ANAVEX®2-73 (*blarcamesine*) Currently in Phase 2b/3 Early Alzheimer's Disease (AD): Analysis of Cognitive Outcome Measures Relevant to AD of Double-blind, Multicenter, Placebo-controlled Phase 2 Clinical Trial in 132 Patients with Parkinson's Disease Dementia

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Disclosures:

Dag Aarsland has served as consult or has received research support and/or honoraria from Astra-Zeneca, H. Lundbeck, Novartis Pharmaceuticals, Biogen, Evonik, Anavex, GE Health, Eisai, Acadia, Heptares, Mentis Cura.
No patents, or stocks or ownerships in relevant companies.

CTAD
Clinical Trials on Alzheimer's Disease

anavex

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Summary of Topline Results:

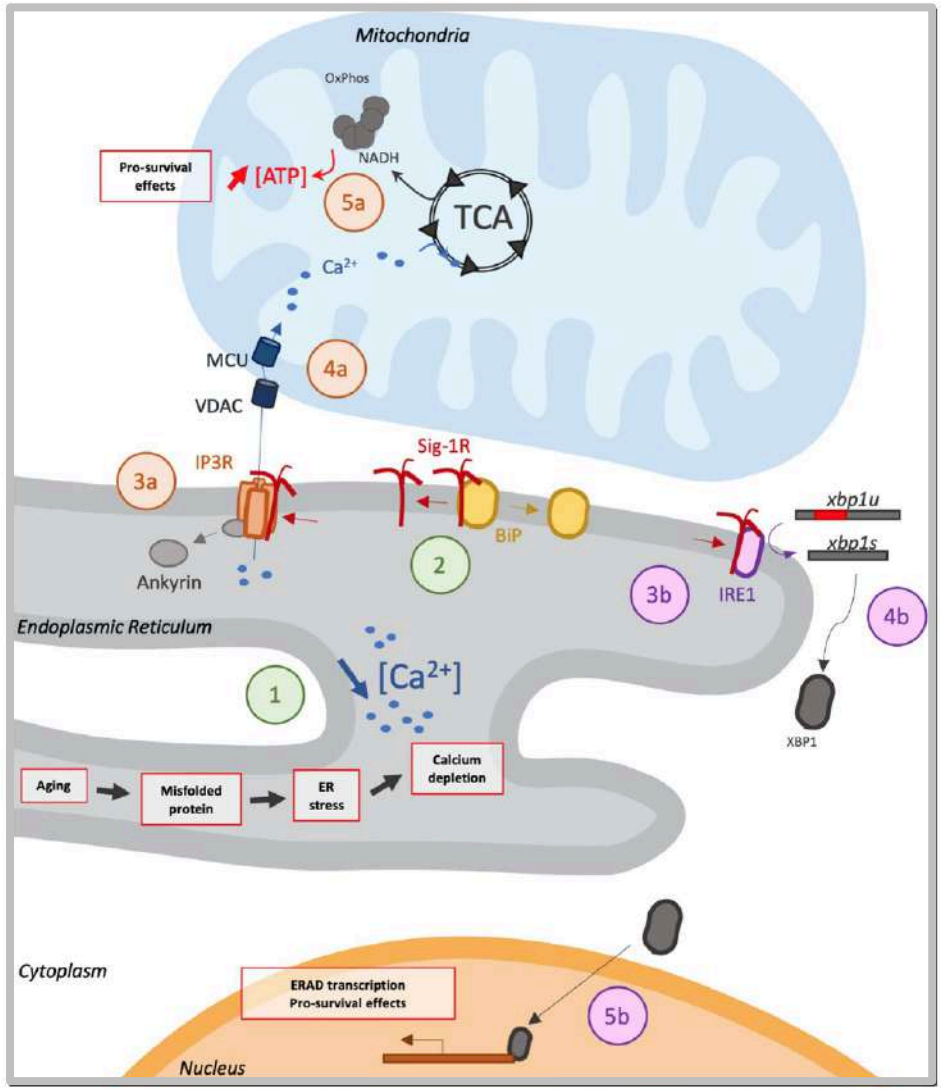
Broad and Significant Effects with ANAVEX®2-73 (*blarcamesine*) in PDD Patients

- ANAVEX®2-73 (*blarcamesine*): a novel, oral, investigational sigma-1 receptor (Sig-1R / SIGMAR1) agonist with multimodal activity
- Data confirm SIGMAR1 as gene "signature" biomarker of response to ANAVEX®2-73 (*blarcamesine*) confirming SIGMAR1 activation as mechanism of action
- Broad and statistically significant improvements in CDR system Cognitive Domain of Attention assessed by Choice Reaction Time ($p = 0.039$) and Digital Vigilance ($p = 0.008$) and CDR system Episodic Memory ($p = 0.047$), representing complex cognitive tasks with impact on quality of life such as making a choice between similar objects and remembering daily personal experiences, which are mostly impaired in both PD and AD[1]
- Statistically significant dose-dependent ($p = 0.003$) improvement of CDR system Episodic Memory, which has been shown to be highly correlated (70%) with the Alzheimer's Disease Assessment Scale–Cognitive score (ADAS-Cog; $r = 0.7$)[2]
- ANAVEX®2-73 (*blarcamesine*) does not impair sleep and has a positive effect on REM sleep behavior disorder
- ANAVEX®2-73 (*blarcamesine*) was generally safe, well tolerated, and improved safety profile compared to dementia drugs associated with typical adverse effects
- These results support continued development in PDD / PD as well as currently ongoing Phase 2 and Phase 2/3 clinical studies with ANAVEX®2-73 (*blarcamesine*) in Rett syndrome[3] and Alzheimer's disease[4]
- Data will be submitted to the U.S. Food and Drug Administration to seek regulatory guidance

1. *Mahurin, R. K., & Pirozzolo, F. J. (1993). Application of Hick's law of response speed in Alzheimer and Parkinson diseases. Perceptual and Motor Skills, 77(1), 107–113*
2. *Wesnes K, Edgar C, Andreasen N, Annas P, Basun H, Lannfelt L, et al. Computerized cognition assessment during acetylcholinesterase inhibitor treatment in Alzheimer's disease. Acta Neurol Scand 2010; 122:270–7*
3. *ClinicalTrials.gov Identifiers: NCT03758924, NCT03941444, NCT04304482*
4. *ClinicalTrials.gov Identifiers: NCT03790709, NCT02756858*

Sig-1R (SIGMAR1) & ANAVEX®2-73 (*blarcamesine*)

Fundamental Functions of Sig-1R (SIGMAR1) on ER Stress Regulation in Neurodegenerative Disorders



①: Misfolded proteins increasing with age induce ER stress and modification in calcium homeostasis

②: Calcium depletion in ER activates Sig-1R, which separates from BiP

Pathway a: IP3R and ATP Production

③a: Sig-1R interacts with IP3R and allows ankyrin to be detached from IP3R, which stabilize and enhance opening of IP3R

④a: Calcium ions efflux from ER lumen into mitochondria through IP3R, VDAC, and MCU

⑤a: Calcium ions increase in mitochondria enhances ATP production through TCA cycle and oxidative phosphorylation

Pathway b: Unfolded Protein Response (UPR)

③b: Sig-1R interacts with IRE1

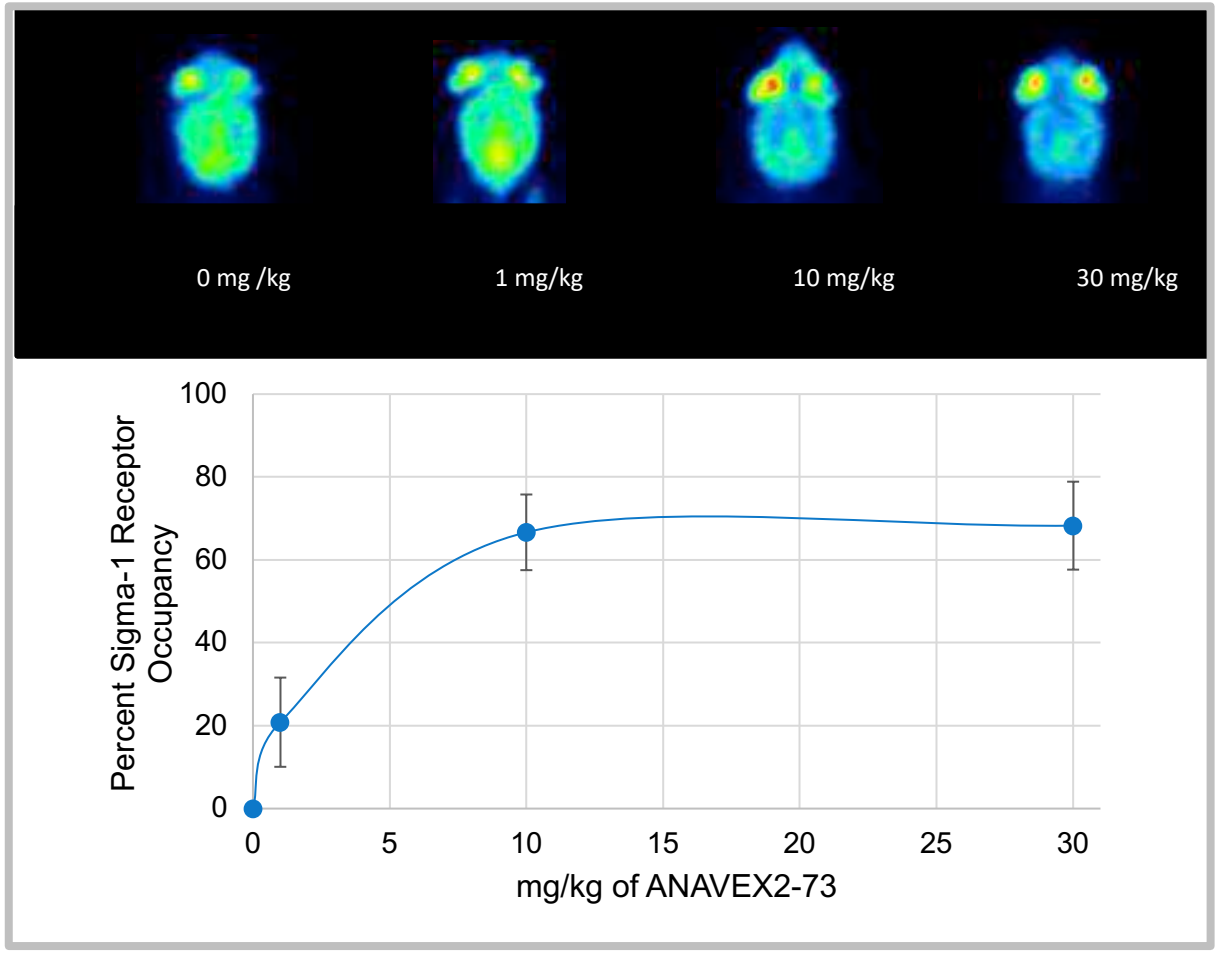
④b: Activated IRE1 acts as an endonuclease and is able to cut an intron from xbp1 to allow its translation

⑤b: XBP1 allows the transcription of ER chaperone genes and pro-survival genes

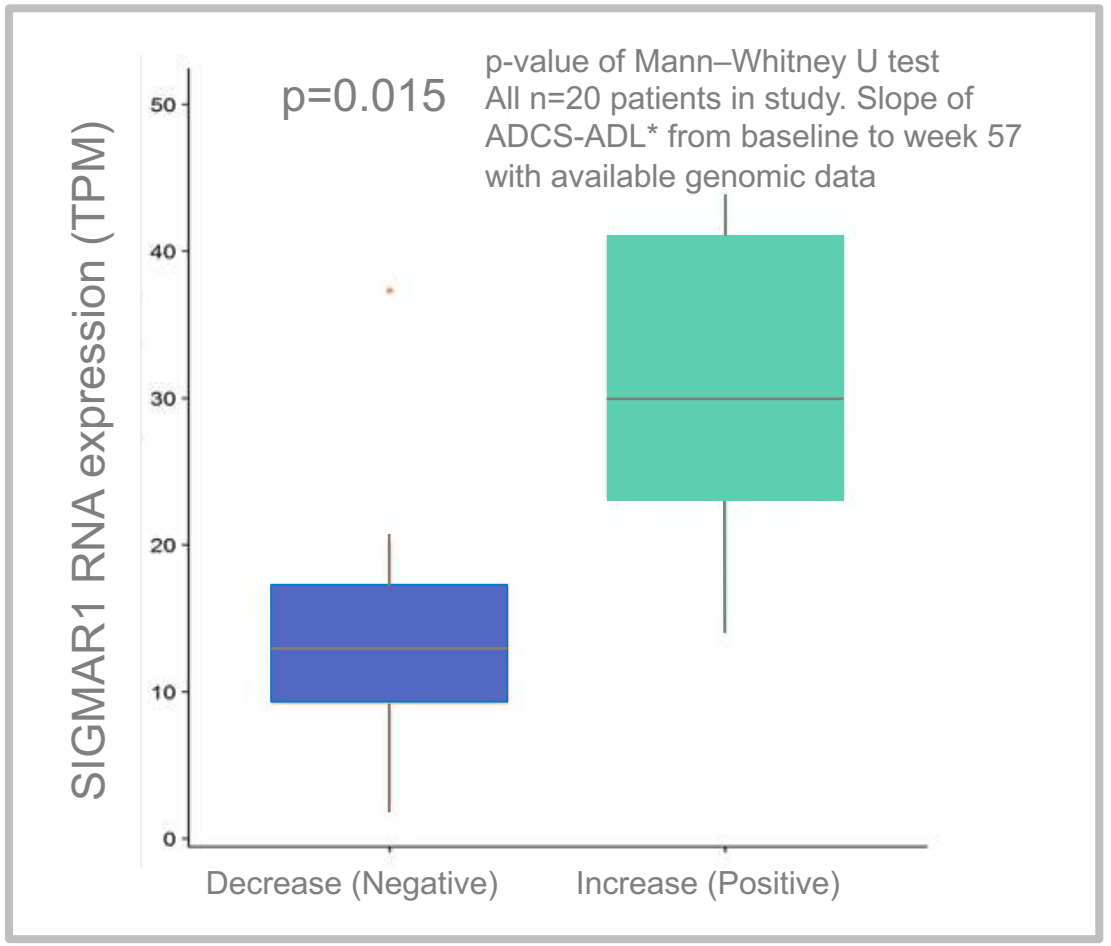
Source: Couly S, Goguadze N, Yasui Y, Kimura Y, Wang SM, Sharikadze N, Wu HE, Su TP. Knocking Out Sigma-1 Receptors Reveals Diverse Health Problems. Cell Mol Neurobiol. 2020 Oct 23. doi: 10.1007/s10571-020-00983-3. Epub ahead of print. PMID: 33095392; ATP: adenosine triphosphate; BiP: binding immunoglobulin protein; ER: endoplasmic reticulum; ERAD: endoplasmic-reticulum-associated protein degradation; IP3R: inositol trisphosphate receptor; IRE1: inositol-requiring enzyme 1; MCU: mitochondrial calcium uniporter; OxPhos: oxidative phosphorylation; TCA: tricarboxylic acid cycle; VDAC: voltage-dependent anion channel; XBP1: X-box binding protein 1; xbp1s: xbp1 mRNA spliced; xbp1u: xbp1 mRNA unspliced

ANAVEX®2-73 (*blarcamesine*) Established Human Proof-of-Concept and SIGMAR1 Target Occupancy

2D [18F]FTC-146-PET imaging of ANAVEX®2-73: Dose-dependent ANAVEX®2-73 Target Engagement in mouse model



ANAVEX®2-73 positive response in functional (ADCS-ADL*) outcome in Alzheimer's disease patients correlate with SIGMAR1 mRNA levels



*Source: Reyes S et al, AAIC 2018; : Hampel et al. Alzheimer's Dement. 2020;00:1–14; *Alzheimer's Disease Cooperative Study Activities of Daily Living 23-item scale (ADCS-ADL)*

Rationale to Advance ANAVEX®2-73 into a PoC Phase 2 PDD Study

ANAVEX®2-73 (*blarcamesine*) normalizes pathophysiological biomarkers in experimental Parkinsonism

Collaboration with MJFF

ANAVEX®2-73 demonstrated critical mediation of nigrostriatal dopamine damage

- ✓ Neuroinflammation
- ✓ mitochondrial dysfunction
- ✓ protein misfolding/degradation
- ✓ nitrosative stress


BRAIN
A JOURNAL OF NEUROLOGY

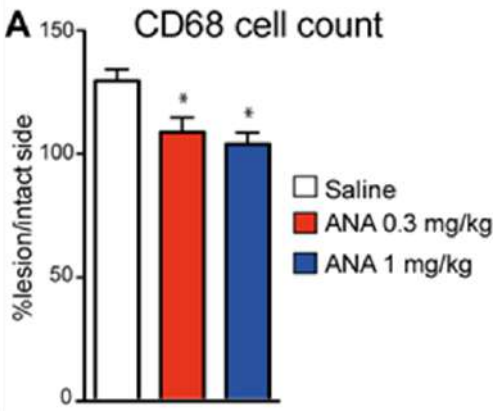
Pharmacological stimulation of sigma-1 receptors has neurorestorative effects in experimental parkinsonism

Veronica Francardo,[1] Francesco Bez,[1] Tadeusz Wieloch,[2] Hans Nissbrandt,[3] Karsten Ruscher[2] and M. Angela Cenci[1]

These results support the hypothesis that pharmacological stimulation of the Sigma-1 receptor may have disease-modifying effects in Parkinson's disease

ANAVEX®2-73 reduces microglia over-activation*

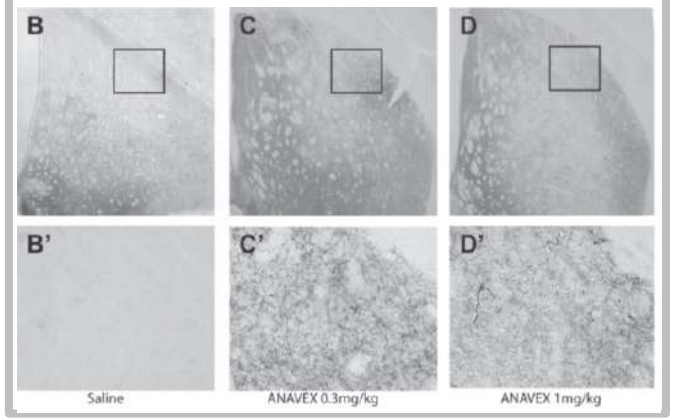
ANAVEX®2-73 significantly decreased the expression of CD68 (marker of activated microglia) in the substantia nigra



ANAVEX®2-73 restores dopaminergic neurons*

ANAVEX®2-73 significantly increases tyrosine-hydroxylase fibers (marker of dopaminergic neurons) in the striatum

Tyrosine-hydroxylase fibers



** Cenci et al., presented at World Parkinson Congress 2016*

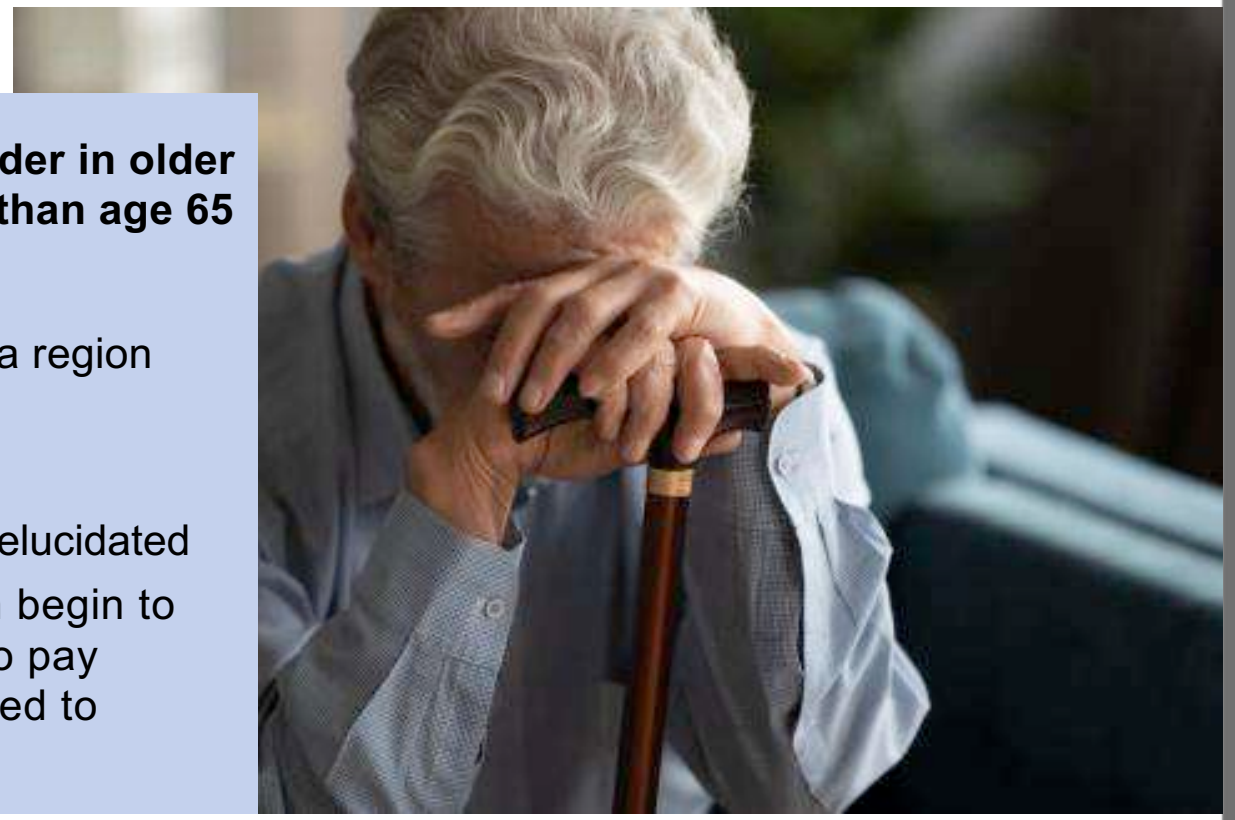
ANAVEX®2-73-PDD-001 Proof of Concept (PoC) Phase 2 Trial in PDD (Parkinson's Disease Dementia) – Design & Top-Line Results

Parkinson's Disease Dementia (PDD)

Up to 80 percent of those with Parkinson's disease eventually experience Parkinson's disease dementia

Parkinson's Disease Dementia

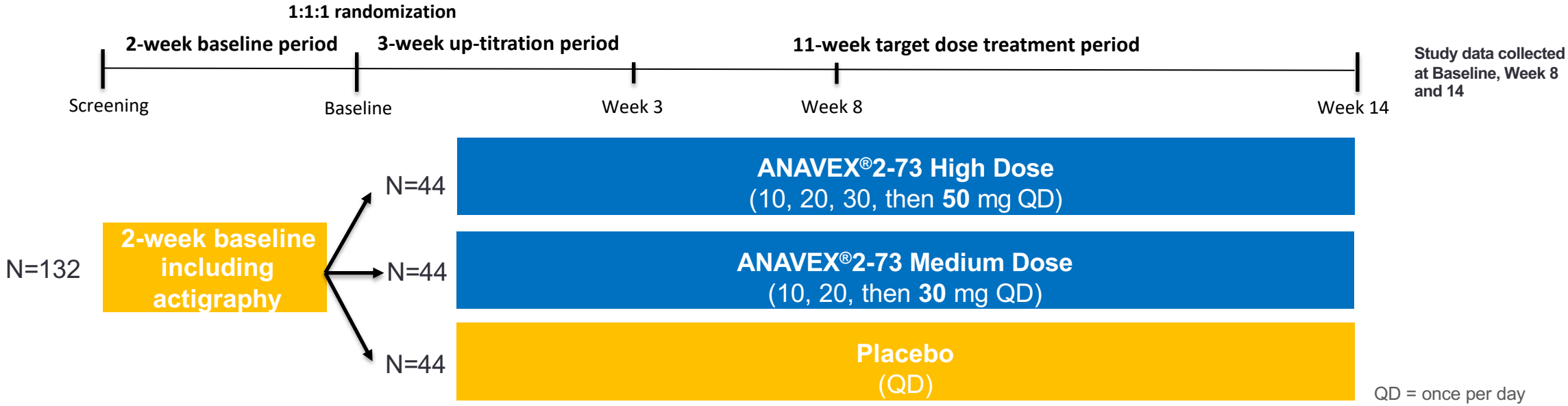
- **Parkinson's disease is a fairly common neurological disorder in older adults, estimated to affect nearly 2 percent of those older than age 65**
  - PD prevalence in US:~1,000,000
  - The brain changes caused by Parkinson's disease begin in a region that plays a key role in movement
  - Highly heterogeneous multisystem disorder
  - Etiology of cognitive impairment in PD has not yet been fully elucidated
  - As Parkinson's brain changes gradually spread, they often begin to affect mental functions, including memory and the ability to pay attention, make sound judgments and plan the steps needed to complete a task



Source: Aarsland D, Creese B, Politis M, Chaudhuri KR, Ffytche DH, Weintraub D, Ballard C. Cognitive decline in Parkinson disease. Nat Rev Neurol. 2017 Apr;13(4):217-231. doi: 10.1038/nrneurol.2017.27. Epub 2017 Mar 3. PMID: 28257128; PMCID: PMC5643027; www.alz.org/alzheimers-dementia/what-is-dementia/types-of-dementia/parkinson-s-disease-dementia

ANAVEX®2-73 PoC Phase 2 PDD Study Design

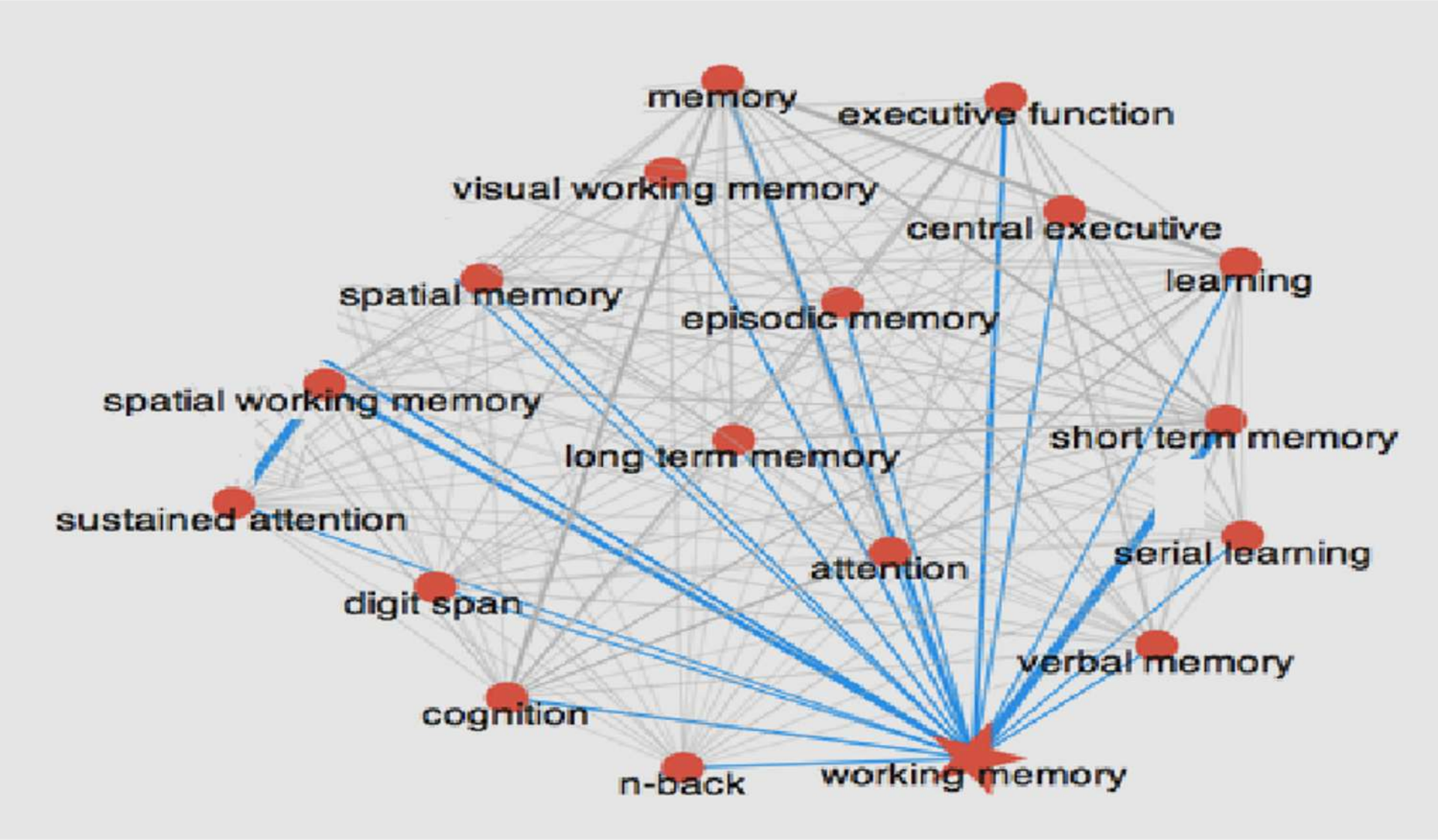
A Phase 2 trial to Assess the Safety, Tolerability and Efficacy of ANAVEX®2-73 (*blarcamesine*) Oral Capsules in the Treatment of Parkinson's Disease Dementia



- **PDD Patient Population**
  - Diagnosis of probable Parkinson's disease dementia
  - Diagnosis of idiopathic Parkinson's disease
  - Patients aged ≥ 50 years
  - MoCA score 13-23
- **Key Primary and Secondary Endpoints**
  - Safety and tolerability
  - CDR Cognitive Domain of Attention
  - Sleep function
  - MDS-UPDRS
  - Actigraphy (24-hour monitoring)
  - Entire DNA and RNA sequencing
- **Pre-specified Endpoints**
  - Genetic variants SIGMAR1 (rs1800866),
  - COMT(rs113895332/rs6114320 3) with influence on treatment effect

ANAVEX®2-73-PDD-001 is a Proof of Concept (PoC) Phase 2, multicenter, randomized, double-blind, placebo-controlled, parallel-group, 3-arm, 14-week study

Cognition is Multidimensional



CDR System Core Domains And Tests

Cognitive Drug Research Computerized Assessment (CDR) System Dimensions

- Cognitive Drug Research computerized assessment (CDR) system is an automated test battery validated for use in PDD, AD and other dementias[1]
- The battery is modular, covering episodic memory, attention/concentration, verbal and visuo-spatial recall and recognition, verbal and visuo-spatial working memory, psychomotor speed and information processing speed
- E.g. comprehensive cognitive dimension “Quality of Episodic Memory”:
    - Quality of Episodic Memory = (DRECOACC+DRECNACC–100) + (DPICOACC+DPICNACC–100) + ((IRCL–IRCLERR)*100/12) + ((DRCL–DRCLERR)*100/12)
    - Where OACC is related to the accuracy of original stimuli and NACC to the accuracy of new stimuli
    - DREC = word recognition
    - DPIC = picture recognition
    - IRCL = number of words recalled at the immediate word recall
    - DRCL = number of words3 recalled at the delayed word recall
    - IRCLERR = number of intrusions words at the immediate word recall
    - DRCLERR = number of intrusions words at the delayed word recall

1. Simpson PM, Surmon DJ, Wesnes KA, Wilcock GR. The cognitive drug research computerised assessment system for demented subjects: a validation study. Int J Geriatr Psychiatr 1991;6:95–102

Key Cognitive Domains

Episodic memory: Key feature that points to AD-related MCI

The criteria from the National Institute on Aging and Alzheimer's Association (NIA-AA) workgroup mention the following five cognitive domains when diagnosing MCI-AD:

(a) Episodic memory

(b) Attention

(c) Language

(d) Visuospatial skills

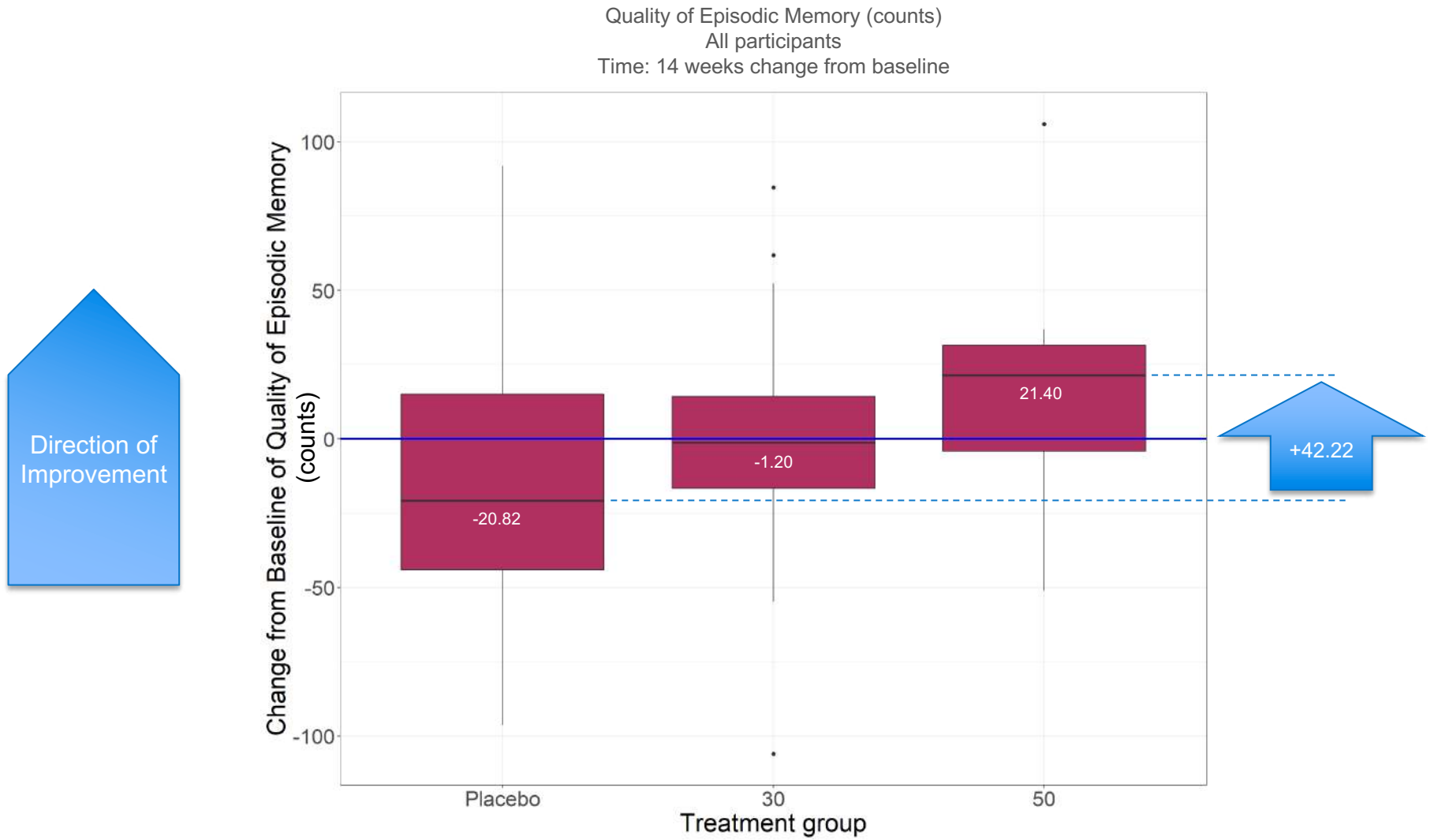
(e) Executive functions

"An impairment in episodic memory (i.e., the ability to learn and retain new information) is seen most commonly in MCI patients who subsequently progress to a diagnosis of AD dementia"

Source: Albert MS, DeKosky ST, Dickson D, Dubois B, Feldman HH, Fox NC, Gamst A, Holtzman DM, Jagust WJ, Petersen RC, Snyder PJ, Carrillo MC, Thies B, Phelps CH. The diagnosis of mild cognitive impairment due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement. 2011 May;7(3):270-9. doi: 10.1016/j.jalz.2011.03.008. Epub 2011 Apr 21. PMID: 21514249; PMCID: PMC3312027.

Significant Improvements in Episodic Memory with Increased Dose

ANAVEX®2-73-PDD-001 Study: Dose-dependent, statistically significant improvement of Quality of Episodic Memory with ANAVEX®2-73 (*blarcamesine*)



A high score reflects a good ability to store, hold and retrieve information of an episodic nature (e.g., an event or name)

All participants; ANAVEX2-73 = Active 30 mg, Active 50 mg vs Placebo
J-T test based on actual maintenance dose: p = 0.003

Key Cognitive Domains

Key cognitive features addressed by ANAVEX®2-73 (*blarcamesine*)

The criteria from the National Institute on Aging and Alzheimer's Association (NIA-AA) workgroup mention the following five cognitive domains when diagnosing MCI-AD:

Addressed in PoC Phase 2 PDD Study

(a) Episodic memory

(b) Attention

(c) Language

(d) Visuospatial skills

(e) Executive functions

Related CDR system domains

Episodic memory ✅

Choice reaction time ✅

Word recognition ✅

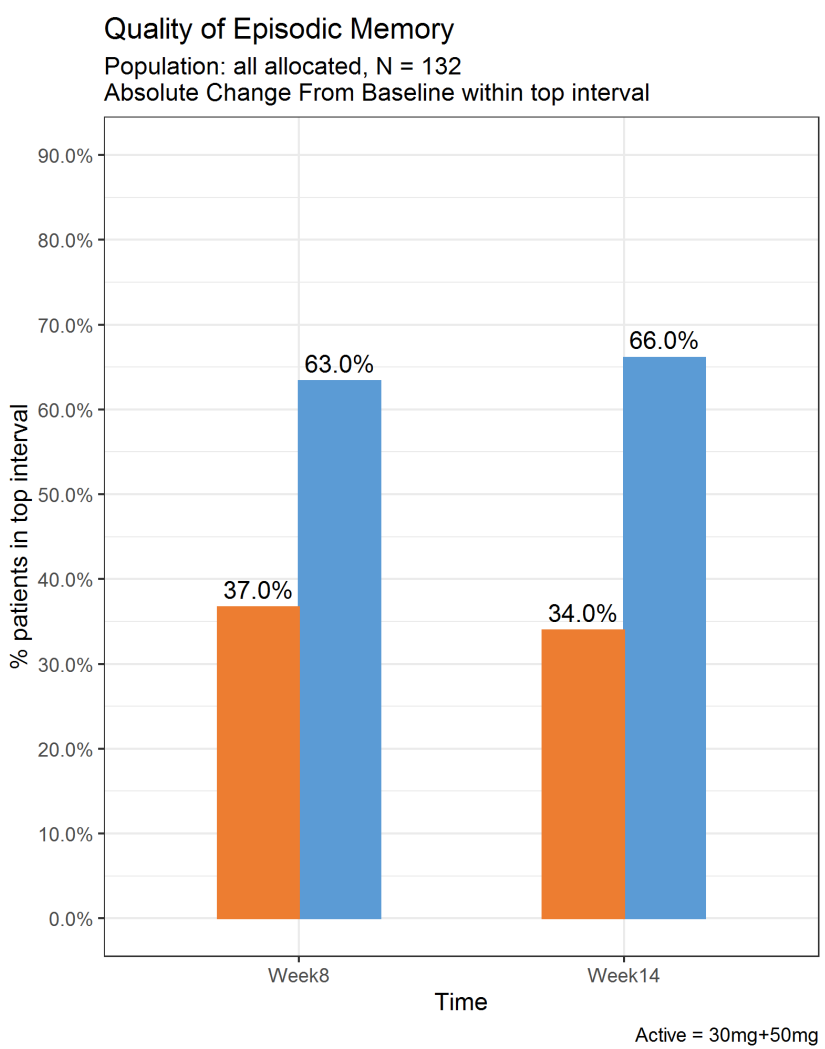
Picture recognition ✅

Numeric working memory ✅

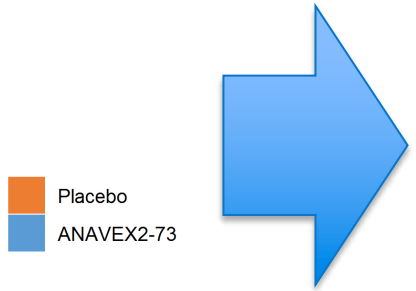
Source: Albert MS, DeKosky ST, Dickson D, Dubois B, Feldman HH, Fox NC, Gamst A, Holtzman DM, Jagust WJ, Petersen RC, Snyder PJ, Carrillo MC, Thies B, Phelps CH. The diagnosis of mild cognitive impairment due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement. 2011 May;7(3):270-9. doi: 10.1016/j.jalz.2011.03.008. Epub 2011 Apr 21. PMID: 21514249; PMCID: PMC3312027.

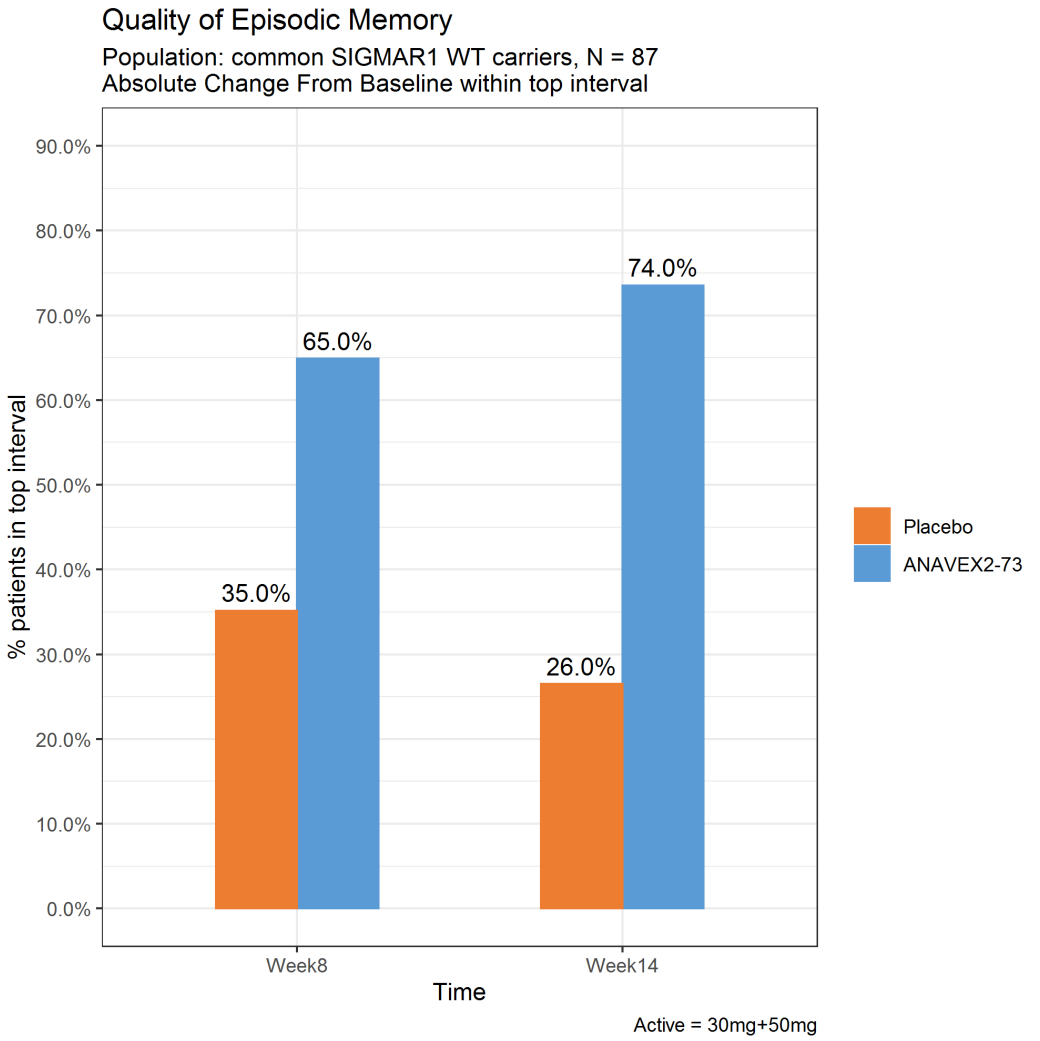
Positive Impact of Pre-specified Common SIGMAR1 WT Carriers

ANAVEX®2-73-PDD-001 Study: Improvements of Quality of Episodic Memory with Pre-specified Common SIGMAR1 WT Carriers[1]



Common SIGMAR1 WT carriers only



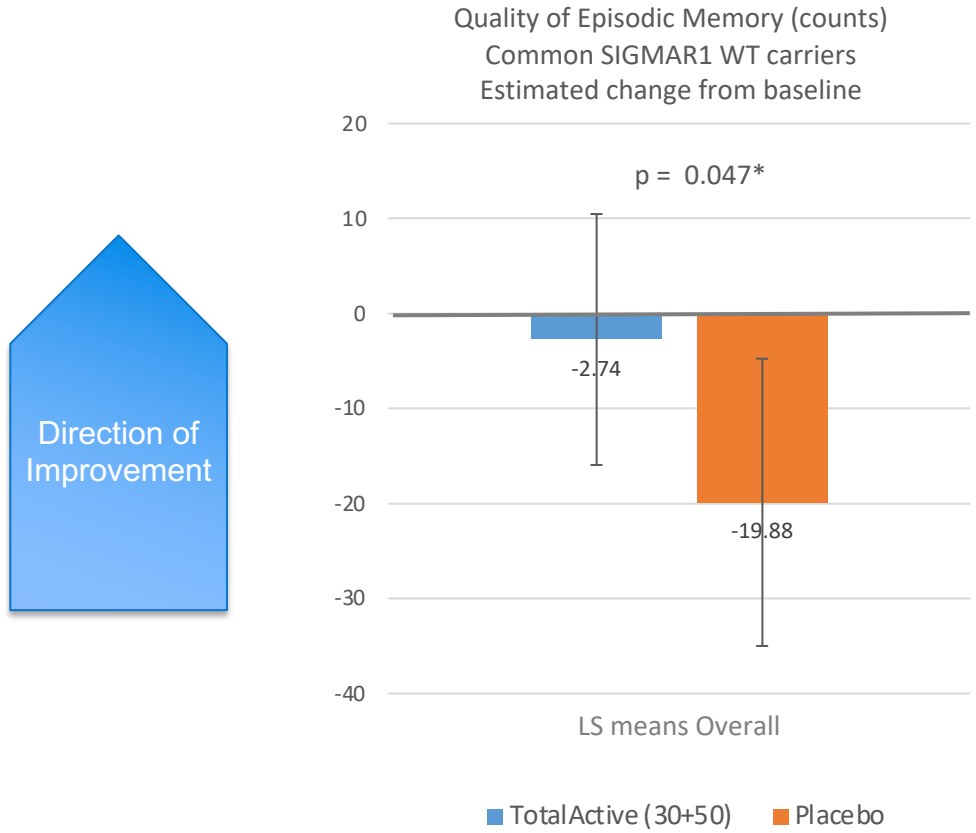


1. Common SIGMAR1 Wild Type (WT) gene, represents 80%-84% of the worldwide population excluding SIGMAR1 rs1800866 gene variant carriers (16%-20%): https://www.ncbi.nlm.nih.gov/projects/SNP/snp_ref.cgi?rs=rs1800866

Improvements in Core Cognitive Functions

ANAVEX®2-73-PDD-001 Study: Change in (CDR) System Quality of Episodic Memory

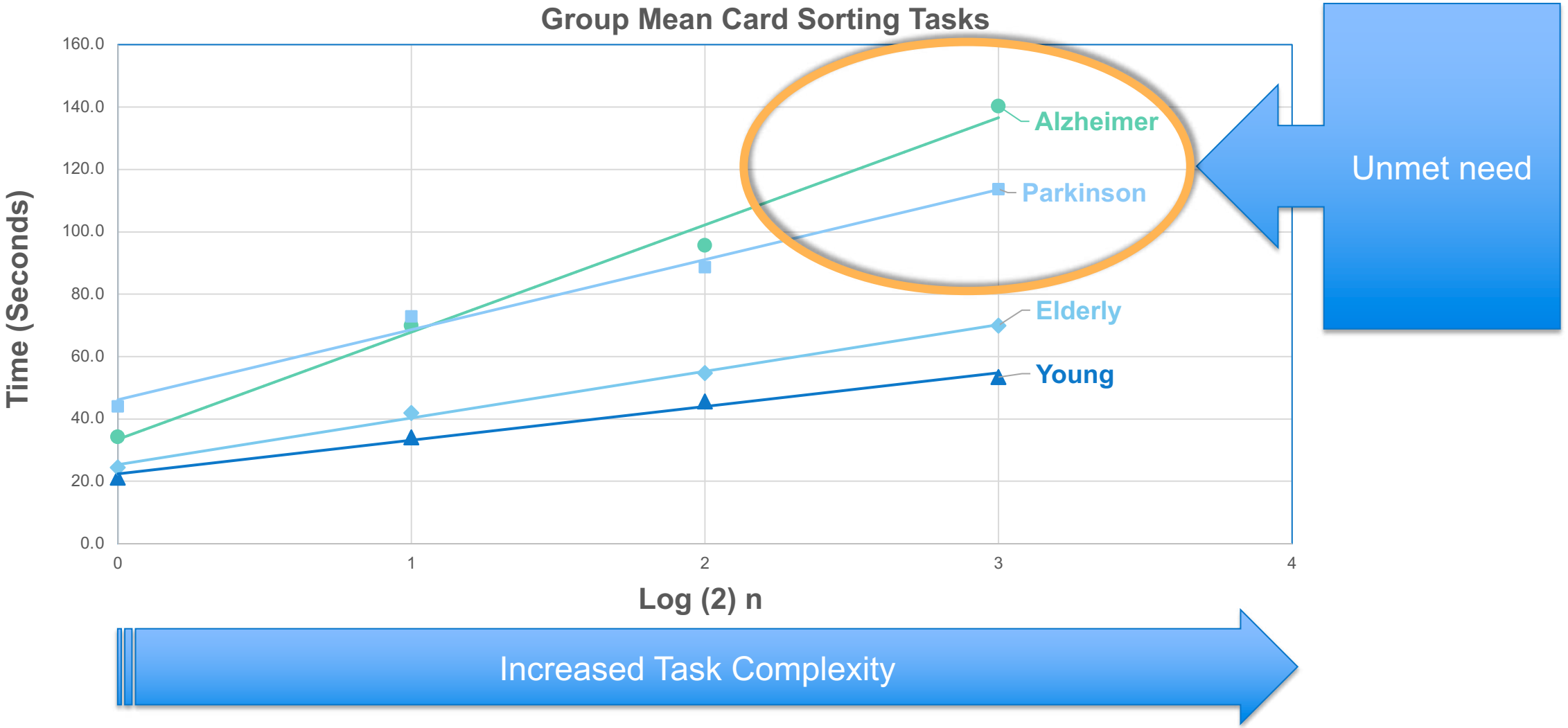
Prevention of on-going decline observed in placebo group



Effects of ANAVEX®2-73 (*blarcamesine*) treatment. Scores are least square means from the analysis of mixed-effect models for repeated measures of the change from baseline scores over 14 weeks, with Multiple Imputation (MCAR) by Visit and Treatment Group. Error bars are 95% confidence intervals. * P-value < 0.05 statistically significant

Choice Reaction Time Increases with Complex Tasks

Affected in Alzheimer's and Parkinson's Diseases



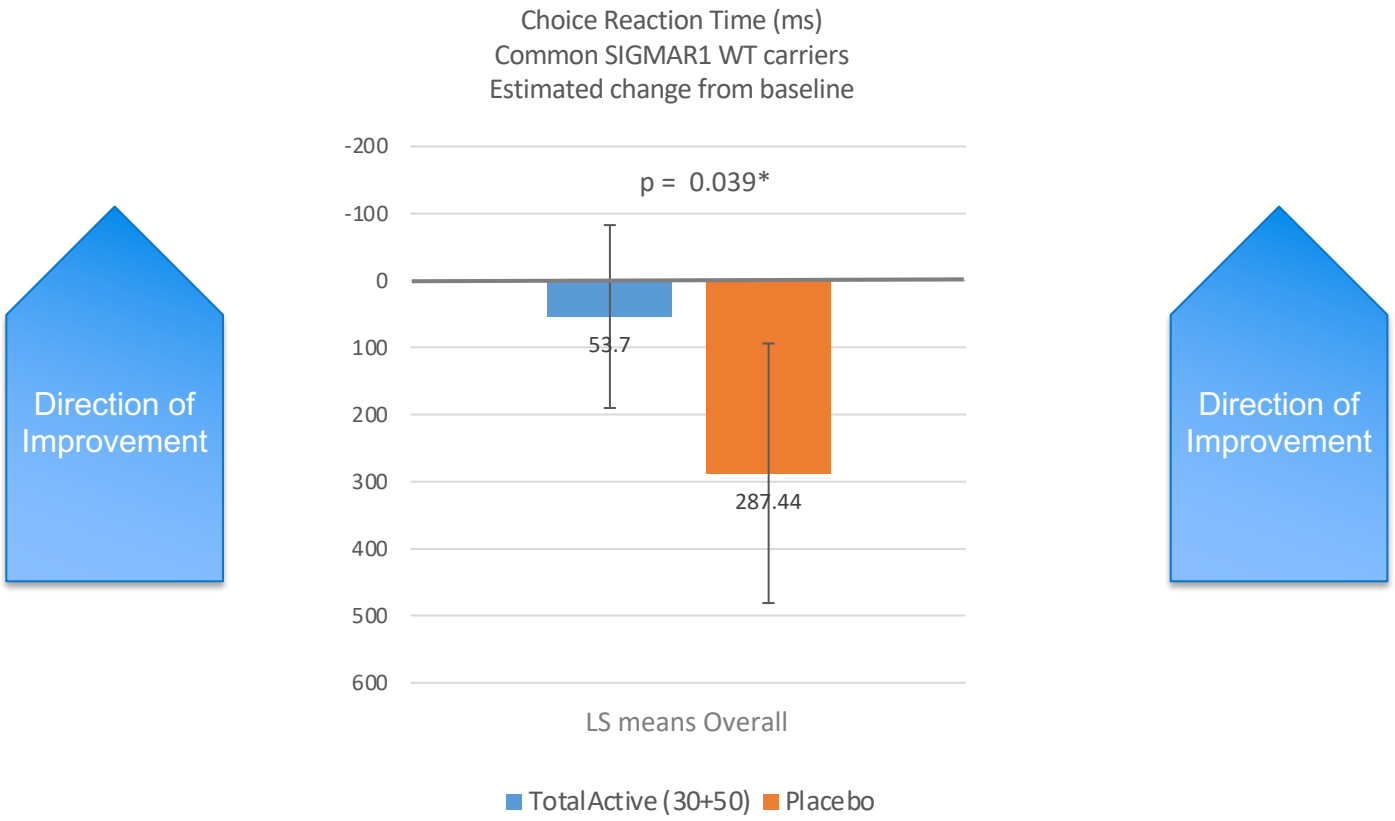
Source: Mahurin, R. K., & Pirozzolo, F. J. (1993). Application of Hick's law of response speed in Alzheimer and Parkinson diseases. Perceptual and Motor Skills, 77(1), 107–113

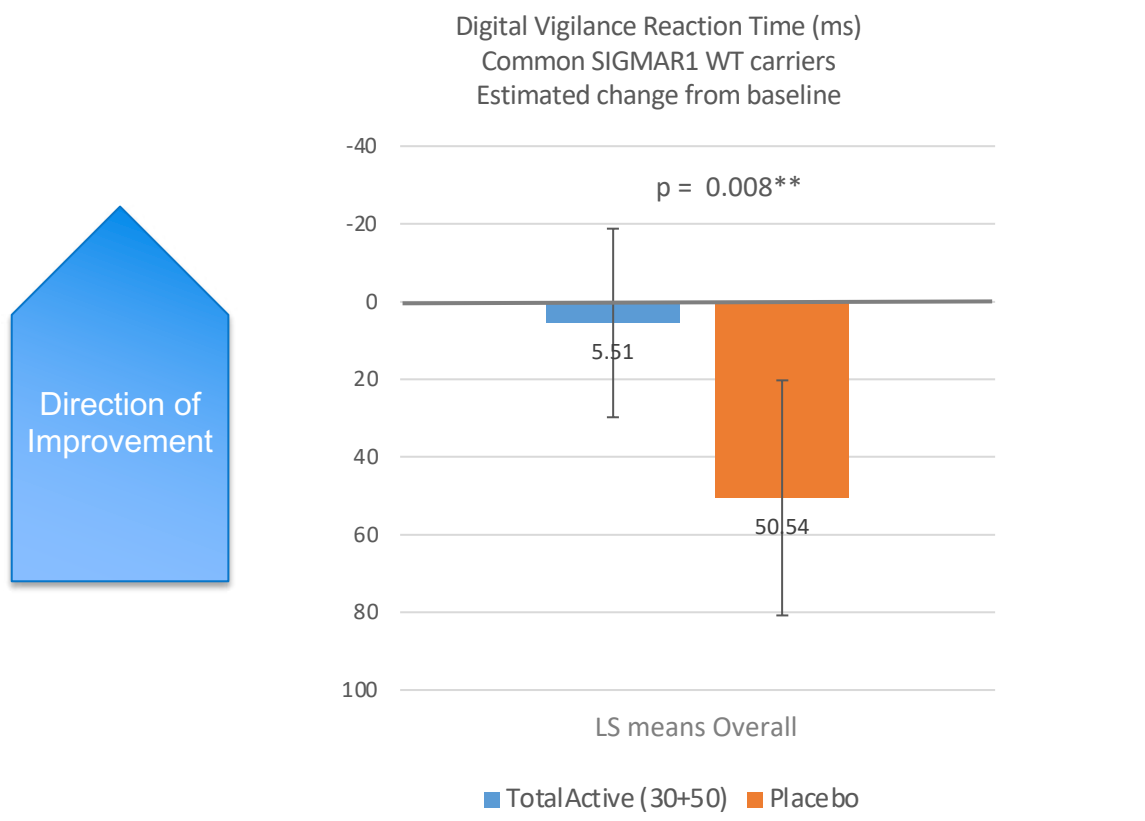
Improvements in Core Cognitive Functions

ANAVEX®2-73-PDD-001 Study: Change in (CDR) System Individual Task Measures

Choice Reaction Time and Digit Vigilance Reaction Time

Prevention of on-going decline observed in placebo group





Effects of ANAVEX®2-73 (*blarcamesine*) treatment. Scores are least square means from the analysis of mixed-effect models for repeated measures of the change from baseline scores over 14 weeks, with Multiple Imputation (MCAR) by Visit and Treatment Group. Error bars are 95% confidence intervals. * P-value < 0.05 statistically significant; ** P-value < 0.01 statistically significant

Effects in Sleep Impairment Symptoms

ANAVEX®2-73-PDD-001 Study: Insomnia Severity Index (ISI) and the REM Sleep Behavior Disorder Screening Questionnaire (RBDSQ)

- Two key prespecified sleep instruments, the Insomnia Severity Index (ISI) and the REM Sleep Behavior Disorder Screening Questionnaire (RBDSQ), showed that there were no overall negative drug effects on sleep since unaffected participants receiving the drug remained unaffected throughout the trial as those treated with standard of care (placebo)
- For a characteristic and debilitating sleep problem in Parkinson's disease there was a marked and marginally significant improvement ($p = 0.054$) in those affected by REM sleep behavior disorder, which was detected as early as 8 weeks after beginning treatment: 50% subjects on 50 mg dose improved from REM sleep disorder 'affected' to 'not affected', compared to 15% in placebo arm ($p = 0.054$)
- Collectively, data indicates that ANAVEX®2-73 (*blarcamesine*) does not impair sleep and has a positive effect on REM sleep behavior disorder

Safety Profile of ANAVEX®2-73 (*blarcamesine*) in PDD

ANAVEX®2-73-PDD-001 Study: Summary

- The were no TEAEs of clinical importance in the ANAVEX®2-73 (*blarcamesine*) cohort
- Subjects with at least one TEAE leading to study discontinuation in the maintenance phase were 4.9% in the active cohort versus 4.7% receiving placebo
- The majority of TEAEs were observed during up-titration of which (light) dizziness (10.2% for active drug versus 2.3% placebo) leading to study discontinuation while typical adverse effects seen in marketed CNS drugs were not observed
- Collectively, analysis of safety data bolsters support for the demonstrated tolerability and safety of ANAVEX®2-73 (*blarcamesine*) in prior clinical trials

Conclusions & Next Steps

Phase 2 Trial Results

ANAVEX®2-73-PDD-001 Study: Summary

- ANAVEX®2-73 (*blarcamesine*) at 30mg and 50mg doses improved key symptoms of dementia in this proof-of-concept study with good safety profile in patients with Parkinson's disease dementia (PDD)
- Broad and statistically significant improvements in CDR system Cognitive Domain of Attention assessed by Choice Reaction Time (p = 0.039) and Digital Vigilance (p = 0.008) and CDR system Episodic Memory (p = 0.047), representing complex cognitive tasks with impact on quality of life such as making a choice between similar objects and remembering daily personal experiences, which are mostly impaired in both PD and AD[1]
- Statistically significant dose-dependent (p = 0.003) improvement of CDR system Episodic Memory, which has been shown to be highly correlated (70%) with the Alzheimer's Disease Assessment Scale–Cognitive score (ADAS-Cog; r = 0.7)[2]
- ANAVEX®2-73 (*blarcamesine*) does not impair sleep and has a positive effect on REM sleep behavior disorder
- ANAVEX®2-73 (*blarcamesine*) was generally safe and well tolerated in this trial, consistent with our prior experience with ANAVEX®2-73 (*blarcamesine*)

1. *Mahurin, R. K., & Pirozzolo, F. J. (1993). Application of Hick's law of response speed in Alzheimer and Parkinson diseases. Perceptual and Motor Skills, 77(1), 107–113*
2. *Wesnes K, Edgar C, Andreasen N, Annas P, Basun H, Lannfelt L, et al. Computerized cognition assessment during acetylcholinesterase inhibitor treatment in Alzheimer's disease. Acta Neurol Scand 2010; 122:270–7*

Next Steps

ANAVEX®2-73-PDD-001 Study: Next Steps

- These results support continued development in PDD / PD as well as the currently ongoing Phase 2 and Phase 2/3 clinical studies with ANAVEX®2-73 (*blarcamesine*) in Rett syndrome[1] and Alzheimer's disease[2]
- Data of cognitive domain improvements highly relevant for broader dementia indications, including Alzheimer's disease
- Complete data analysis, including MDS-UPDRS, actigraphy (24-hour monitoring), entire DNA and RNA sequencing, ongoing
- ANAVEX®2-73-PDD-EP-001 48-week open-label extension (OLE) study ongoing, which continues to assess safety, long term efficacy and changes in gut microbiota[3]
- Data will be submitted to the U.S. Food and Drug Administration to seek regulatory guidance

1. *ClinicalTrials.gov Identifiers: NCT03758924, NCT03941444, NCT04304482*
2. *ClinicalTrials.gov Identifiers: NCT03790709, NCT02756858*
3. *ClinicalTrials.gov Identifier: NCT04575259*

Upcoming: Application of Artificial Intelligence Methodologies to ANAVEX®2-73-PDD-001 Study

Unbiased, data-driven analysis of the heterogenous PDD patient population using DNA and RNA Whole Exome Genomic Sequencing

Parkinson's disease dementia (PDD): Highly heterogeneous neurodegenerative disorder

Genetic subtypes of Parkinson's disease

Genetic subtypes of Alzheimer's disease

Lewy body dementia pathology

Other dementia pathology

Integrated data

Genomic characterization
Deep molecular understanding of response

Changes in outcome measures
Treatment response based on cognitive dysfunctions, sleep impairments, etc.

Clinical assessment
Impact of vital signs, co-medication, etc.

Life experience
Impact of disease history, environmental factors

Data driven categories

Cluster 1

Cluster 2

Cluster 3

Cluster 4

Identification of homogeneous clusters of patients

Precision medicine can go beyond traditional symptom-based categories. PDD and other neurodegenerative disorders with heterogenous pathophysiology can be categorized into homogeneous clusters sharing same molecular disease

Acknowledgements

- Principal Investigators & clinical sites' study staff
- Michael J Fox Foundation (MJFF)
- Anavex SAB
- Most of all, grateful acknowledgement of the contribution of the participating PDD patients and their caregivers

Supplemental

Alzheimer's Disease (AD)

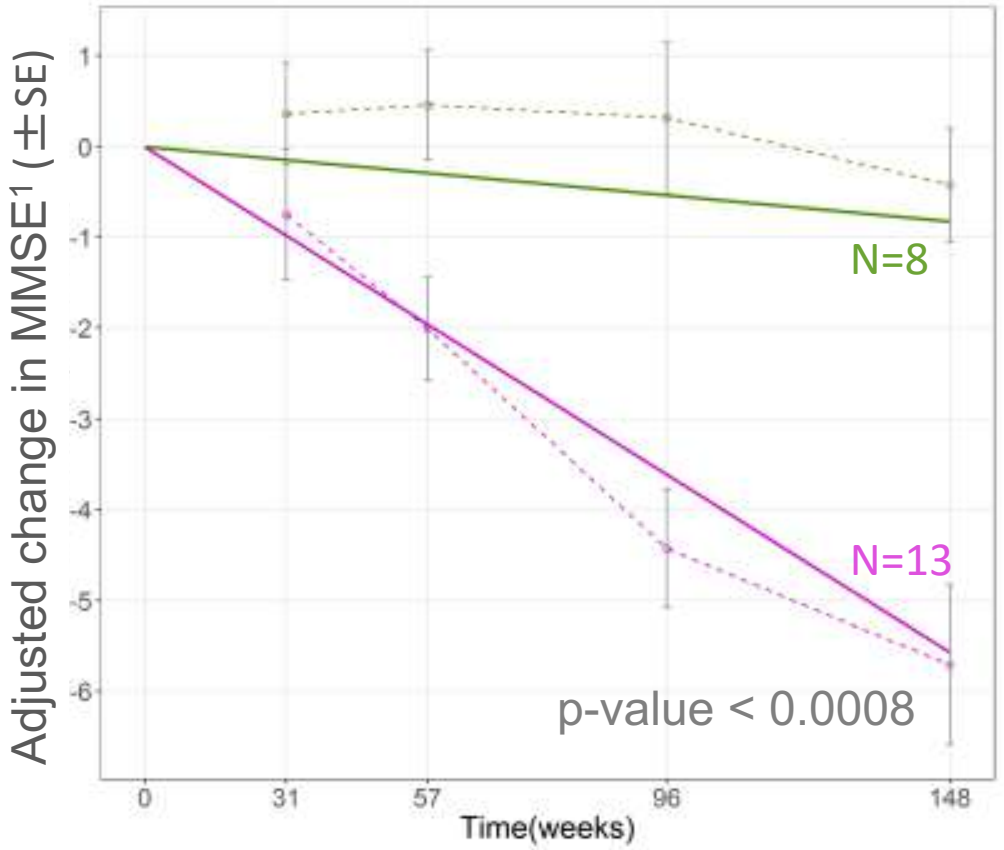
Alzheimer's disease is a progressive, irreversible neurological disease and the most common cause of dementia

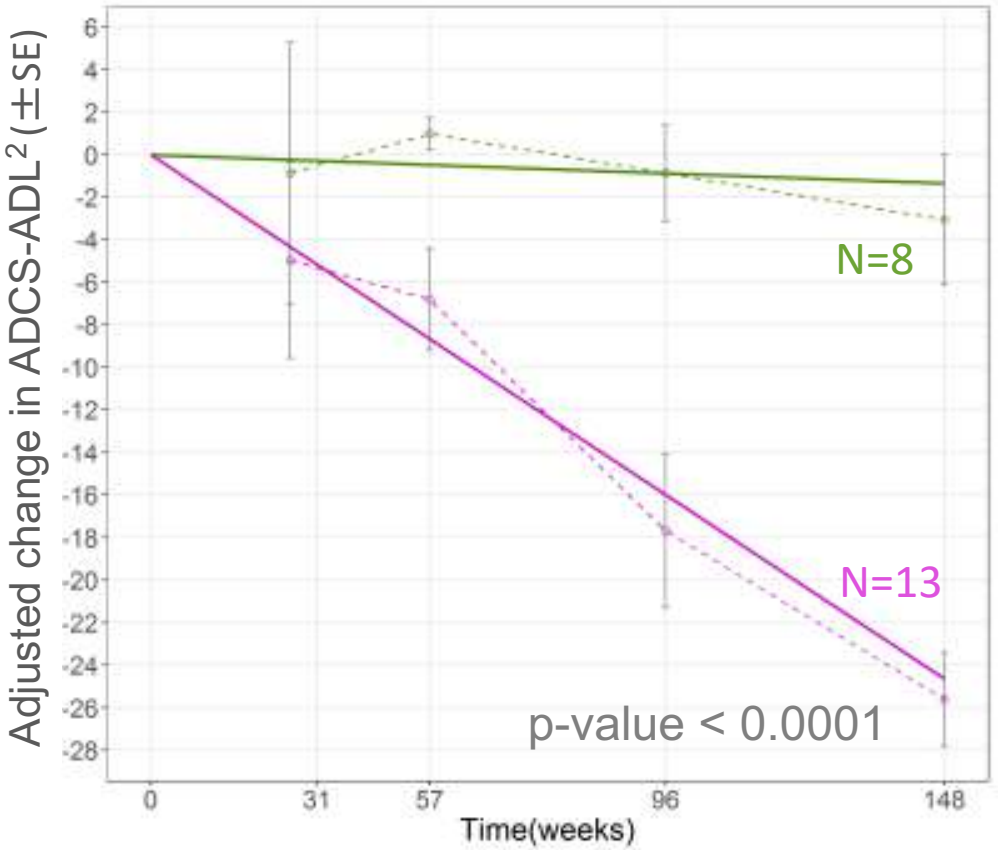
Alzheimer's Disease (AD)

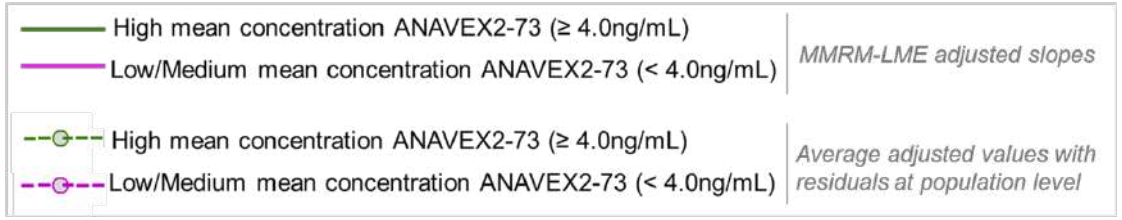
- **Alzheimer's disease incidence highly correlates with age**
  - AD prevalence in US:~5,700,000
  - Estimated 50 million people live with dementia worldwide
  - Today, there are no commercially available therapies to address the underlying cause of Alzheimer's
  - The current annual cost of dementia is estimated at $1 trillion, a figure set to double by 2030

Source: www.alz.org/alzheimers-dementia/what-is-dementia/types-of-dementia/parkinson-s-disease-dementia

ANAVEX®2-73 Demonstrated Improved MMSE[1] and ADCS-ADL[2] Scores in Phase 2a AD Study through 148 Weeks







Source: *Hampel et al. A precision medicine framework using artificial intelligence for the identification and confirmation of genomic biomarkers of response to an Alzheimer's disease therapy: Analysis of the blarcamesine (ANAVEX2-73) Phase 2a clinical study. Alzheimer's Dement. 2020;00:1–14*

[1] Mini Mental State Examination (MMSE)
[2] Alzheimer's Disease Cooperative Study Group - Activities of Daily Living Inventory (ADCS-ADL)

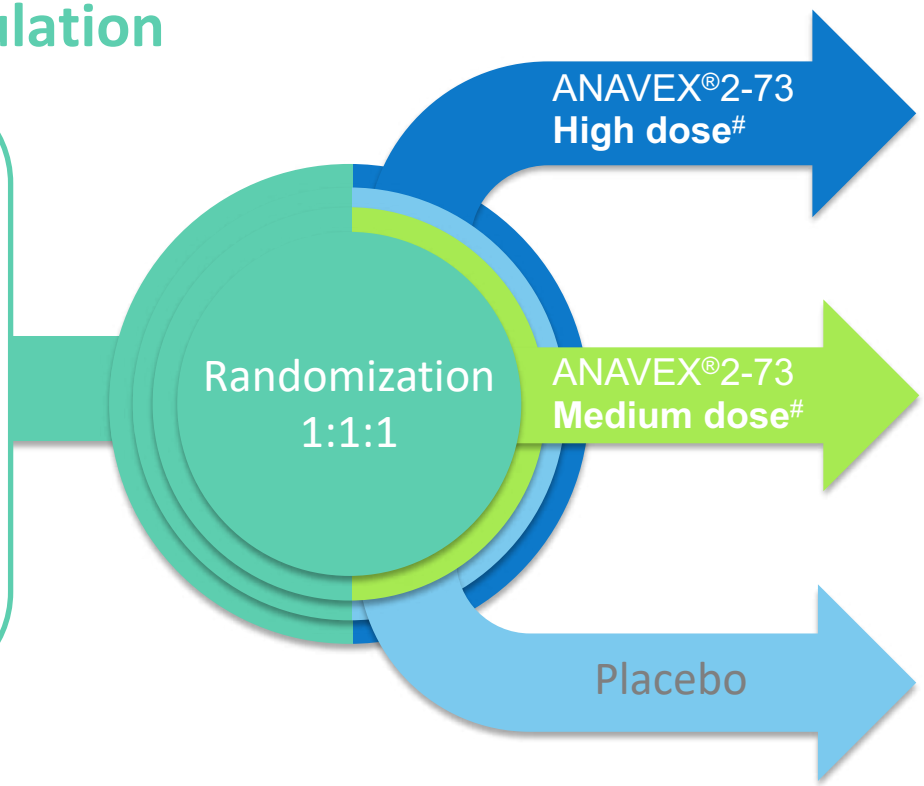
ANAVEX®2-73 Phase 2b/3 Alzheimer's Disease and ATTENTION-AD OLE Study

N=450

48 WEEK STUDY
… and Open Label Extension (OLE) **96 weeks**

Early AD patient population

- Confirmed amyloid pathophysiology (CSF/amyloid PET)
- Patients aged 60 to 85 years
- MMSE score 20-28
- Entire DNA and RNA sequencing



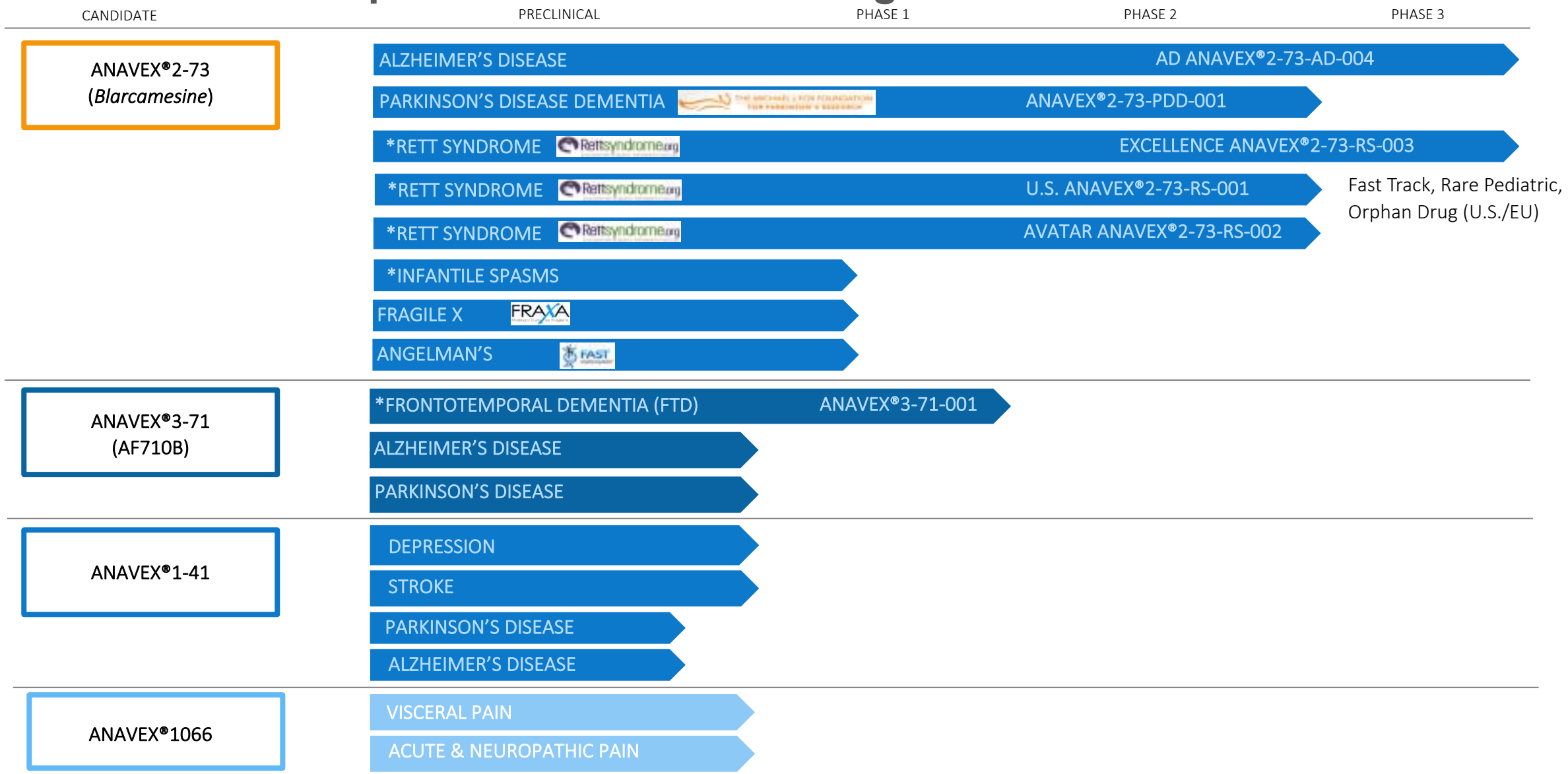
Primary Endpoints
- ADAS-Cog
- ADCS-ADL
- Safety and tolerability of ANAVEX®2-73

Key Secondary Endpoints
- CDR-SB
- Structural and functional MRI
- Biomarkers: $Abeta_{40}$/$Abeta_{42}$, T-tau, P-tau, NFL, YKL-40, neurogranin, BACE1

Pre-specified Endpoints
- Genetic variants SIGMAR1 (rs1800866), COMT (rs113895332/rs61143203) with influence on treatment effect

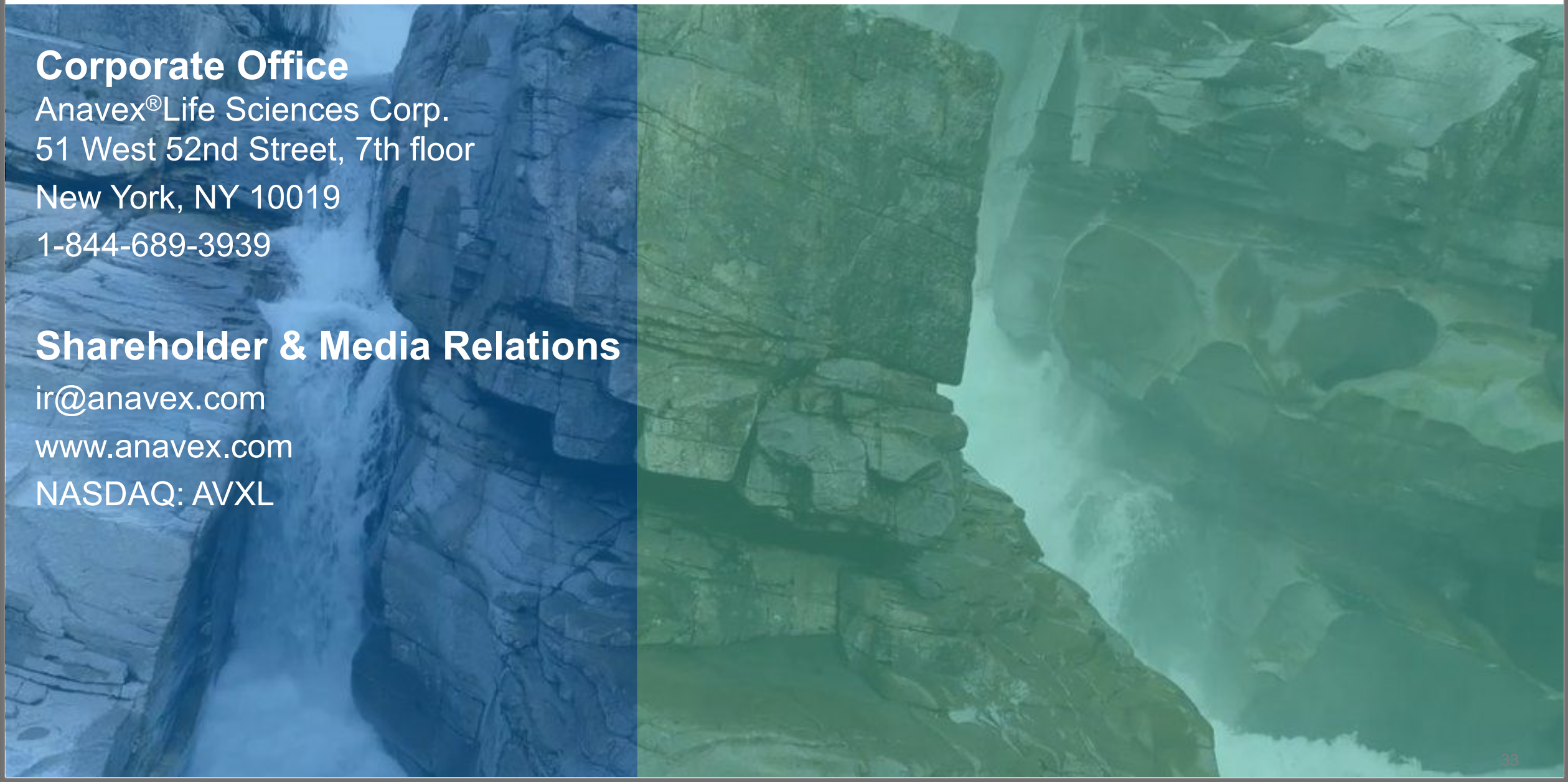
 # Oral capsule once daily; Dose restricted to maintain complete blinding

Broad Pipeline Targeting Neurodegenerative and Neurodevelopmental Diseases with Significant Unmet Medical Need



** = Orphan Drug Designation by FDA*

Contact Us



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