Corporate Presentation

Christopher U Missling, PhD | President & CEO
Forward Looking Statement

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Neurological chronic conditions: Impaired housekeeping function and impaired homeostasis

SIGMAR1 activation as compensatory mechanism to chronic CNS diseases

Large Markets by Applying Precision Medicine Platform

Today
• SIGMAR1 activation established as a New Platform Class
- ANAVEX®2-73 (blarcamesine) Clinical study results in broad CNS indications confirm SIGMAR1 technology

Tomorrow
• SIGMAR1 technology to Succeed Traditional Modalities
- Alzheimer’s disease
- Parkinson’s disease
- Rett syndrome
- Fragile X syndrome
- Other rare diseases

The Future
• SIGMAR1 to open up new opportunities Beyond the Horizon
- Expanded CNS indications
- Regenerative medicine¹
- Disease prevention²

² L. Nguyen et al., Role of sigma-1 receptors in neurodegenerative diseases, Journal of Pharmacological Sciences, Volume 127, Issue 1, 2015, Pages 17-29, ISSN 1347-8613, https://doi.org/10.1016/j.jphs.2014.12.005
Precision Medicine

Biomarkers Increase Probability of Success

- Patient selection biomarkers
- Higher therapeutic response
- Lower variability in the target population

Thomas DW et al. Clinical Development Success Rates 2011-2020. BIO | QLS Advisors | Informa UK Ltd 2021
ANAVEX®2-73 Establishes SIGMAR1 mRNA Predictive Biomarker of Efficacy in Alzheimer’s, Parkinson’s and Rett Syndrome

ANAVEX®2-73 improves functional (ADCS-ADL*) outcome in Alzheimer’s disease patients correlating with SIGMAR1 mRNA levels

p=0.015

p-value of Mann–Whitney U test
All n=20 patients in study (dose range 10mg-50mg). Change of ADCS-ADL* from baseline to week 57 with available genomic data

ANAVEX®2-73 positive response in functional outcome in patients with Parkinson’s disease correlate with SIGMAR1 mRNA levels

Clinical improvements measured by:
- CDR system CoA (p = 0.029)
- CDR system PoA (p = 0.015)
- MDS-UPDRS Part III (p = 0.024)
- MDS-UPDRS Total (p = 0.038)

ANAVEX®2-73 positive response in functional outcome in patients with Rett syndrome correlate with SIGMAR1 mRNA levels

Clinical improvements measured by:
- RBQ (p = 0.035)
- CGI-H (p = 0.029)

Source: Hampel H et al. Alzheimer’s Dement. 2020;00:1–14; *Alzheimer’s Disease Cooperative Study Activities of Daily Living 23-item scale (ADCS-ADL)
Aiming to Change the Course of Dementia …

... Dementia is progressive and over time a patient’s cognition will worsen

Trajectory changed with ANAVEX®2-73

Visualize the improvement in calculated ADAS-Cog scores in Alzheimer’s patients treated with ANAVEX®2-73, relative to the placebo arms of other sponsors’ trials

Parkinson’s disease dementia (PDD) patients improved with ANAVEX®2-73 in calculated corresponding ADAS-Cog scores from baseline to 14 weeks

AI Powered, Biomarker Driven, Accelerated Development Built on in-depth Molecular Understanding of SIGMAR1 Pathway

**Goal:** Expedited Regulatory Process

- Increased Probability of Phase II / III Success
- Optimal Dose
- Drug Related Efficacy Biomarker
- Surrogate Endpoints
- Additional Therapeutic Indications at the Intersection of Pathway Biology and Disease Biology

**Data from ~700 study participants, 3 indications, 6 trials**

- Clinical Scores
- Dose / Arm
- Clinical Impact
- Whole Exome DNA
- Detailed PK
- Radiomic Impact
- Transcriptome
- Radiomic (incl. PET)
- Microbiota Impact
- Shotgun Microbiota
- Molecular Impact
- Medical history
- Co-medication

**KEM® Integrative AI**

Assessing Impact on large number of Parameters

**Real World Evidence Data (~7,000 patients)**
<table>
<thead>
<tr>
<th>CANDIDATE</th>
<th>PRECLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANAVEX®2-73 (Blarcamesine)</td>
<td>ALZHEIMER’S DISEASE</td>
<td>AD ANAVEX®2-73-AD-004</td>
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<td></td>
<td>PARKINSON’S DISEASE</td>
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<td></td>
<td>PARKINSON’S DISEASE DEMENTIA</td>
<td>ANAVEX®2-73-PDD-001</td>
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<td></td>
<td>*RETT SYNDROME</td>
<td>EXCELLENCE ANAVEX®2-73-RS-003</td>
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<tr>
<td></td>
<td>*RETT SYNDROME</td>
<td>U.S. ANAVEX®2-73-RS-001</td>
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</tr>
<tr>
<td></td>
<td>*RETT SYNDROME</td>
<td>AVATAR ANAVEX®2-73-RS-002</td>
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<tr>
<td></td>
<td>*INFANTILE SPASMS</td>
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<td></td>
<td>FRAGILE X</td>
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<td>ANGELMAN’S</td>
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<td></td>
<td>UNDISCLOSED RARE DISEASE</td>
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<tr>
<td>ANAVEX®3-71 (AF710B)</td>
<td>*FRONTOTEMPORAL DEMENTIA (FTD)</td>
<td>ANAVEX®3-71-001</td>
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<td></td>
<td>NEURODEGENERATIVE DISEASES</td>
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<tr>
<td>ANAVEX®1-41</td>
<td>DEPRESSION</td>
<td></td>
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<td></td>
<td>STROKE</td>
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<td></td>
<td>NEURODEGENERATIVE DISEASES</td>
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<td>ANAVEX®1066</td>
<td>VISCERAL PAIN</td>
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<td>ACUTE &amp; NEUROPATHIC PAIN</td>
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</table>

- Differentiated clinical-stage CNS assets targeting significant and growing markets
- Patent protection to 2030-2039, worldwide rights for all product candidates

* = Orphan Drug Designation by FDA; Dashed lines indicate planned clinical studies
Worldwide Dementia Cases Projected to Grow to Over 130M by 2050

Costs Associated with Alzheimer’s Treatment and Care in the U.S. are Unsustainable

Age Prevalence of Global Alzheimer’s Disease and Dementias

> $20 trillion
Cumulative costs of Alzheimer’s and dementia care from 2015 to 2050

1 in 3
Medicare dollars will be spent on people living with Alzheimer’s and other dementias in 2050

> 11 million
The number of Americans providing unpaid care for people with Alzheimer’s or other dementias

Targeting Large Market Opportunities with Significant Unmet Medical Need

All U.S. Patient Numbers

2) Marras C et al 2018. npj Parkinson's Disease volume 4, Article number: 21
3) Based on prevalence number on orphaned
Anavex’s Transformative Precision Medicine Platform

› ANAVEX®2-73 (*Blarcamesine*) Rett Syndrome Program Received Fast Track Designation and is Eligible for Pediatric Priority Review Voucher

› Pursuing Large Markets with High Unmet Need by Applying Genetic Precision Medicine

› Novel Upstream CNS Mechanism of Action for both Neurodevelopment and Neurodegeneration

› Compelling Human Patient Data in Rett Syndrome (RTT), Parkinson’s Disease Dementia (PDD) and Alzheimer’s Disease (AD)

› Sufficient Cash for >5 Years To Achieve Key Milestones – Including non-dilutive Cash from Michael J Fox Foundation, International Rett Syndrome Foundation and Australian Government

Continued Significant Value-creating Pipeline Expansion Opportunities for ANAVEX®2-73:

› Novel approach of targeting SIGMAR1 using precision medicine with potential for biomarker-focused pivotal Fragile X and Parkinson’s disease dementia clinical trials
Catalysts to Drive Value
The company has multiple clinical milestones

- Complete data ANAVEX®2-73 U.S. Rett syndrome Phase 2 study
- Complete data ANAVEX®2-73 Parkinson’s disease dementia (PDD) Phase 2 study
  - Top-line data AVATAR: Potentially pivotal Phase 2/3 adult RTT clinical trial – expected 2H 2021
  - Top-line data Phase 1 ANAVEX®3-71 clinical trial – expected 2H 2021
  - Top-line data EXCELLENCE: Potentially pivotal Phase 2/3 pediatric RTT clinical trial – expected 1H 2022*
  - Top-line data ANAVEX®2-73-AD-004: Potentially pivotal Phase 2b/3 AD clinical trial – expected 2H 2022
  - Initiation of ANAVEX®2-73 imaging-focused Parkinson’s disease clinical trial – expected 2021
  - Pipeline expansion opportunities for ANAVEX®2-73
    - Initiation of potentially pivotal Phase 2/3 Fragile X clinical trial – expected 2021
    - Initiation of potentially pivotal Phase 2/3 clinical trial for the treatment of a new, rare disease indication – expected 2021

* Increased patient study participants to 84 from 69
Clinical Trials
Mechanism of Action (MoA) and Clinical Data:
• Rett Syndrome (RTT)
• Parkinson’s Disease Dementia (PDD)
• Alzheimer’s Disease (AD)
Sigma-1 receptor agonists have been shown to restore neuronal functions in neurodegenerative processes.

**ANAVEX® 2-73 enhances autophagy and alleviates Tau pathology in neurodegenerative disease models**

Sigma-1 receptor agonists have a neuroprotective effect in neurodegenerative disease models.

**SIGMAR1 Activation has been Shown to Modulate Multiple Aspects of Neurodegenerative Processes**

Critical review

Role of sigma-1 receptors in neurodegenerative diseases


MDPI

Sigma-1 Receptor Activation Induces Autophagy and Increases Proteostasis Capacity In Vitro and In Vivo


Institute of Pathohistochemistry, University Medical Center of the Johannes Gutenberg University, D-55101 Mainz, Germany; maximilian.christ@kgz.uni-mainz.de (M.C.C.); karen.huesemann@medizin.uni-mainz.de (H.H.); nagel@medizin.uni-mainz.de (H.N.); akern@medizin.uni-mainz.de (A.K.)

Correspondence: christ@medizin.uni-mainz.de; Tel.: +49-6131-385-0360

Received: 29 January 2019; Accepted: 27 February 2019; Published: 2 March 2019

Neuronal Sigma-1 receptors: signaling functions and protective roles in neurodegenerative diseases

Daniel A. Ryskamp, Sveta Borozdina, Vladimir Zhemkov, Nina Kraskovskaya, and Ilya Bezprozvanny.

Department of Physiology, UT Southwestern Medical Center, United States

Laboratory of Molecular Neurodegeneration, Saint Petersburg State Polytechnical University, Russia

Neuroprotective effects of sigma-1 receptor agonists against beta-amyloid-induced toxicity

Gizelle Mansur, Filip Carasa, Elisa Trizio Jahanbegloo, Sangeet Pratap Agashe, and Giuseppe Ronis.
ANAVEX®2-73 MoA: SIGMAR1 Activation Prevents Cellular Stress Before and After RNA Gene Transcription

ANAVEX®2-73 Establishes Proof-of-Concept and SIGMAR1 Target Occupancy

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

Interface of ANAVEX®2-73-activated Pathway Analysis and Disease Biology Using mRNA Differential Gene Expression with Focus on SIGMAR1 Pathway

Differential Gene Expression

Baseline

mRNA₀

~700 Patients
X 26K genes
X 2 timepoints

Gene of interest

mRNA₁

ANAVEX®2-73
Molecular Pathway
Signatures

Gene of interest

Patient Biology

Mechanism of Action

Patient Selection Biomarker

Surrogate Endpoints

Optimal Indications
What is Rett Syndrome?

Rett Syndrome (RTT)

- Non-inherited genetic postnatal disorder caused by mutations in the MECP2 gene
  - Occurs almost exclusively in girls
  - Leads to severe impairments, affecting nearly every aspect of the child’s life
  - Impairment includes ability to speak, walk, eat and even breathe easily
  - Hallmark of RTT is near constant repetitive hand movements while awake
  - Occurs worldwide in approximately one in every 10,000 to 15,000 live female births
  - The population of patients with Rett syndrome is estimated to be ~11,000 patients in the U.S.
  - There is currently no cure for Rett syndrome

Source: https://www.rettsyndrome.org/about-rett-syndrome
Rett Syndrome U.S. ANAVEX®2-73-RS-001 Phase 2 Trial Design Overview

Randomized, Double-blind, Placebo-controlled Clinical Trial

<table>
<thead>
<tr>
<th>Arm</th>
<th>Number of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANAVEX2-73</td>
<td>n=15</td>
</tr>
<tr>
<td>(once daily 5mg liquid dose)</td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>n=10</td>
</tr>
<tr>
<td>(once daily PBO liquid dose)</td>
<td></td>
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</tbody>
</table>

Week 0 (Baseline)  | Week 4 | Week 7 (End of Trial [EOT])

Efficacy Assessments:
- Primary: RSBQ (Rett Syndrome Behaviour Questionnaire), CGI-I (Clinical Global Impression – Improvement)
- Secondary: Behavior (ADAMS), Sleep (CSHQ), VAS (top caregiver concerns), Seizure diary
- Biomarkers of response and/or surrogate endpoints: Genomic biomarker: DNA & mRNA profiles; Glutamate, GABA
- SIGMAR1 variants: Prespecified analyses of population with wild type (WT) variant (n = 14)

ClinicalTrials.gov: NCT03758924
Separate patient cohort (n=6) underwent a 7-week intensive pharmacokinetic (PK) assessment with safety, tolerability, pharmacokinetic and efficacy evaluation of ANAVEX®2-73
Open-label-extension after End of Trial for at least 36 weeks
Phase 2: Improvement in All Key Domains

ANAVEX®2-73 Treatment Resulted in a Statistically Significant Improvement for All Patients with Rett Syndrome in the RTT-Relevant Endpoints RSBQ, CGI-I, ADAMS

All participants ITT (n = 25: 15 on ANAVEX2-73 and 10 on Placebo)

Responder analysis capturing the progression of the disease and treatment effect over the course of the study

Improvements in this adult population with Rett syndrome are considered clinically meaningful according to published criteria applied to neurodevelopmental disorders (Chatham et al. Adaptive behavior in autism, Autism Res. 2018;11(2):270-283; Luu et al. Response to Placebo in Fragile X Syndrome Clinical Trials, Brain Sci. 2020 Sep 11;10(9):629)
**Favorable Efficacy Already at Low ANAVEX®2-73 Doses**

<table>
<thead>
<tr>
<th>Estimated Difference between Active and Placebo</th>
<th>Age, y median</th>
<th>Weight, kg median</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RSBQ Total Score</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ANAVEX2-73 low dose (5 mg)*</td>
<td>-14.5</td>
<td>24.00</td>
</tr>
<tr>
<td>trofinetide high dose (400 mg/kg)**</td>
<td>-4.4</td>
<td>9.41</td>
</tr>
</tbody>
</table>

ANAVEX®2-73 Phase 2 RSBQ Total Score compares favorably with other published historical trial – despite lower dose and older patient cohort

* Prespecified WT SIGMAR1 population (n = 14)
# Favorable Adverse Event Profile of ANAVEX®2-73

## ANAVEX2-73 (5 mg)*

<table>
<thead>
<tr>
<th>Adverse Events (&gt;10%)</th>
<th>Diarrhea</th>
<th>Vomiting</th>
<th>Fever (Pyrexia)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANAVEX2-73</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>trofinetide (400 mg/kg)**</td>
<td>56%</td>
<td>22%</td>
<td>11%</td>
</tr>
</tbody>
</table>

*All participants ITT

Clinically meaningful and statistically significant Improvement for ANAVEX®2-73 treated adult patients with Rett syndrome vs placebo

14.5-point improvement at Week 7 with p=0.009 (-8.92 ANAVEX®2-73 vs. 5.56 placebo)

Statistical separation at every assessed time point
RSBQ Subscale Scores

Significant and Balanced Improvements across all Subscales (observed at End of Trial)

• Cohen’s d effect size of 1.11

<table>
<thead>
<tr>
<th>Subscale</th>
<th>Placebo</th>
<th>ANAVEX2-73</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Mood</td>
<td>20%</td>
<td>-23%</td>
</tr>
<tr>
<td>Breathing Problems</td>
<td>14%</td>
<td>-18%</td>
</tr>
<tr>
<td>Hand Behaviors</td>
<td>1%</td>
<td>-10%</td>
</tr>
<tr>
<td>Repetitive Face Movements</td>
<td>16%</td>
<td>-22%</td>
</tr>
<tr>
<td>Body Rocking and Expression less Face</td>
<td>26%</td>
<td>-15%</td>
</tr>
<tr>
<td>Night-time Behaviors</td>
<td>-4%</td>
<td>-65%</td>
</tr>
<tr>
<td>Fear/Anxiety</td>
<td>12%</td>
<td>-12%</td>
</tr>
<tr>
<td>Walking/Standing</td>
<td>-16%</td>
<td>-28%</td>
</tr>
</tbody>
</table>

Prespecified WT SIGMAR1 population
ADAMS Total Score

Clinically Validated Efficacy Endpoint

- Clinically meaningful and statistically significant Improvement for ANAVEX®2-73 treated adult patients with Rett syndrome vs placebo
- 12.9-point improvement at Week 7 with p=0.005 (-10.10 ANAVEX®2-73 vs. 2.75 placebo)

Prespecified WT SIGMAR1 population
ADAMS Subscale Scores

Significant and Balanced Improvements across all Subscales (observed at End of Trial)

<table>
<thead>
<tr>
<th></th>
<th>Placebo</th>
<th>ANAVEX2-73</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manic/Hyperactive Behavior</td>
<td>3%</td>
<td>-25%</td>
</tr>
<tr>
<td>Depressed Mood</td>
<td>3%</td>
<td>-17%</td>
</tr>
<tr>
<td>Social Avoidance</td>
<td>-11%</td>
<td>-41%</td>
</tr>
<tr>
<td>General Anxiety</td>
<td>9%</td>
<td>-37%</td>
</tr>
<tr>
<td>Obsessive Complulsive Behavior</td>
<td>3%</td>
<td>-31%</td>
</tr>
</tbody>
</table>

- **Cohen’s d effect size of 1.31**

**Prespecified WT SIGMAR1 population**
ANAVEX®2-73-RS-002 Phase 2/3 Rett Syndrome AVATAR Study

ClinicalTrials.gov: NCT03941444

Primary and Secondary Endpoints
- RSBQ, CGI-I
- ADAMS, Sleep function
- Seizure activity
- Safety and tolerability of ANAVEX®2-73
- Glutamate biomarker

Pre-specified Analysis
- Excluding genetic variants SIGMAR1 (rs1800866), COMT (rs113895332/rs61143203) with influence on treatment effect

N=33*

RTT patient population
- Diagnosis of confirmed RTT
- Patients age >18
- DNA and RNA sequencing

Randomization 3:2

ANAVEX®2-73 Active dose*

Placebo

* Includes a 3 patient cohort undergoing a 3-week pharmacokinetic (PK) assessment with safety, tolerability, pharmacokinetic and efficacy evaluation of ANAVEX®2-73

* Oral liquid solution once daily; Dose restricted to maintain complete blinding
ANAVEX®2-73-RS-003 Phase 2/3 Rett Syndrome EXCELLENCE Study

**N=84**

RTT patient population

- Diagnosis of confirmed RTT
- Patients age 5-18
- DNA and RNA sequencing

Randomization 2:1

- ANAVEX®2-73 Active dose#
- Placebo

Primary and Secondary Endpoints

- RSBQ, CGI-I
- ADAMS, Sleep function
- Seizure activity
- Safety and tolerability of ANAVEX®2-73
- Glutamate biomarker

Pre-specified Analysis

- Excluding genetic variants SIGMAR1 (rs1800866), COMT (rs113895332/rs61143203) with influence on treatment effect

ClinicalTrials.gov: NCT04304482

- Oral liquid solution once daily; Dose restricted to maintain complete blinding
Parkinson’s Disease Dementia (PDD)

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

• 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/rs61143203) with influence on treatment effect

ANAVEX®2-73 High Dose
(10, 20, 30, then 50 mg QD)

ANAVEX®2-73 Medium Dose
(10, 20, then 30 mg QD)

Placebo (QD)

2-week baseline period
3-week up-titration period
11-week target dose treatment period

N=132

2-week baseline including actigraphy

N=44

1:1:1 randomization

Screening

Baseline

Week 3

Week 8

Week 14

Study data collected at Baseline, Week 8 and 14

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

QD = once per day
Randomized, double-blind, placebo-controlled Phase 2 trial that randomized 132 patients with Parkinson’s disease dementia equally (ratio of 1:1:1) to target doses of 30mg (medium), 50mg (high) ANAVEX®2-73 or placebo.

MDS-UPDRS Total score -14.51 improvement is clinically relevant and corresponds to a relative improvement of 18.9 % over 14 weeks.
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

Related CDR system domains

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

Addressed in PoC Phase 2 PDD Study

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 ability to store, hold and retrieve information of an episodic nature (e.g., an event or name)
- CDR system Quality of Episodic Memory highly correlated (70%) with ADAS-Cog ($r = 0.7$)

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


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\(^1\) Mini Mental State Examination (MMSE)

\(^2\) Alzheimer’s Disease Cooperative Study Group - Activities of Daily Living Inventory (ADCS-ADL)

Dose range 10mg-50mg ANAVEX®2-73 oral once daily.
ANAVEX®2-73 Biomarker Driven Development Strategy in Alzheimer’s Disease

Demonstrated Improved MMSE and ADCS-ADL through 148 weeks for all patients

Novel Genomic Biomarkers of Response Identified in Phase 2a AD study -> Pre-specified Efficacy Endpoints in all ANAVEX®2-73 studies (AD, PDD, RTT)

Applied to Phase 2b/3 Alzheimer’s disease (AD) study and other indications: Parkinson’s disease dementia (PDD) and Rett syndrome (RTT)
ANAVEX®2-73 Phase 2b/3 Alzheimer's Disease and ATTENTION-AD OLE Study

N=509

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

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 Analysis
- Excluding genetic variants SIGMAR1 (rs1800866), COMT (rs113895332/rs61143203) with influence on treatment effect

ClinicalTrials.gov: NCT03790709

Randomization 1:1:1

ANAVEX®2-73 High dose#

ANAVEX®2-73 Medium dose#

Placebo

\* Oral capsule once daily; Dose restricted to maintain complete blinding
Anavex is pursuing Large Markets by Applying Precision Medicine Platform to Develop Treatments for both Global Aging CNS diseases (Alzheimer’s, Parkinson’s), as well as catastrophic Orphan Genetically caused diseases, Rett Syndrome with High Unmet Needs

$ 277B

Economic burden
2018 Alzheimer’s Association

OVERARCHING MESSAGE
A novel platform approach to address the totality of CNS diseases

PRECISION MEDICINE PLATFORM IMPROVES CHANCE OF CLINICAL SUCCESS
Testing for biomarkers demonstrated improved clinical response to ANAVEX®-2-73 in Rett syndrome, Parkinson’s and Alzheimer’s patients correlated with mRNA SIGMAR1 gene expression

NOVEL CNS MECHANISM OF ACTION
ANAVERX®-2-73, an orally available SIGMAR1 agonist, is upstream of neurodevelopment and neurodegeneration and has been shown to restore homeostasis

COMPELLING INITIAL HUMAN DATA
ANAVERX®-2-73 Phase 2 in Rett syndrome, Phase 2 in Parkinson’s disease dementia and Phase 2a trial in Alzheimer’s with favorable safety and initial efficacy results through 148 weeks

WORLDWIDE COMMERCIAL RIGHTS AND STRONG IP FOUNDATION
We retain global commercial rights to all of our product candidates and our lead product candidate, ANAVEX®-2-73, including patent protection to 2030-2039

SUFFICIENT CASH TO ACHIEVE KEY MILESTONES
Sufficient cash for >5 years to achieve key milestones, including non-dilutive cash from Michael J Fox Foundation, International Rett Syndrome Foundation, Australian government
Anavex Life Sciences Expertise

Management Team

Christopher U. Missling PhD - President & CEO

Walter E Kaufmann, MD - Chief Medical Officer

Stephan Toutain, MS, MBA – Chief Operating Officer

Emmanuel O Fadiran, RPh, PhD - SVP of Regulatory Affairs

Daniel Klamer, PhD - VP of Business Development & Scientific Strategy

Scientific Advisory Board Members

Jeffrey Cummings, MD - Cleveland Clinic

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Jacqueline French, MD

Dag Aarsland, MD, PhD - Kings College London

Tangui Maurice, PhD - Université de Montpellier
Contact Us

Corporate Office
Anavex®Life Sciences Corp.
51 West 52nd Street, 7th floor
New York, NY 10019
1-844-689-3939

Shareholder & Media Relations
ir@anavex.com
www.anavex.com
NASDAQ: AVXL