Unlocking the science of longevity to develop transformative therapies

Corporate Presentation • June 2024

Forward-looking statements

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Overview

Our lead asset bezisterim (formerly NE3107) modulates the production of TNFα. In clinical trials, many patients treated with bezisterim experienced:

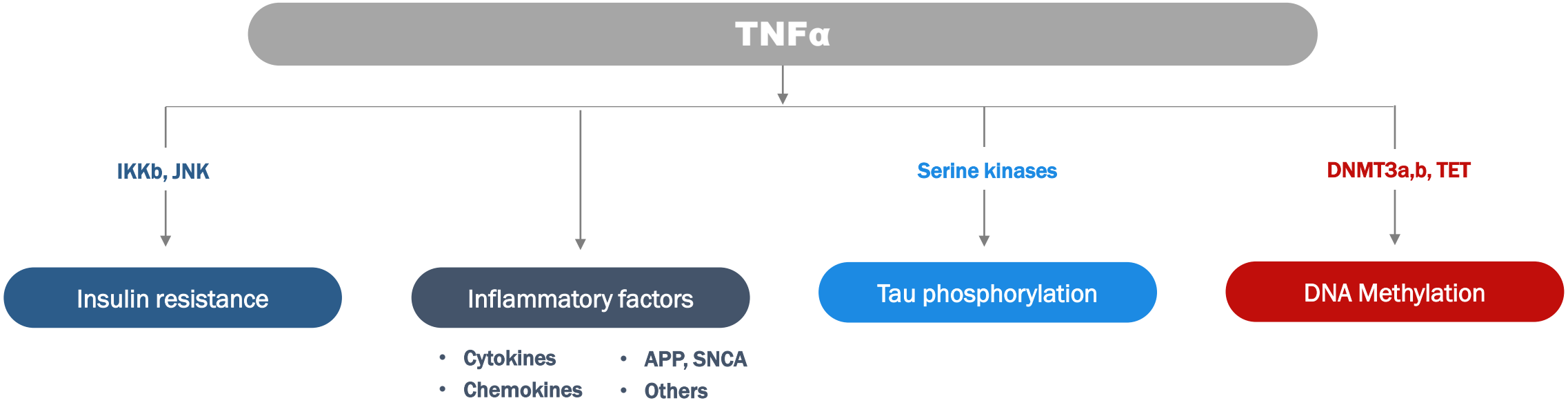
- Reduced inflammation and the associated insulin resistance
- Improved motor control and “morning on” symptoms in Parkinson’s disease (PD)
- Improved cognition and function, lowered amyloid β and p-tau levels, and improved brain imaging scans in Alzheimer’s Disease (AD)
- Lowered DNA methylation levels

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

Our priorities:

- Launch Parkinson’s Phase 2b trial Fall 2024
- Launch next Alzheimer’s Phase 3 trial in mid-2025 using new once-daily formulation of bezisterim
- Continue partnering conversations for bezisterim (geographic rights)
- Launch ascites Phase 3 when partner identified

Far-reaching impact of TNFα-mediated chronic low-grade inflammation



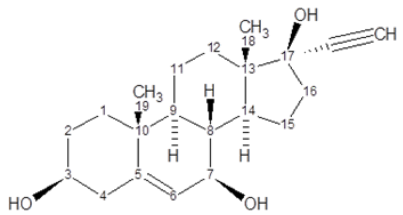
Diabetes
Metabolic disorders
Parkinson's

Alzheimer's
Parkinson's
Metabolic disorders
Various cancers
Rheumatoid arthritis
Various autoimmune diseases

Alzheimer's

Systems dysregulation of gene expression
Accelerated aging
Various cancers
Cognitive impairment and dementia
Parkinson's disease
Cardiovascular disease
COPD and respiratory disease
Chronic kidney disease
Inflammatory bowel disease
Sepsis
Others

Bezisterim's mechanism of action

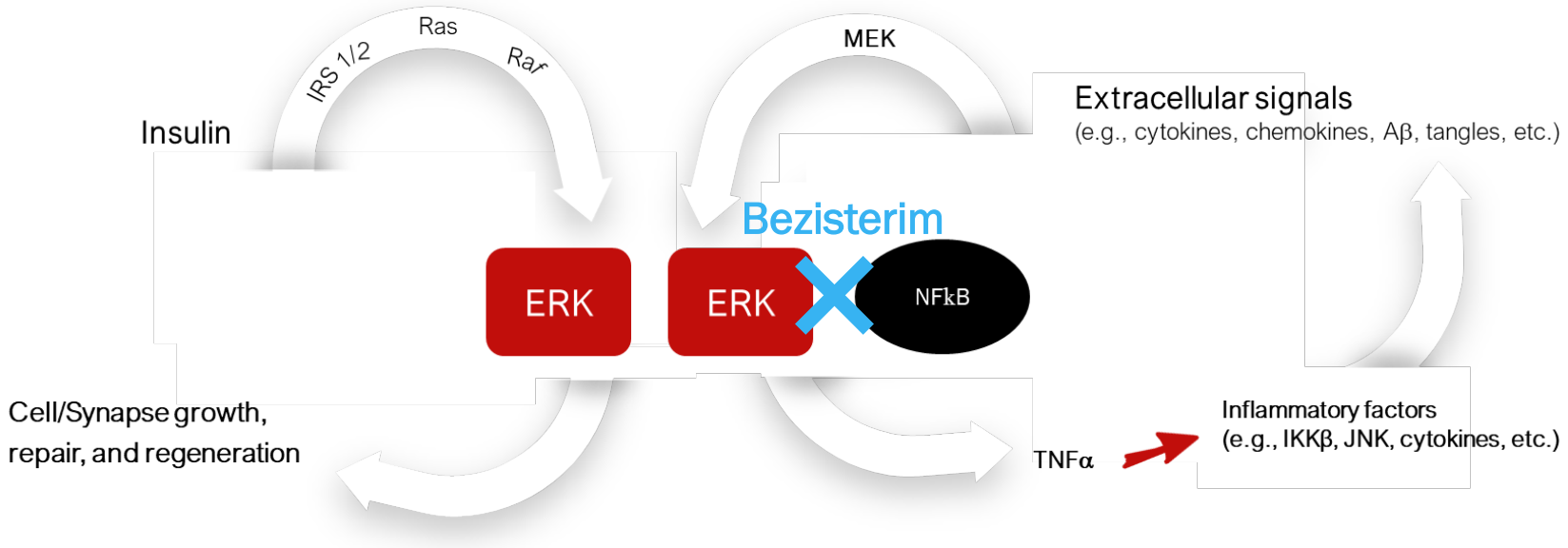


First-in-class molecule with desirable characteristics

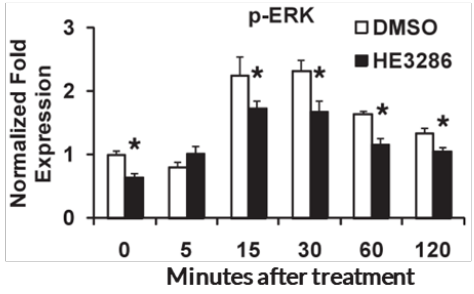
Small molecule; orally bioavailable

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)

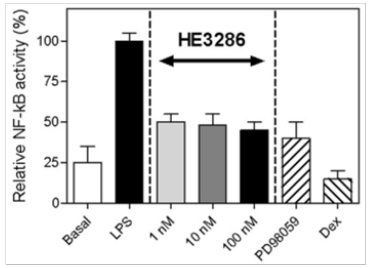


NE3107 Reduces ERK Activation



Lu 2010 Am J Physiol Endocrinol Metab 298 E1036

NE3107 Reduces NFkB Activity

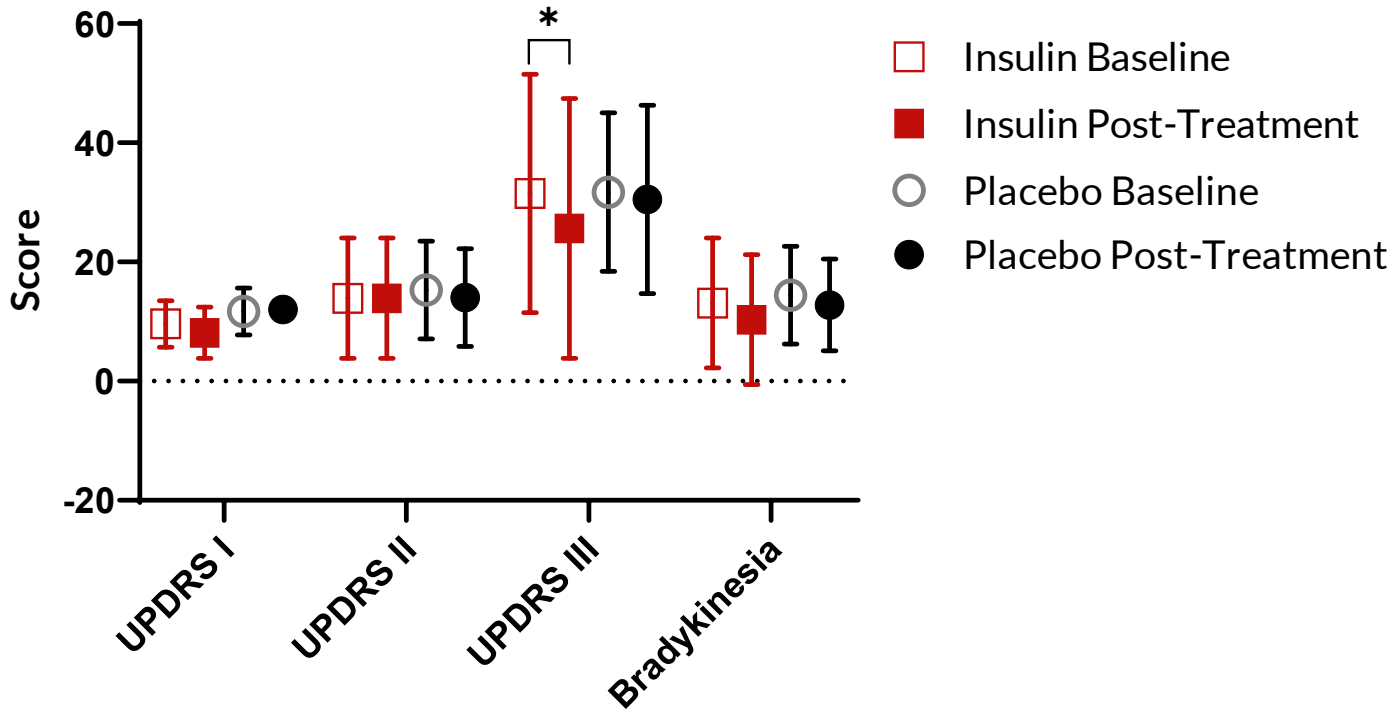


Wang 2010 J Pharmacol Exp Ther 333 70

Bezisterim
in Parkinson’s Disease

Low Dopamine *and* inflammation are required to develop Parkinson symptoms in patients

Intranasal Insulin treatment reduced inflammation and improved motor activity



UPDRS: Unified Parkinson's Disease Rating Scale; Part I (mentation, behavior and mood); Part II (activities of daily living); Part III (Motor)
From: Novak 2019 *J Pone 0214364*

Bezisterim has similar promotoric activity to L-dopa in rodent* and marmoset* models

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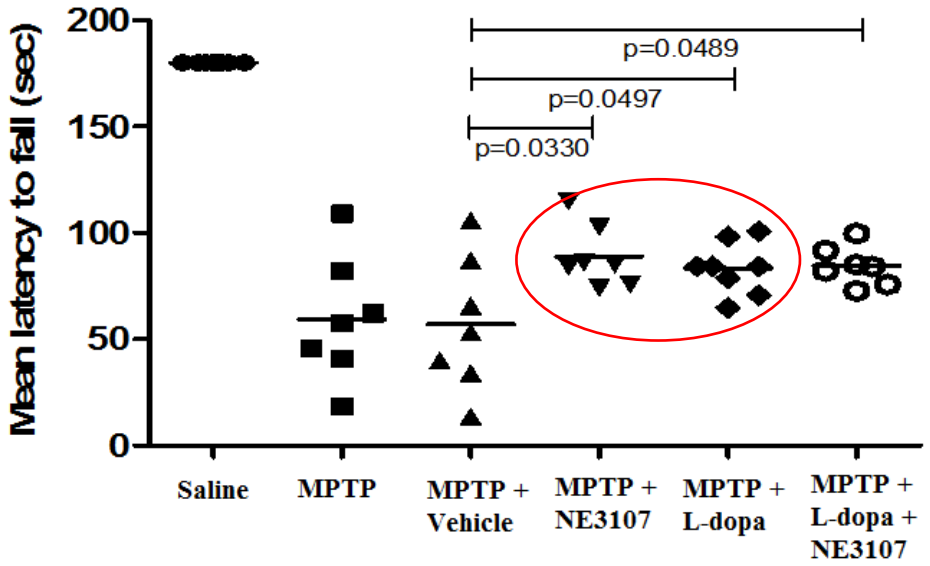
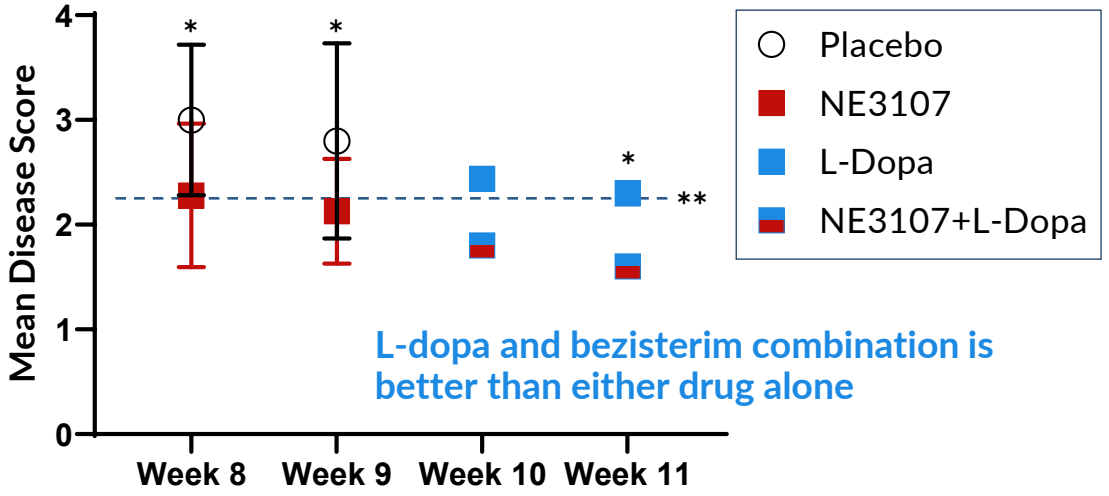
MPTP Mouse



MPTP Marmoset treated at Week 8



L-dopa and bezisterim combination is better than either drug alone

*p<0.001 compared to other treatment arm in time period
** L-Dopa at week 11 not statistically different from bezisterim at weeks 8 and 9

bezisterim's promotoric effects observed within 4 days of treatment

MPTP: 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine, a toxin used to mimic many aspects of PD

Bezisterim decreases L-Dopa-induced dyskinesia (LID) in marmosets*

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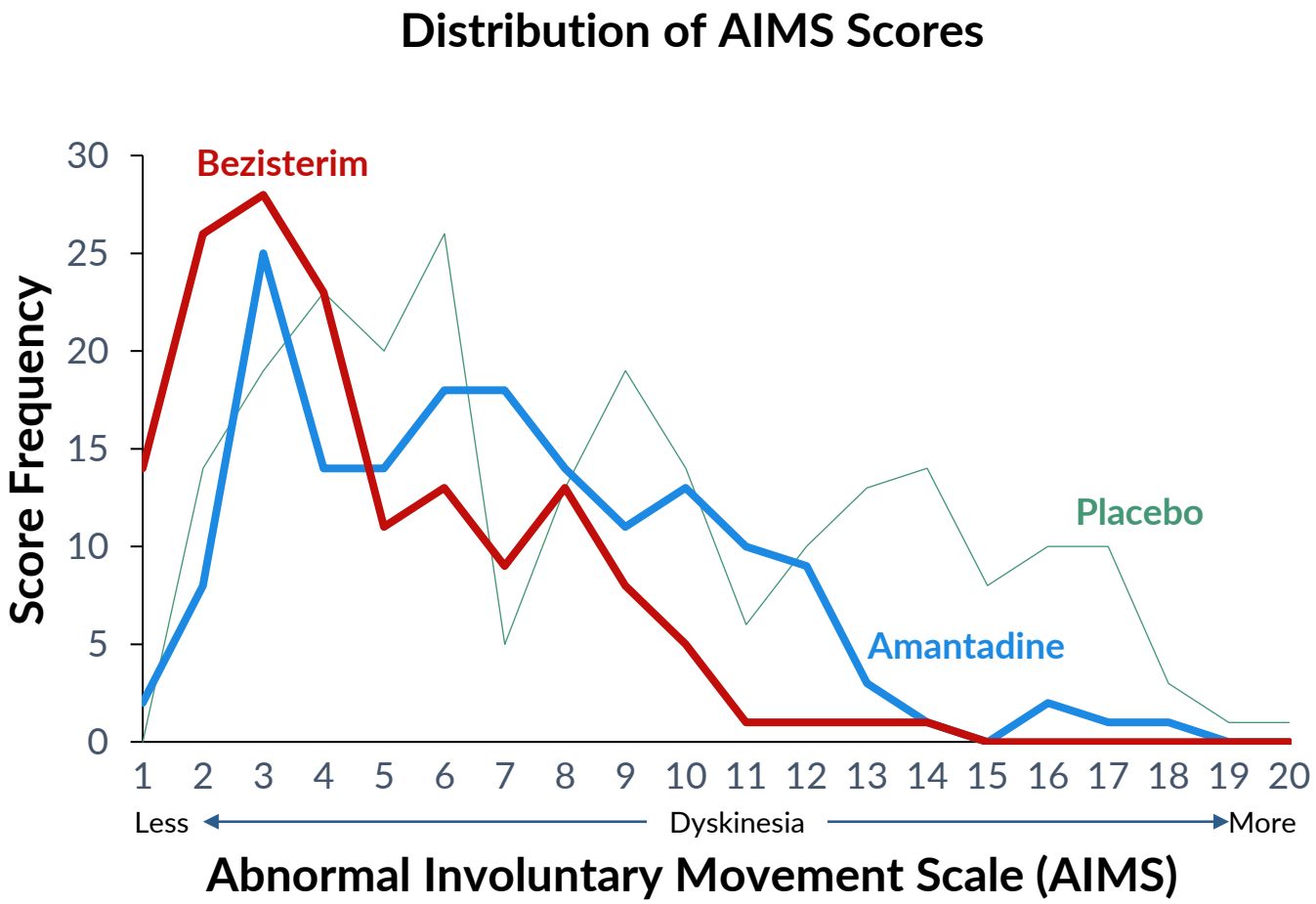

Bezisterim preserved ~2X TH+ (dopaminergic) neurons in MPTP marmosets*

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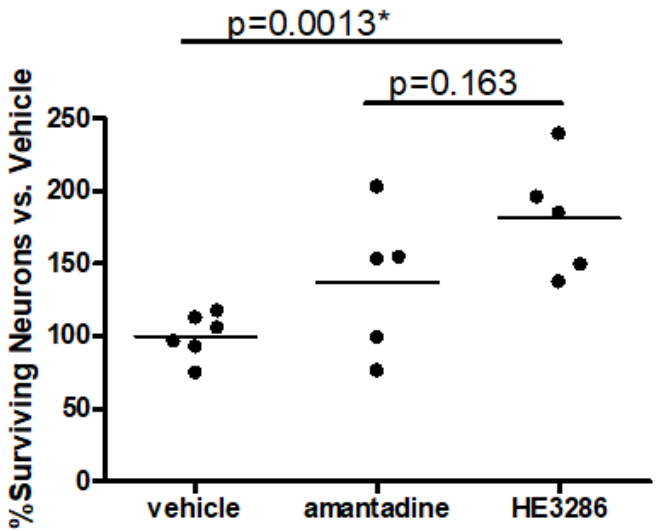
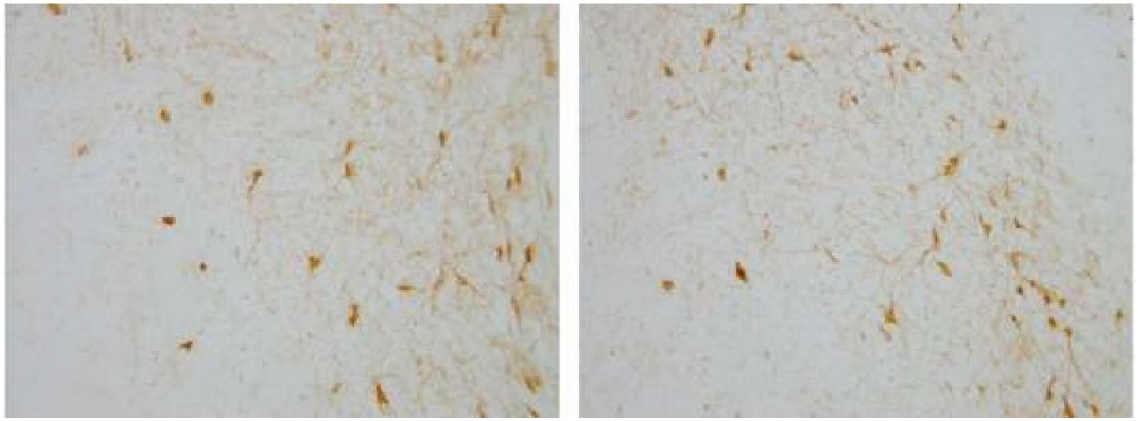
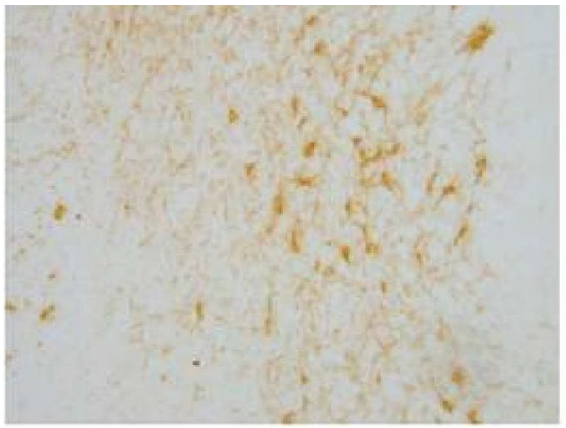


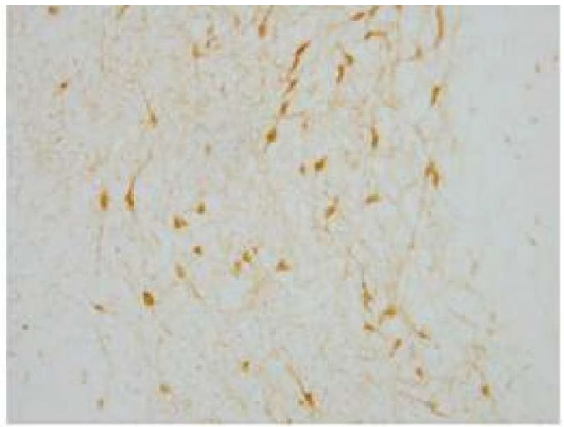
Control moneys (M09100 and M11008)



Bezisterim



Amantadine (M10084)



Parkinson's Disease Clinical Development Program

NM201 Phase 2

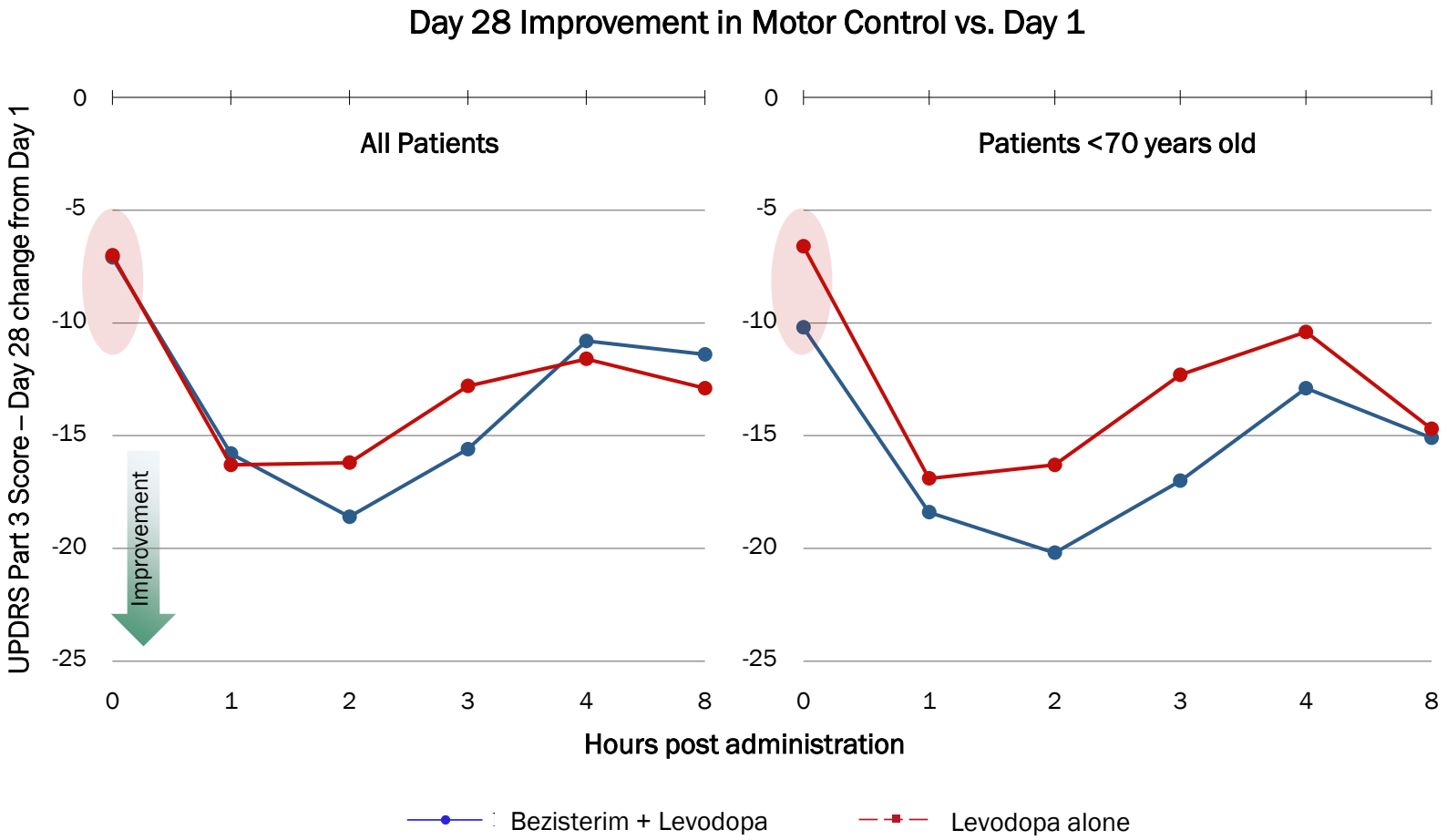
- Satisfying FDA requirement for drug-drug interaction study with L-dopa
- Detect efficacy signal for bezisterim's pro-motoric activity

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

* Motor Disease Society Unified Parkinson's Disease Rating

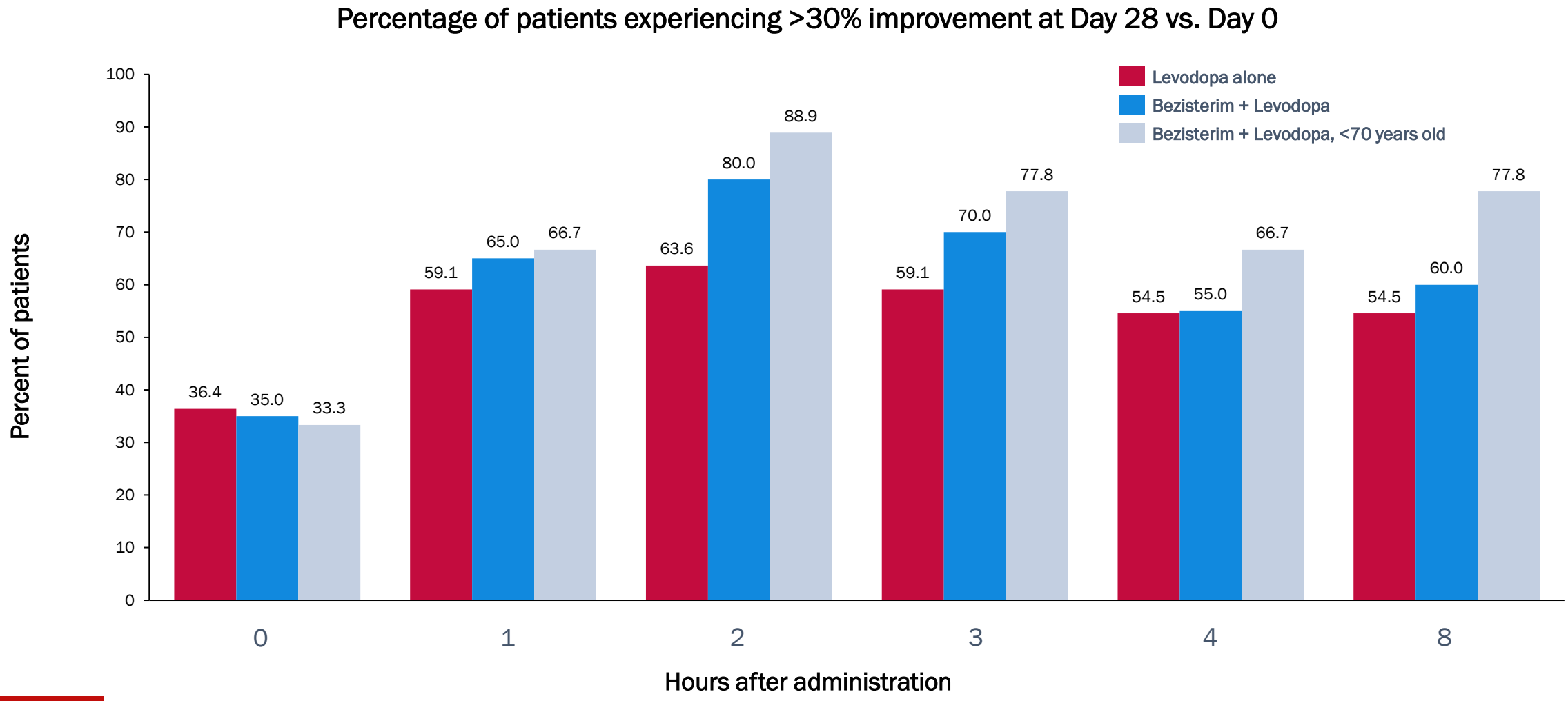
Bezisterim-treatment patients experienced fewer motor symptoms before morning drug administration



	Bezisterim	Placebo
"On" at t=0	6	0
Total patients	20	19
P-value*	0.02	

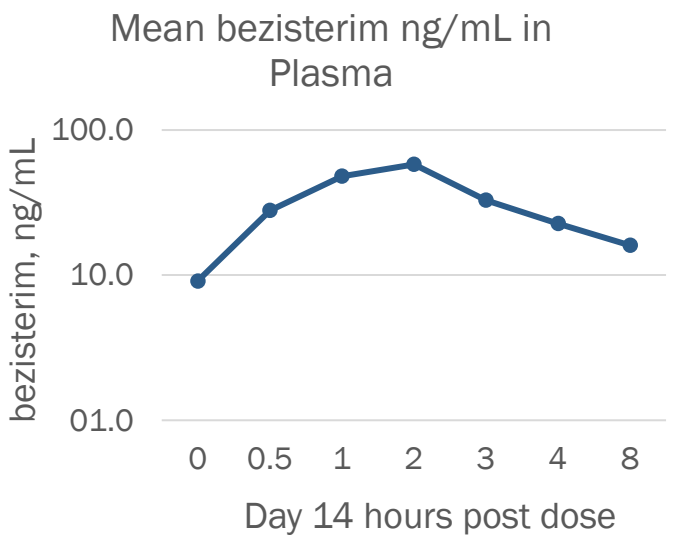
* Fisher's exact test

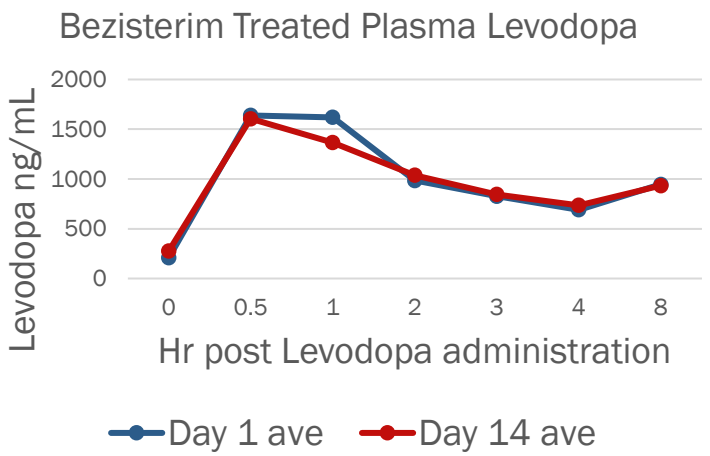
Larger proportion of patients treated with bezisterim had >30% improvements in motor control

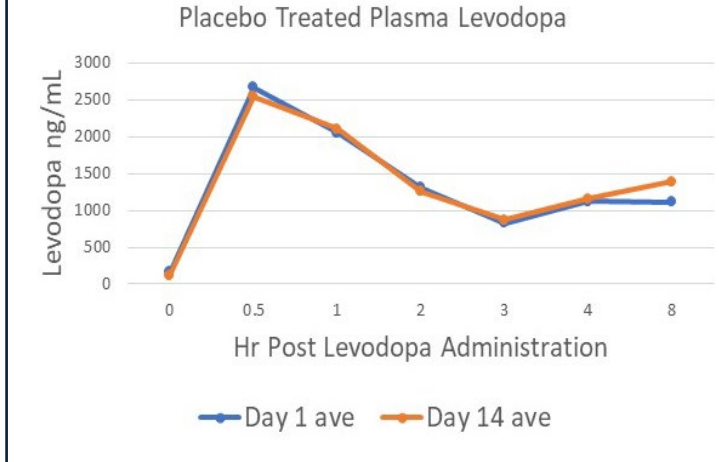


Desirable pharmacokinetics – no observed DDI

0-8 hr 231 ngh/mL (SD 22.38)

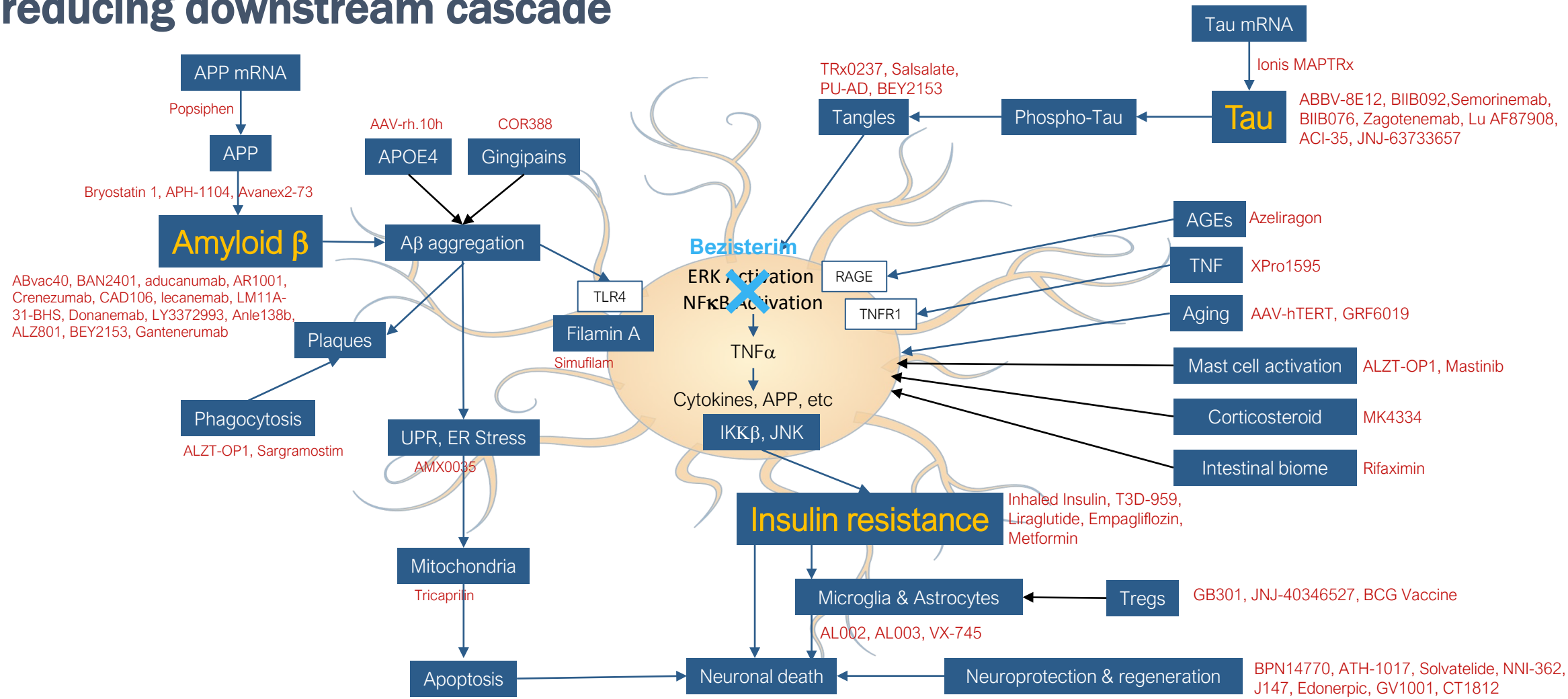






Bezisterim
in Alzheimer's Disease

Bezisterim 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 bezisterim. 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 bezisterim 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 bezisterim 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

- Bezisterim appears to be biologically active
- Cognitive, functional, biomarker efficacy signal suggest that bezisterim:
  - 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

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

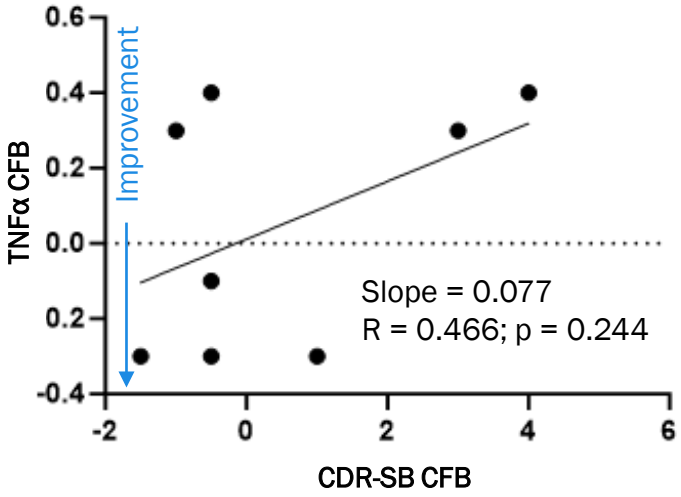
Change from baseline

	Placebo Decline	Bezisterim	Bezisterim 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]

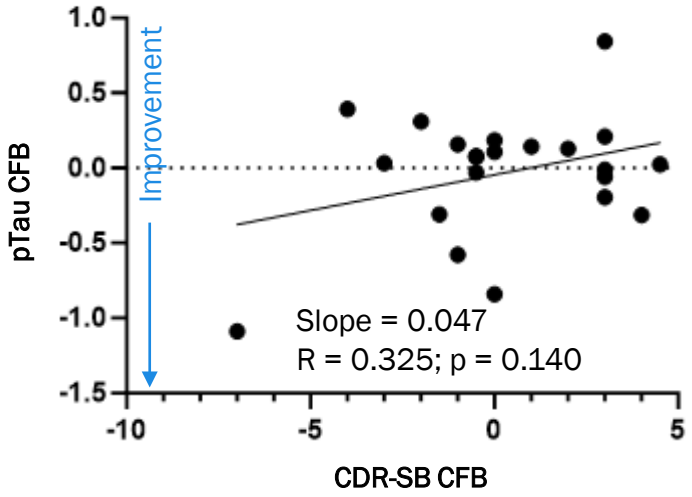
[1] Lecanamab after 18 months; van Dyck et al. *N Engl J Med* 2023;388:9-2
[2] Aducunumab after 18 months; Haeberlein et al. *J Prev Alz Dis* 2022;2(9):197-210

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

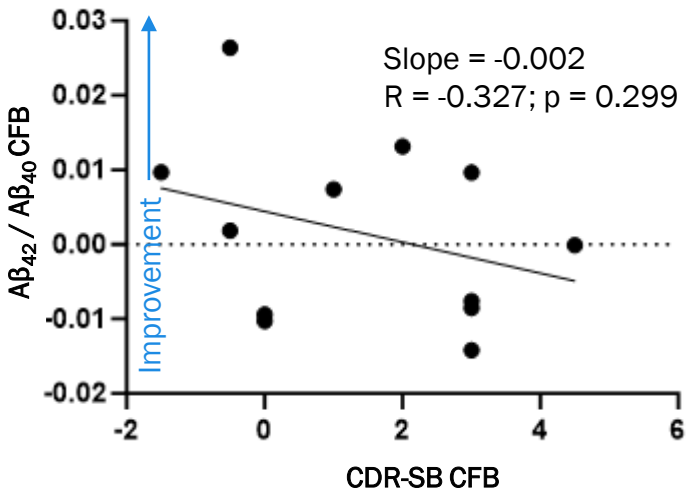
TNFα



Phospho-Tau



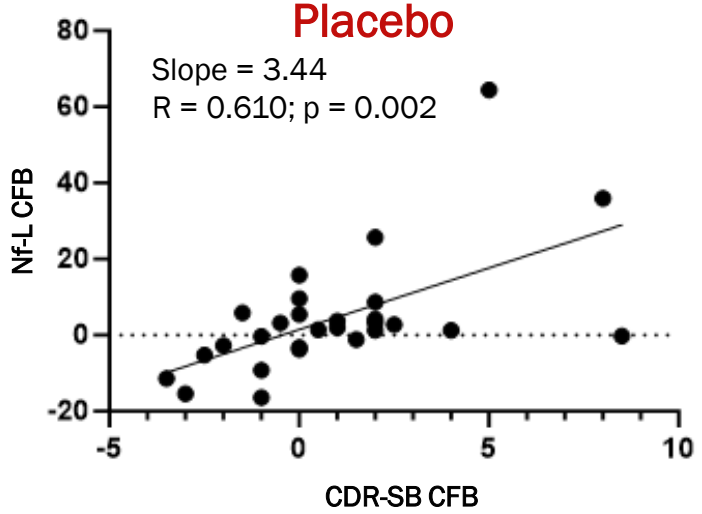
$A\beta_{42}$ / $A\beta_{40}$



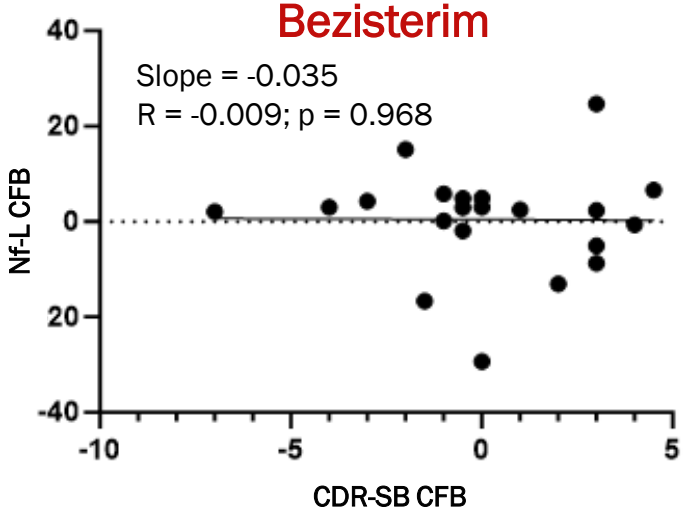
Bezisterim Appears to Decrease the Neuroinflammatory Processes that Link Nf-L and GFAP to Cognitive Decline

Nf-L

Placebo

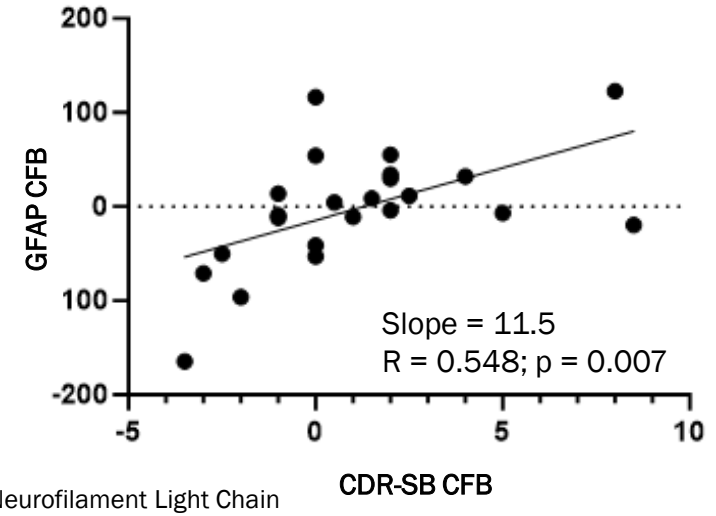


Bezisterim

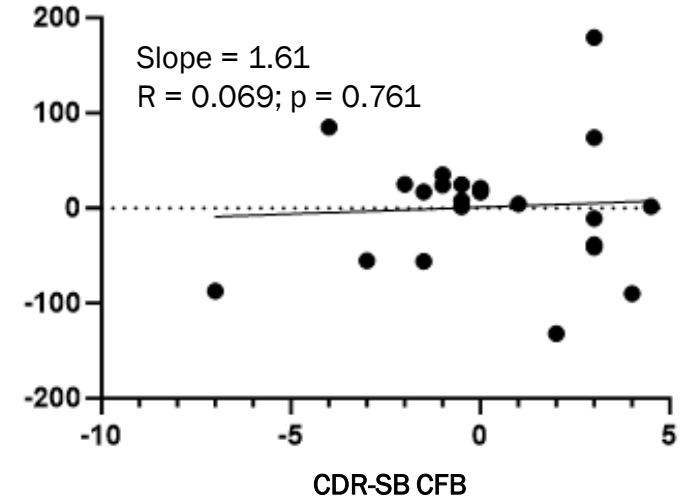


GFAP

Placebo



Bezisterim



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

Safety Profile

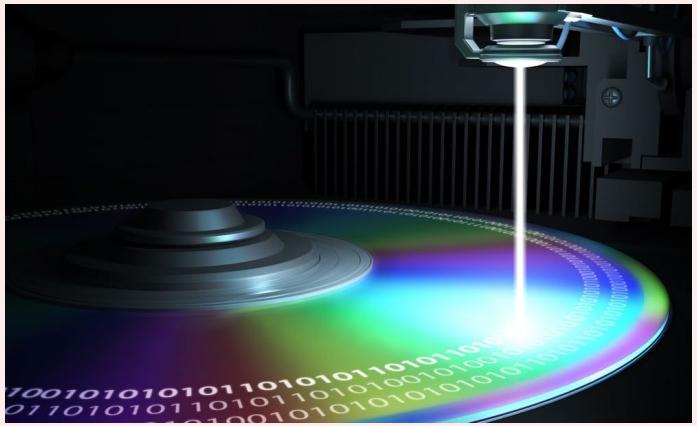
	NE3107	Placebo	Total
COVID-19	9.5%	17.6%	13.2%
Urinary tract infection	7.1%	8.8%	7.9%
Blood thyroid stimulating hormone increased	7.1%	2.9%	5.3%
Fall	2.4%	8.8%	5.3%
Headache	9.5%	0.0%	5.3%
Diarrhoea	4.8%	2.9%	3.9%
Dizziness	2.4%	5.9%	3.9%
Hypertension	2.4%	5.9%	3.9%
Nausea	4.8%	2.9%	3.9%
Pneumonia	4.8%	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%

Bezisterim in Longevity

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

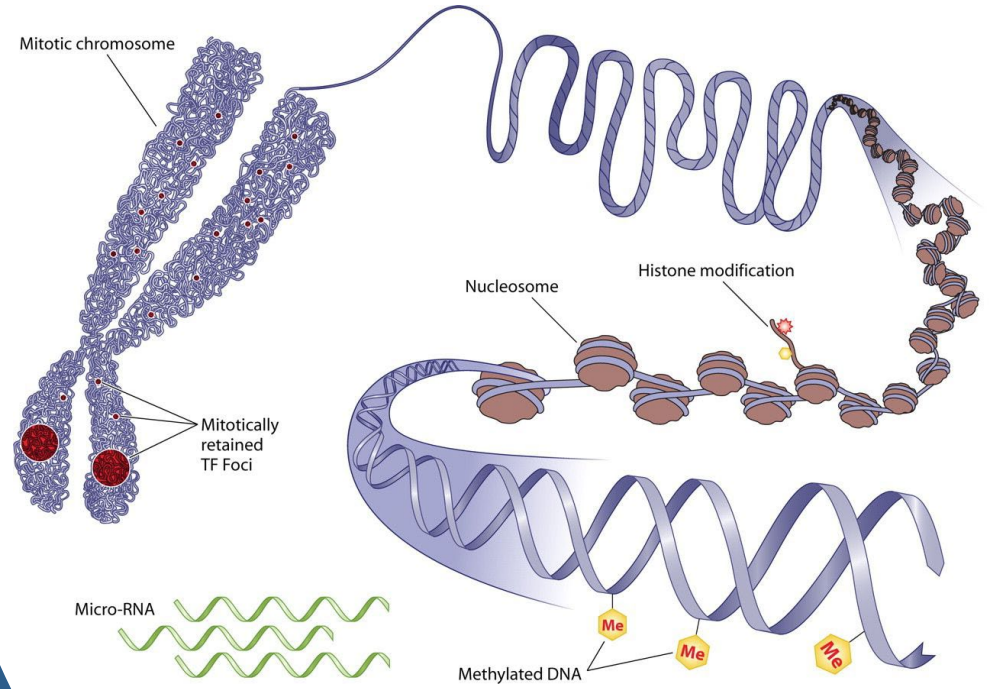
DNA methylation happens when methyl groups are added to our DNA

- 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; Kraiczy 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

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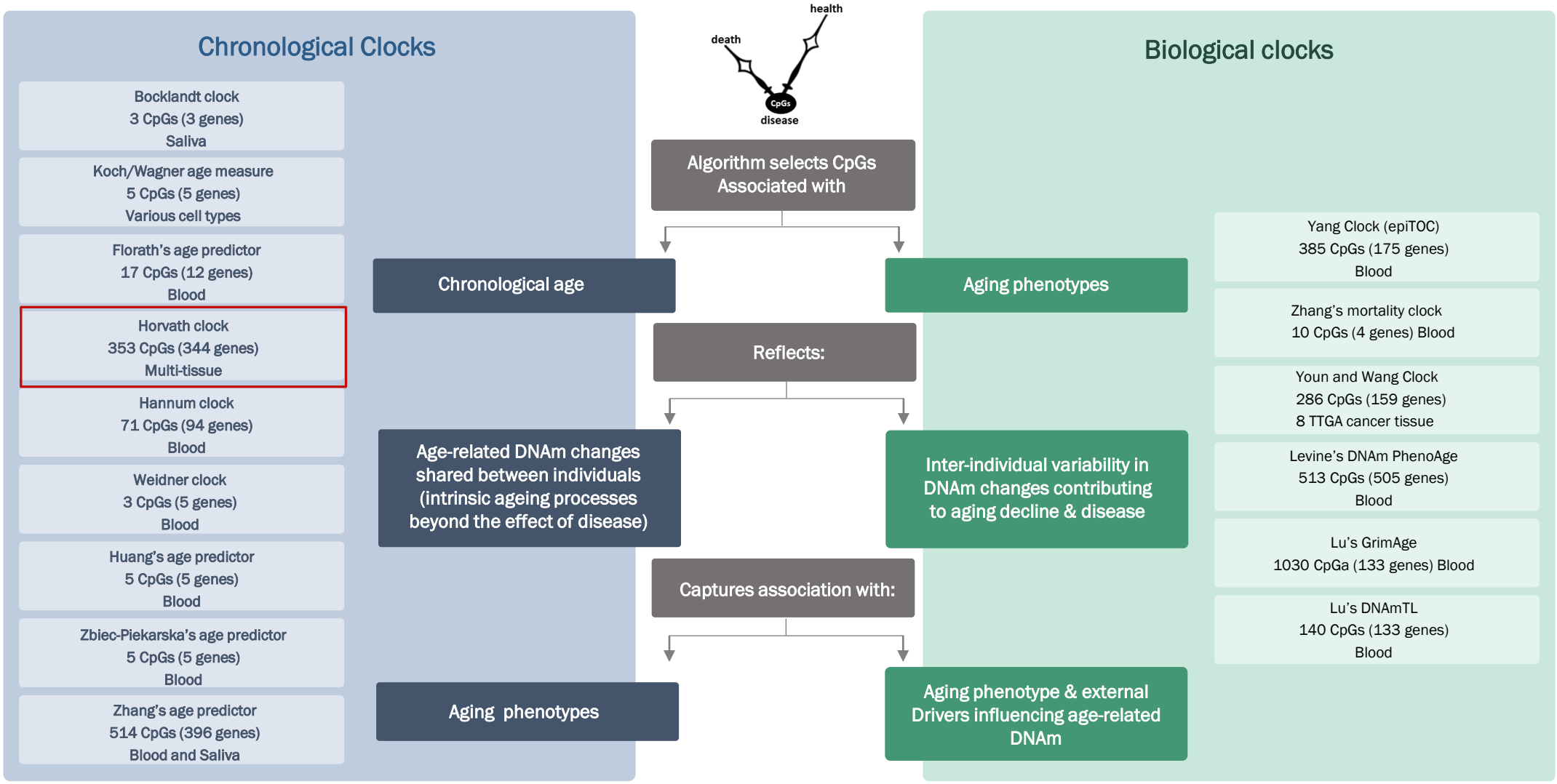
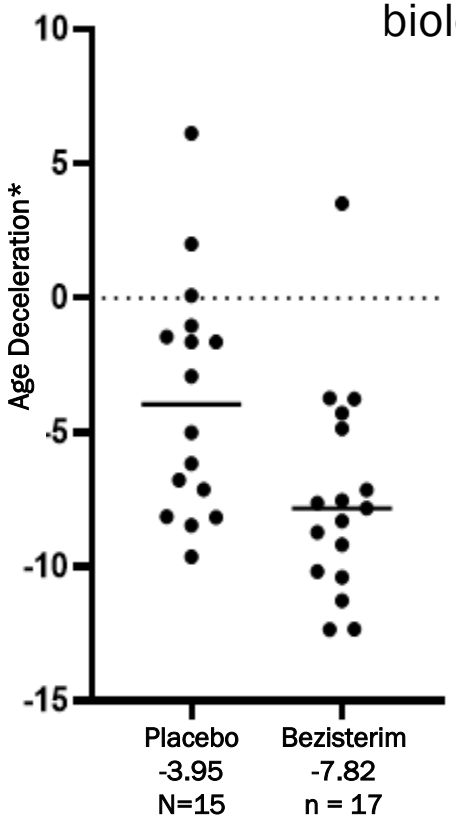
DNA methylation “clocks” measure extent of aging and biological function



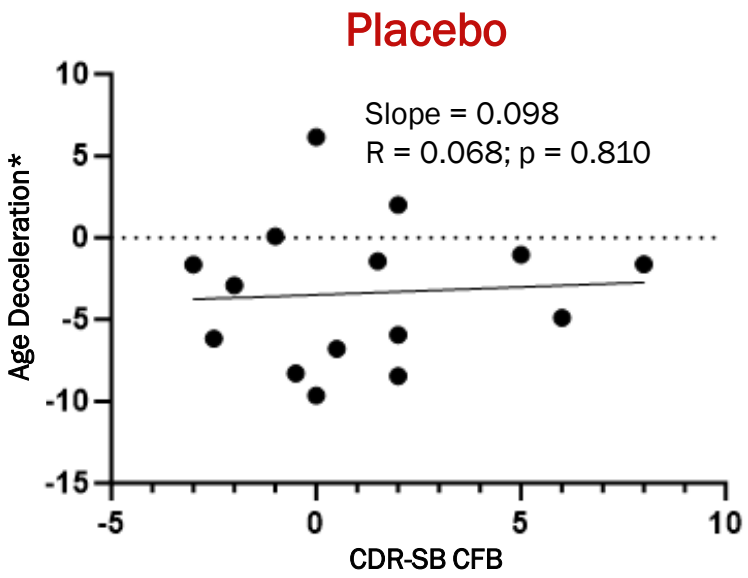
Bezisterim-treated patients experienced significant “age deceleration” in a manner correlated to cognitive and functional improvements

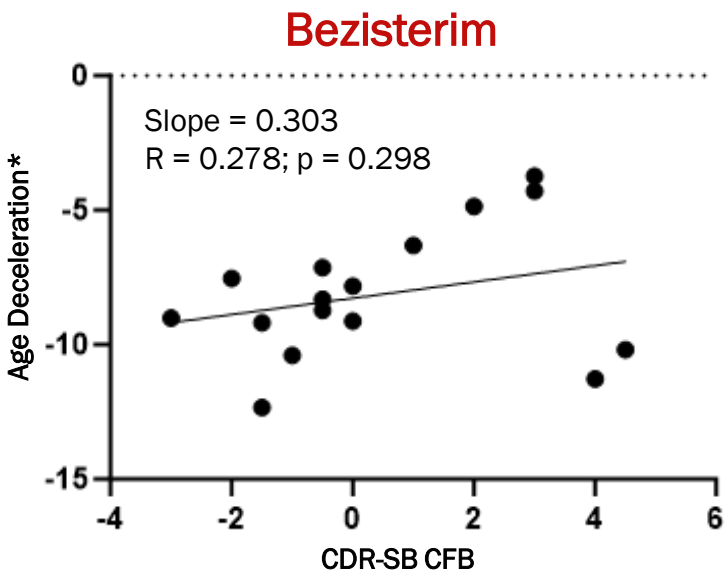
Age Deceleration[1] is used by longevity researchers[2] to measure the difference between a person’s biological age and the actual chronological age.



Difference = -3,87 years

p = 0.012





[1] DNA Methylation Skin Blood Clock Age – Chronological Age

[2] Yusupov et al. *Neuropsychopharmacology* vol 48, 1409–1417 (2023)

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BIV201
in Ascites

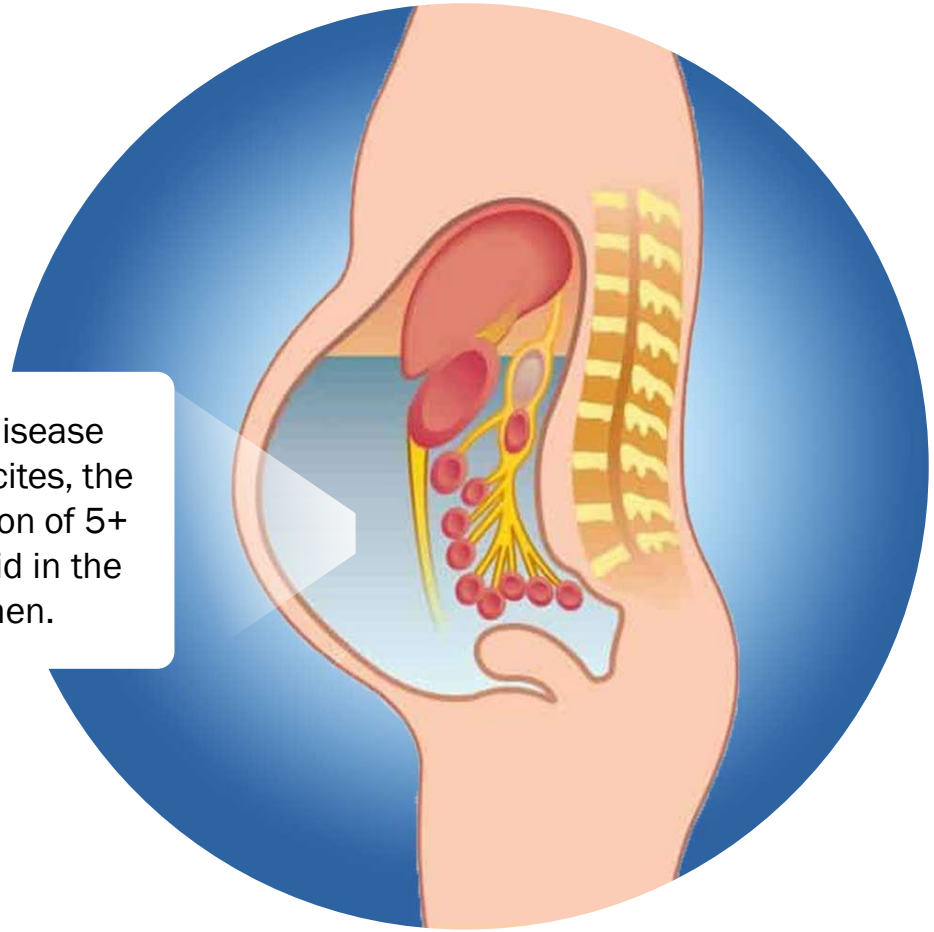
BIV201 Disease Target: Refractory Ascites

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[1] surgery or liver transplant
- Estimated $1.6 billion addressable US market with 20,000[2] 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.

1. TIPS = transjugular intrahepatic portosystemic shunt to channel blood flow around the liver
2. Derived from Scaglione J Clin Gastroenterol.49(8):690-6; D'Amico Journal of Hepatology, Volume 44, pp. 217-231; D'Amico Aliment Pharmacol Ther. 39(10):1180-93; Samonakis World Journal of Hepatology, 6(7), pp. 504-512; Sivanathan Dtsch Med Wochenschr, Volume 139, pp. 1758-1762 and Gines New England Journal of Medicine, 350(16), pp. 1646-1654.

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.

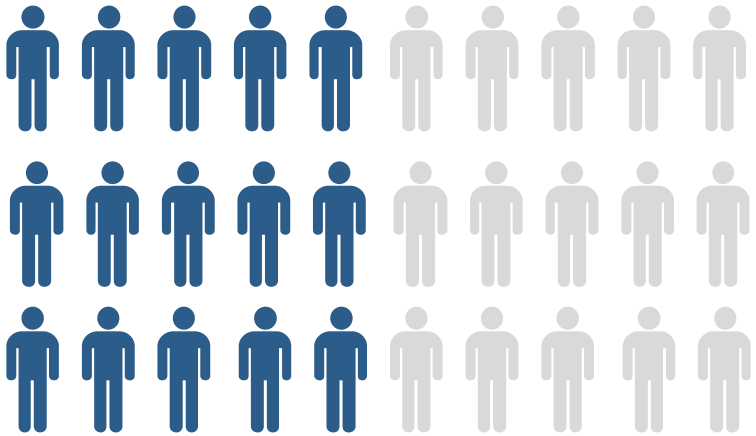
Needle or Connector

50 mL bag of saline for insertion into pump

Portable pump
Carried in small satchel

*In clinical trials; not approved by FDA

BIV201 Phase 2b trial

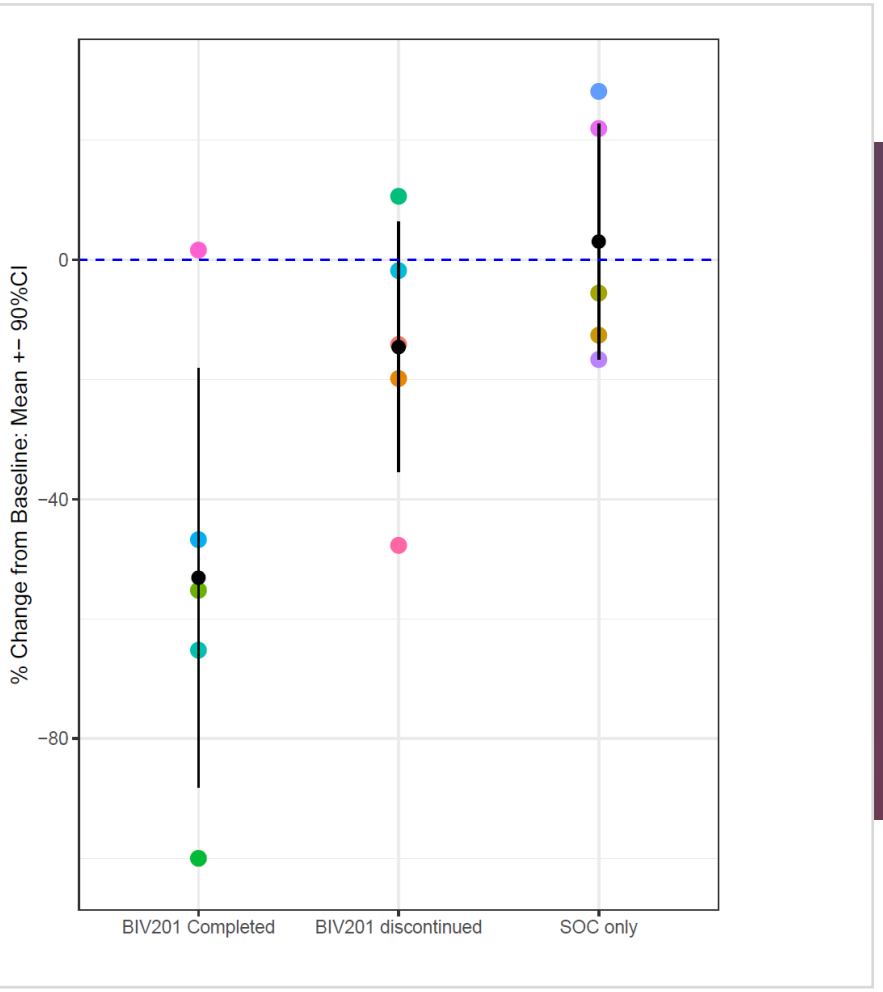


Originally targeted 30 patients randomized 2:1

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 ≥ 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

SBP = spontaneous bacterial peritonitis; HE = hepatic encephalopathy; HRS = hepatorenal; GI = gastrointestinal; PRO = patient reported outcome

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Commercial potential in US market alone*

Alzheimer's

$30B

Annual sales for every 1 million people treated

15% market penetration

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

Parkinson's

$3B

Annual sales for every 100,000 people treated

10% market penetration

$30K/year

Ascites

$1.6B

US peak sales

45% market penetration

$45K/year

2026 launch

2032 peak sales

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

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

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

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

Joseph Palumbo, MD, EVP, R&D and Chief Medical Officer
30+ years treating patients; 25+ years in biopharma
CMO, Zynerba
Global Head of Medical Science & Translational Research, Global Head & Psychiatry Franchise Medical Leader, J&J

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.

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

Recap

Our lead asset Bezisterim modulates the production of TNFα. In clinical trials, many patients treated with Bezisterim experienced:

- Reduced inflammation and the associated insulin resistance
- Improved cognition, lowered 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

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Thank You