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.
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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
- 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)
- 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 and Alzheimer’s disease
- Data will be submitted to the U.S. Food and Drug Administration to seek regulatory guidance

3. ClinicalTrials.gov Identifiers: NCT03758924, NCT03941444, NCT04304482
4. ClinicalTrials.gov Identifiers: NCT03790709, NCT02756658
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

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

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

**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_

**2-week baseline period**

- Screening
- Baseline

**1:1:1 randomization**

- **ANAVERX®2-73 High Dose**
  - (10, 20, 30, then 50 mg QD)
  - N=44

- **ANAVERX®2-73 Medium Dose**
  - (10, 20, then 30 mg QD)
  - N=44

- **Placebo**
  - (QD)
  - N=44

- _N=132 2-week baseline including actigraphy_

**3-week up-titration period**

- Week 3

**11-week target dose treatment period**

- Week 8
- Week 14

- Study data collected at Baseline, Week 8 and 14

- **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

- **PDD Patient Population**
  - Diagnosis of probable Parkinson’s disease dementia
  - Diagnosis of idiopathic Parkinson’s disease
  - Patients aged ≥ 50 years
  - MoCA score 13-23

- **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

- **Phase 2, 3-week up-titration period**
  - Week 3

- **Phase 2, 11-week target dose treatment period**
  - Week 8
Cognition is Multidimensional
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

• 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 words 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

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”

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)**

All participants; ANAVEX®2-73 = Active 30 mg, Active 50 mg vs Placebo

J-T test based on actual maintenance dose: p = 0.003

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

Quality of Episodic Memory (counts)
All participants
Time: 14 weeks change from baseline

Direction of Improvement

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<th>Change from Baseline of Quality of Episodic Memory (counts)</th>
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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:

(a) Episodic memory
(b) Attention
(c) Language
(d) Visuospatial skills
(e) Executive functions

Episodic memory
Choice reaction time
Word recognition
Picture recognition
Numeric working memory

Addressed in PoC Phase 2 PDD Study

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 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 (blarcaminesine) 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


Increased Task Complexity

Unmet need
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

ANAVERX®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

ANAVENT®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.
- 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).
- 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).

Next Steps

ANADEX®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 syndrome¹ and Alzheimer's disease²

• 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 microbiota³

• 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 heterogeneous 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 heterogeneous pathophysiology can be categorized into homogeneous clusters sharing same molecular disease.
• 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
Alzheimer’s disease is a progressive, irreversible neurological disease and the most common cause of dementia.

- 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/parkinsons-disease-dementia
ANAVEX®2-73 Demonstrated Improved MMSE\(^1\) and ADCS-ADL\(^2\) Scores in Phase 2a AD Study through 148 Weeks


\(^1\) 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

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

Randomization 1:1:1
- ANAVEX®2-73 High dose#
- ANAVEX®2-73 Medium dose#
- Placebo

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

... and Open Label Extension (OLE) 96 weeks

48 WEEK STUDY

Oral capsule once daily; Dose restricted to maintain complete blinding
## Broad Pipeline Targeting Neurodegenerative and Neurodevelopmental Diseases with Significant Unmet Medical Need

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* = Orphan Drug Designation by FDA

Fast Track, Rare Pediatric, Orphan Drug (U.S./EU)
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