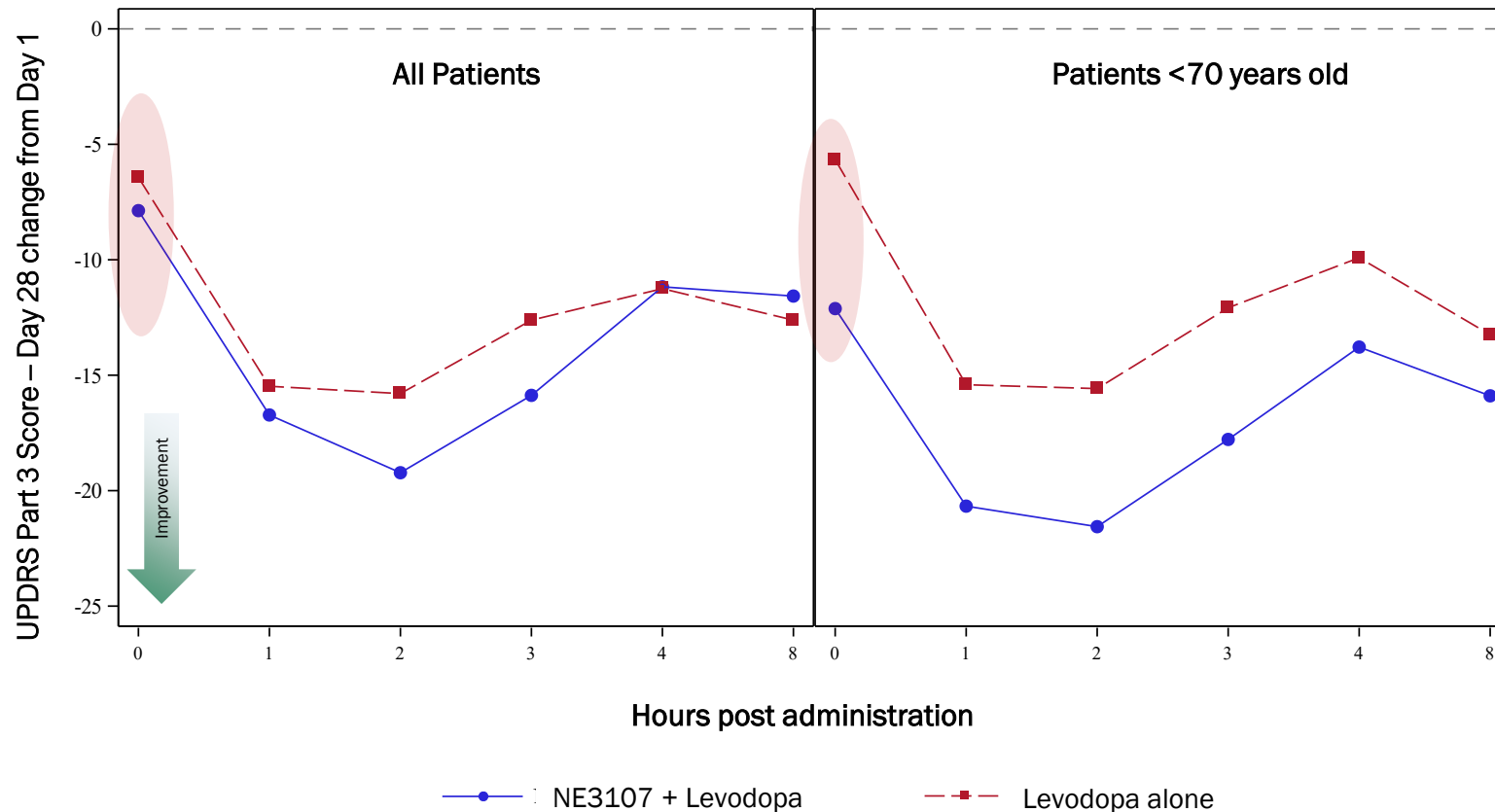
- Satisfying FDA requirement for drug-drug interaction study with L-dopa
- Detect efficacy signal for NE3107's pro-motoric activity

40 patients with defined L-dopa "off state", 1:1 active: placebo, 20 mg BID for 28 days

- **Safety assessments:** Standard measures of patient health, L-dopa PK and DDI
- **Efficacy assessments:** MDS-UPDRS\* parts 1-3, Hauser ON/OFF Diary, Non-Motor Symptom Scale

# NE3107-treatment patients experienced fewer motor symptoms before morning drug administration

Day 28 Improvement in Motor Control vs. Day 1

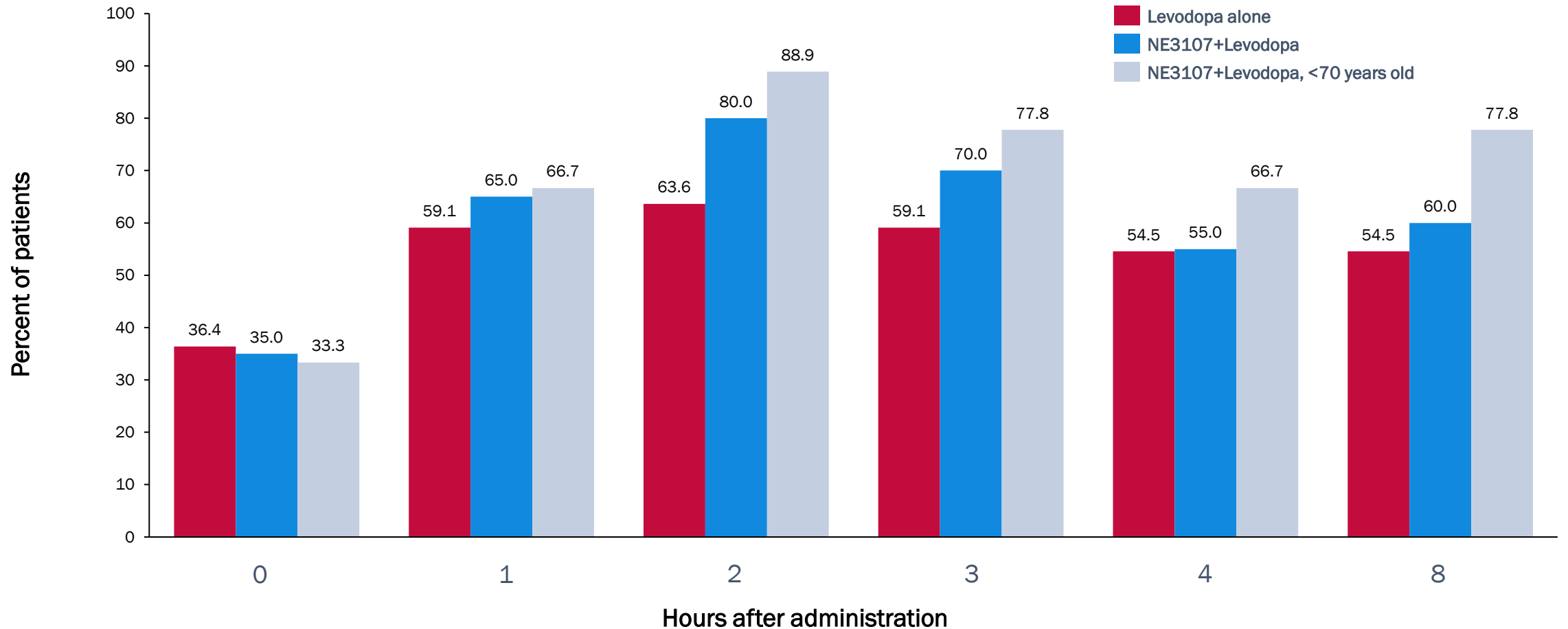


	NE3107	Placebo
"On" at t=0	5	0
Total patients	19	19
P-value*	0.046	

\* Fisher's exact test

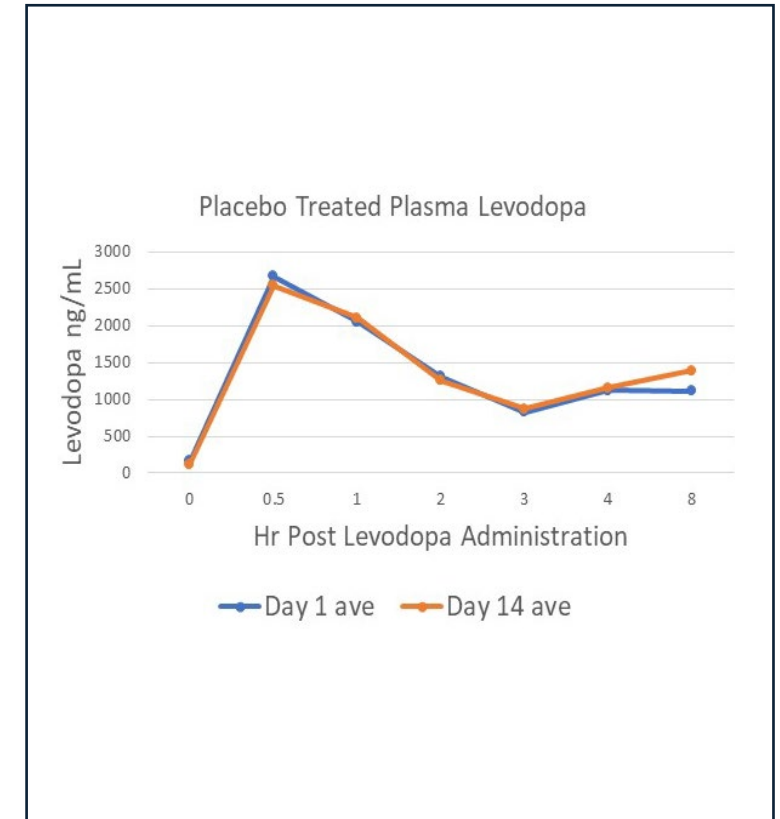
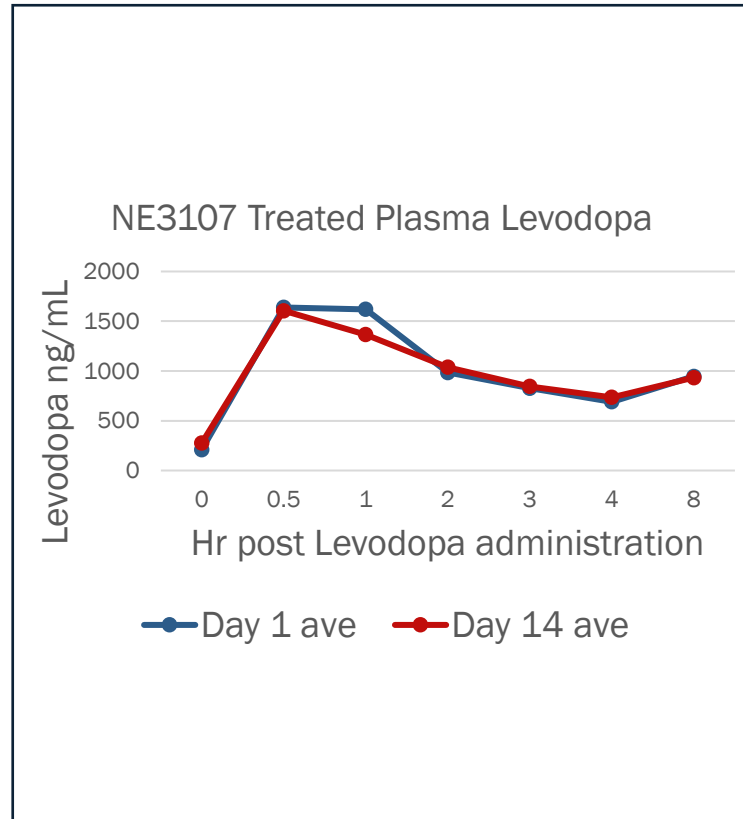
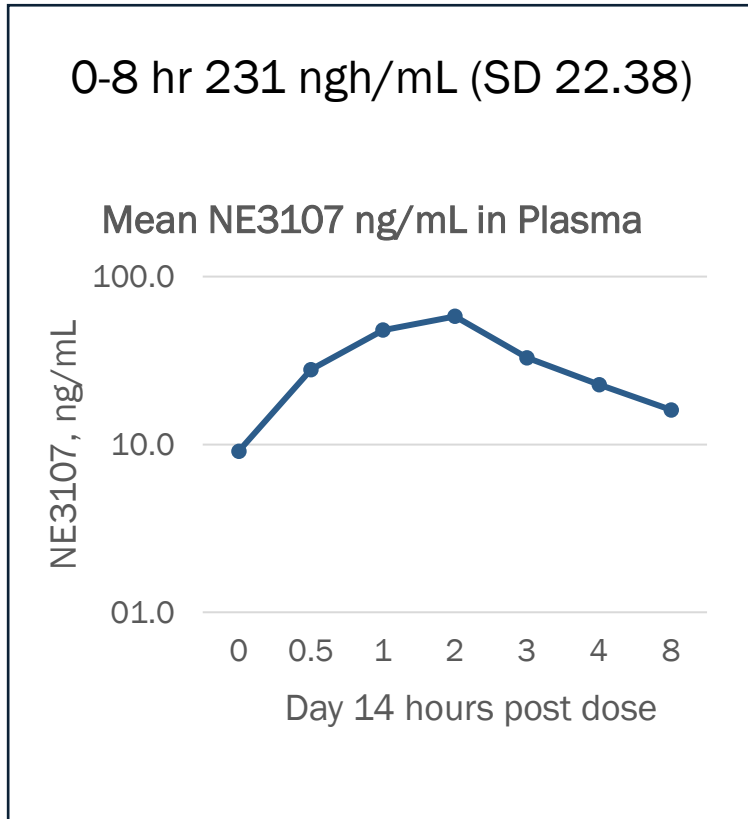
# Larger proportion of patients treated with NE3107 had >30% improvements in motor control

Percentage of patients experiencing >30% improvement at Day 28 vs. Day 0





# Desirable pharmacokinetics – no observed DDI



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The title text "BIV201 in Ascites" is positioned in the bottom left corner. It is written in a white, bold, sans-serif font. The background behind the text features a blue gradient with abstract, flowing lines and faint, light-colored technical diagrams, including gears and circuit-like patterns, suggesting a scientific or technological theme.

BIV201  
in Ascites

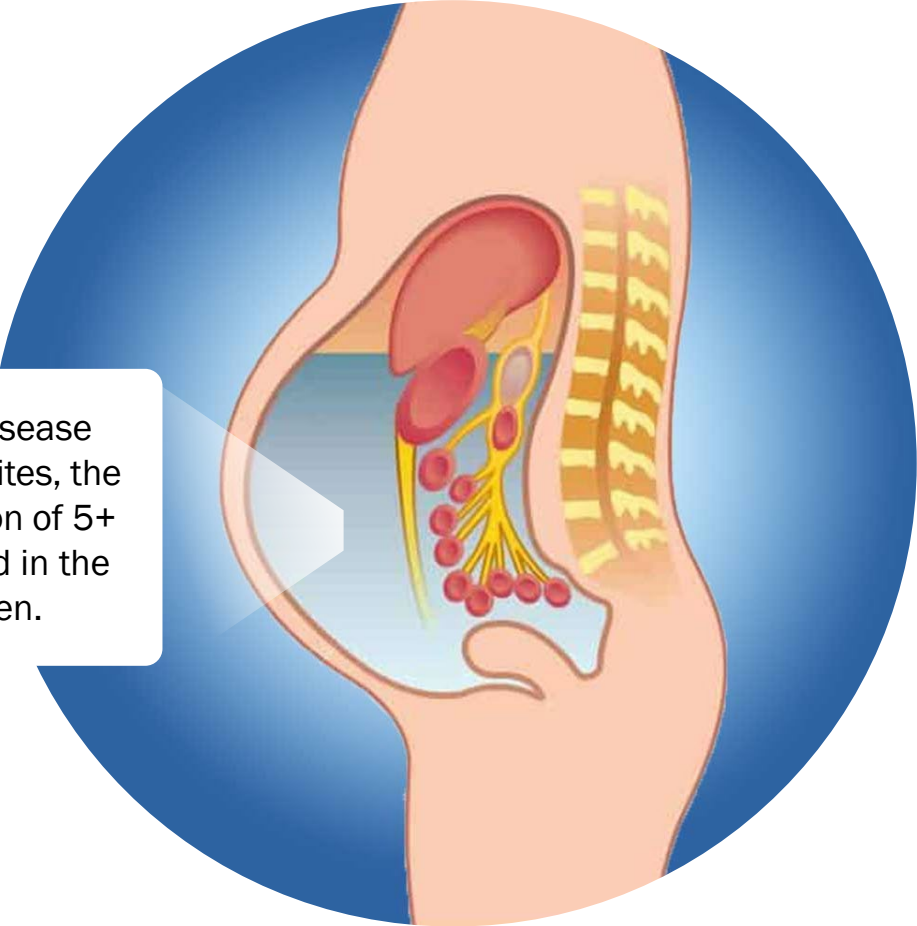
# BIV201 Disease Target: Refractory Ascites

Refractory ascites patients typically undergo **paracentesis** to remove ascites fluid every week to 10 days

## Paracentesis:

- Withdrawal of 5–10L of ascites fluid (on average) from abdomen using a large bore needle
- Provides a few days of symptomatic relief
- The kidneys are “burning out” by retaining massive quantities of salt and water
- Patients suffer frequent life-threatening complications
- No remaining options except for TIPS<sup>1</sup> surgery or liver transplant
- Estimated \$1.6 billion addressable US market with 20,000<sup>2</sup> targeted patients

No drugs ever approved by FDA to treat ascites



Our first disease target is ascites, the accumulation of 5+ liters of fluid in the abdomen.

# Prefilled Syringe with Patent-pending Liquid Formulation

- BIV201\*** Our liquid formulation of terlipressin. We will seek patent protection in the US, Europe, China and Japan
- Accurate dosing** Eliminates mixing minute quantities of powder terlipressin that could result in medication errors or sterility loss
- Enhanced convenience** Simply inject fluid into the saline bag and attach to pump

BIV201 Prefilled Syringe  
Stable for 18+months at room temp.

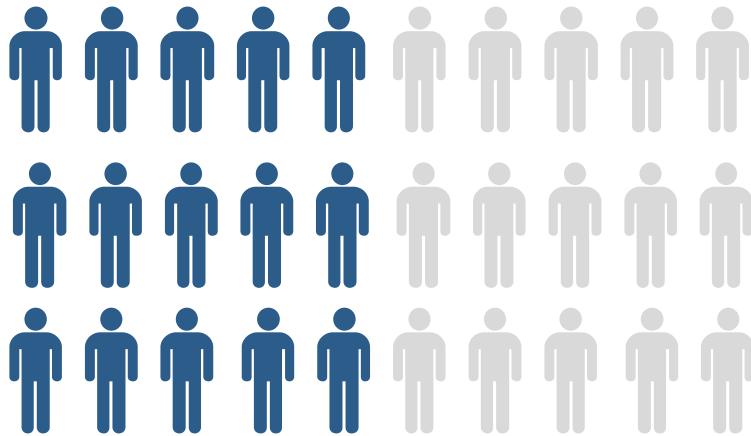
Needle or Connector

50 mL bag of saline for insertion into pump

Portable pump  
Carried in small satchel



# BIV201 Phase 2b trial



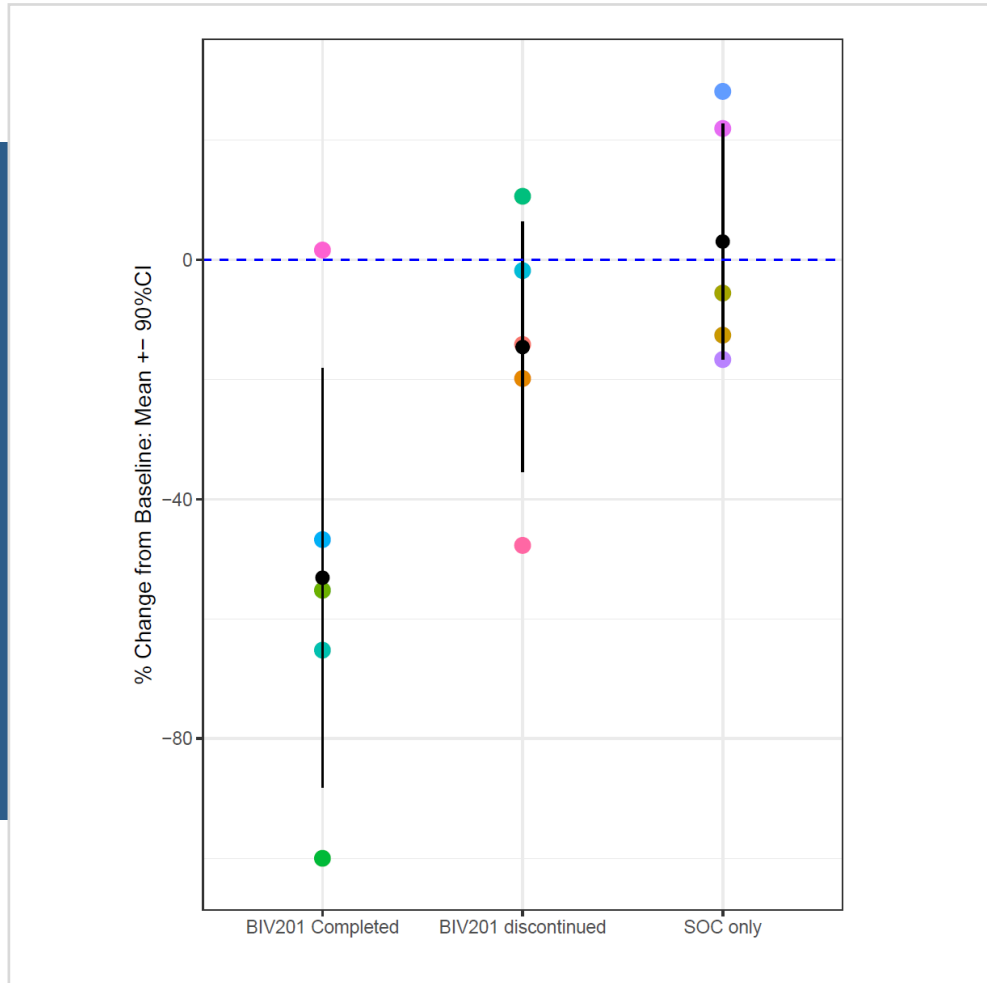
Originally targeted 30 patients randomized 2:1

Paused enrollment based on encouraging data from the first 15 patients informing next steps

- 10 randomized to BIV201; 5 randomized to standard of care
- 5 completed 2 X 28-day cycles
- 5 discontinued treatment during or at end of Cycle 1



# Change in ascites volume 28d pre- vs post-treatment



53% reduction in ascites volume among patient completing BIV201 treatment

15% reduction among patients who started but did not complete treatment

3.1% increase for SOC patients

$p < 0.001$

# Next Steps: Phase 3 trial in participants with decompensated liver cirrhosis and ascites who have experienced a recent acute kidney injury

A Phase 3 randomized, open-label study evaluating the safety and efficacy of BIV201 continuous infusion compared to standard of care (SOC) alone to reduce further decompensation in participants with decompensated liver cirrhosis and ascites who have experienced a recent acute kidney injury (AKI).

- Male and female  $\geq 18$  years old diagnosed with cirrhosis and ascites
- Recent (within 2 weeks) recovery from an AKI experienced in outpatient or inpatient setting
- Required at least 2 paracenteses in previous 3 months.
- Randomized (1:1) to 3 months treatment with BIV201 (continuous intravenous infusion of terlipressin acetate) or SOC with 3 months follow-up for adverse events and outcomes and 6 months additional follow-up for major events from medical records. About 150 randomized participants to reach 80% power. 15-20 clinical sites (global)
- **Primary endpoint**
  - Incidence of any new or repeated occurrence of Grade 3 ascites, SBP, HE, AKI (including HRS-AKI), portal-hypertension-related GI bleeding at 3 months
- **Secondary endpoints**
  - Time to any primary outcome event including death or transplant
  - Incidence of Major Adverse Kidney Events at 3 and 6 months
  - Change in total number of therapeutic paracenteses
  - Days of hospitalization
  - Ascites-related symptoms (novel BioVie PRO under development)
  - Health related quality of life

# Commercial potential in US market alone\*

## Alzheimer's

**\$30B**

Annual sales for every  
1 million people treated

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15% market penetration

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\$30K/year much lower all-in cost vs.  
competition

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## Parkinson's

**\$3B**

Annual sales for every  
100,000 people treated

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10% market penetration

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\$30K/year

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## Ascites

**\$1.6B**

US peak sales

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45% market penetration

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\$45K/year

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2026 launch

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2032 peak sales

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# Leadership Team

Deep expertise provides a strong foundation for success



**Cuong Do, President & Chief Executive Officer**

30+ years in biopharma & technology  
President, Samsung Global Strategy Group  
Chief Strategy Officer for Merck, Senior partner at McKinsey & Company



**Joseph Palumbo, MD, EVP, R&D and Chief Medical Officer**

30+ years treating patients; 25+ years in biopharma  
CMO, Zynerva  
Global Head of Medical Science & Translational Research, Global Head & Psychiatry Franchise Medical Leader, J&J



**Chris Reading, PhD, Neurodegenerative Disease Program**

40+ years in biopharma  
Chief Scientific Officer, Hollis-Eden Pharmaceuticals  
VP of Product and Process Dev. for Systemix  
U Texas Dept. of Tumor Biology



**Penelope Markham, Liver Cirrhosis Program**

25 years in biopharma drug development  
Lead Scientist Terlipressin (LATPharma/ BioVie 11 years)  
Head Research Biology Protez Pharma  
Co-founder/Director of Research Influx Inc.



**David Morse, Chief Regulatory Officer**

35 years experience Regulatory Affairs and multi-region product development strategy  
Former VP with two top-5 international CRO's  
Former Associate Director CDER, FDA



**Clarence Ahlem, Operations**

35+ years in biopharma  
Vice President, Product Development Harbor Therapeutics  
Director, Product Development, Hollis-Eden Pharmaceuticals  
US San Diego



**J. Wendy Kim, Chief Financial Officer**

35 years in finance/ accounting  
As CFO managed corporate finance and operations groups  
Closed M&A transactions and secured financings  
Combined 22 years at KPMG and BDO LLP

# Recap

Our lead asset NE3107 modulates the production of TNF $\alpha$ . In clinical trials, many patients treated with NE3107 experienced:

- Reduced inflammation and the associated insulin resistance
- Improved cognition and function, lowered amyloid  $\beta$  and p-tau levels, and improved brain imaging scans in Alzheimer's Disease (AD)
- Improved motor control and “morning on” symptoms in Parkinson's disease (PD)
- Lowered DNA methylation levels

BIV201 reduces fluid build up and has the potential to become the first therapeutic for ascites, a condition with 50% mortality rate within 12 months

biovie

**Thank You**