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Anavex™ Mission

Developing Differentiated Therapeutics for the Treatment of Neurodevelopmental and Neurodegenerative Diseases
Convergence of Pathological and Genetic Lesions in All Neurodegenerative Diseases: ER-Mitochondria Axis Disruption

Common in All Neurodegenerative Diseases: ER-Mitochondria Axis Disruption ... Sigma-1R Restores Association ...

Endoplasmic reticulum (ER)-Mitochondria associations are disrupted in neurodegenerative diseases ...#

... Sigma-1R restores association##

# Cause of disruption is multifactorial, e.g. Abeta oligomers build-up inside ER; Source: Meli et al. NATURE COMMUNICATIONS | DOI: 10.1038/ncomms4867; Miller et al. Trends in Neurosciences, March 2016, Vol. 39, No. 3; ##Lahmy et al. Neuropsychopharmacology (2013) 38, 1706–1723
ANAVEX™ 2-73: Confirmed Targeted Indications: From Rare Disease Indication to Largest CNS Indication ...

Rett Syndrome (RTT)
Rare neurodevelopmental disease
Preclinical validation, RettSyndrome.org ✔
Planning blinded controlled Phase 2 ☐

Alzheimer’s Disease (AD)
Neurodegenerative disease
Clinical validation Phase 2a ✔
Planning blinded controlled Phase 2/3 ☐

ANAVEX 2-73
Sigma-1 Receptor Agonist
"Pluripotent Modulator"

Modulating Ca²⁺
Reducing mitochondrial dysfunction
Reducing protein misfolding
Reducing oxidative stress
Reducing inflammation

Neuroprotective

Depression
Preclinical validation ✔

Anxiety
Preclinical validation ✔

Epilepsy (seizures)
Preclinical validation ✔

Multiple Sclerosis (MS)
Preclinical validation ✔

Parkinson’s#
Preclinical validation, MJFF ☐

# Neurodegenerative Disease Pipeline

<table>
<thead>
<tr>
<th><strong>ANAVEX™ 2-73</strong></th>
<th>PRECLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
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<tbody>
<tr>
<td>ALZHEIMER’S COGNITION IN NEUROPSYCHIATRIC EPILEPSY PARKINSON’S MULTIPLE SCLEROSIS (MS) RARE DISEASE, RETT SYNDROME</td>
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<th><strong>ANAVEX™ 3-71 (AF710B)</strong></th>
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<tr>
<td>CANCER (PROSTATE) CANCER (PANCREAS) ACUTE &amp; NEUROPATHIC PAIN</td>
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- **In Progress**
- **In Preparation**
- **Alzheimer’s and CNS**
- **Oncology and Pain**
Positive Preclinical Data of ANAVEX™ 2-73 in Rare Disease: Rett Syndrome

What is Rett Syndrome?
- Rare non-inherited genetic postnatal progressive neurodevelopmental disorder
- Caused by mutation of MECP2 gene
- Occurs almost exclusively in girls and leads to severe impairments
- One in 10,000 to 15,000 girls
- Seizures
- Anxiety disorder
- Cognitive impairment
- Loss of speech
- Loss of purposeful hand movements and development of stereotypic hand movements
- Balance and coordination issues, decrease or loss of ability to walk

Experiment to Study ANAVEX 2-73 in MECP2 Rett syndrome disease mouse model supported by Rettsyndrome.org
Assessment of ANAVEX 2-73 in a MECP2 Rett Syndrome Model

- Administration of ANAVEX 2-73 results in both significant and dose related improvements in an array of behavioral paradigms in the MECP2 HET Rett syndrome disease model.

- Taken together, these behavioral paradigms measure different aspects of muscular coordination, balance, motor learning and muscular strengths, some of the core deficits observed in Rett syndrome.

Coupled with positive human safety and cognition data, as well as preclinical anti-seizure and anti-anxiety data, ANAVEX 2-73 might be a potential drug candidate to investigate in Rett syndrome.
Clasping as a Behavioral Paradigm

**Clasping at 8 weeks**

- Mice treated with AV2-73 (30 mg/kg) clasped less than vehicle-treated mutant mice (p<0.05 at 8 and 12 weeks).

**Clasping at 12 weeks**

- Mice treated with AV2-73 (30 mg/kg) clasped less than vehicle-treated mutant mice (p<0.05 at 8 and 12 weeks).

Mice treated with AV2-73 (30 mg/kg) clasped less than vehicle-treated mutant mice (p<0.05 at 8 and 12 weeks).
Multiple Behavioral Rett Syndrome Paradigms Demonstrate Significant Improvement

**Startle:** Wild type (WT) mice have a higher startle response compared to impaired mice: AV2-73 treated mice showed a significant increase in startle response compared to vehicle-treated mutant mice.

**Rotarod:** Motor Coordination and exercise capacity are assessed: AV2-73 treated mice took significantly more time to fall off rod & fell at higher speeds compared to vehicle-treated mutant mice.

**Neurocube:** Platform that employs computer vision to detect changes in gait geometry and gait dynamics: Gait, Correlation, Body Motion demonstrate significant improvement.

<table>
<thead>
<tr>
<th></th>
<th>WT vehicle v. Het vehicle</th>
<th>Het vehicle v. Het AV2-73, 10 mg/kg</th>
<th>Het vehicle v. Het AV2-73, 30 mg/kg</th>
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<tbody>
<tr>
<td>Overall</td>
<td>90, p=0</td>
<td>53, p&gt; 0.69</td>
<td>62, p&gt; 0.24</td>
</tr>
<tr>
<td>GAIT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paw Features</td>
<td>78, p&lt; 0.01</td>
<td>63, p&gt; 0.09</td>
<td>69, p&lt; 0.05</td>
</tr>
<tr>
<td>Correlation</td>
<td>91, p&lt; 0.001</td>
<td>52, p&gt; 0.78</td>
<td>55, p&gt; 0.56</td>
</tr>
<tr>
<td>Body Motion</td>
<td>53, p&gt; 0.66</td>
<td>56, p&gt; 0.40</td>
<td>76, p&lt; 0.005</td>
</tr>
<tr>
<td>Paw Positioning</td>
<td>71, p&lt; 0.02</td>
<td>60, p&gt; 0.20</td>
<td>81, p&lt; 0.003</td>
</tr>
</tbody>
</table>

**Bold represents significance**
Anti-Depressant and Anti-Anxiety Effect of ANAVEX™ 2-73 in Porsolt Swim Test (PST) and in Open Field Test

Effect of ANAVEX2-73 on immobility time on PST. P<0.01, *p<0.05 and **p<0.01 for 50 and 100 mg/kg vs vehicle treated group. Statistical analysis performed with ANOVA followed by Dunnett’s post-hoc test.

Effect of ANAVEX2-73 on the number of crosses (motility-exploratory behavior) in the Open Field Test. Statistical analysis performed with ANOVA followed by Dunnett’s post-hoc test. P<0.05, **p<0.01

No observed “sedative” effect of ANAVEX 2-73

Presented at AES Meeting 2015
ANAVEX™ 2-73 Pre-Clinical Epilepsy Data

Significant Seizure Reduction with ANAVEX2-73 in both MES and PTZ-Induced Seizure Models

**Long-Lasting Effect Shown in PTZ-Induced Seizures**

ANAVEX 2-73 also shows *synergistic* activity with three generations of epilepsy drugs currently on the market: ETS (Zarontin®), VPA (Depakene®) and Gabapentin (Neurontin®)

Presented at AES Meeting 2015, # results have been confirmed by the NINDS screening program
ANAVEX™ 2-73 Potential Protective Role in Treatment of Patients with MS (Multiple Sclerosis)

- ANAVEX 2-73 reduces both oligodendrocytes (OL) and OL precursor cell death induced by 4 different toxic molecules by over 50%
- **Conclusion**: ANAVEX 2-73 protects oligodendrocytes (OL) from cytotoxic mechanisms involved in pathogenesis of MS lesions

ANAVEX 2-73 protects both OL and OL precursor cells from toxic agents: staurosporine (inducer of apoptosis), glutamate (excitotoxicity), reactive oxygen species (ROS) induced by H₂O₂ and quinolinic acid (QA, a tryptophan indoleamine metabolite associated with inflammation). ANAVEX 2-73 also protects against NMDA, AMPA and kainate

---

Presented by Lisak et al. at ACTRIMS 2016
$307 billion spent caring for AD patients - expected to reach $1.5 trillion by 2050

FDA has approved 4 drugs for AD that only temporarily slow worsening of symptoms for 6-12 months in ~50% of patients
Alzheimer’s Disease is Complicated ...

- Removing amyloid beta (A-beta) plaques in the brain might be not sufficient to be completely effective
  - Recent disappointments of large Phase 3 studies: bapineuzumab (Pfizer), solanezumab (Eli Lilly), crenezumab (Roche) and gantenerumab (Roche)
- More likely: Free-floating particles of A-beta (oligomers) damage brain cells in conjunction with:
  - Tau hyper-phosphorylation
  - Ca\(^{2+}\) imbalance
  - Inflammation
  - Mitochondrial dysfunction
- Healthy brain cells can clear A-beta very quickly when not distressed

A further “upstream” Mixed muscarinic / Sig-1R agonist mechanism of action targeting neurodegeneration
Sigma-1R Reduces Chronic Stress and Protein Misfolding

Aβ plays important role in hippocampal memory formation

Hyper-Phospho Tau

Tangles

Proteosome

Mitochondrial Dysfunction

ROS

Synaptic Dysfunction

Ca2+ dysfunction

Healthy Cell: Quick Removal After Utilization

Chromically Distressed Cell: Misfolded Proteins

Sigma-1R Helping / Stimulating Own Body to Regain Functionality – Analogy to Cancer Immunotherapy

ANAVEX™ 3-71 Significantly Decreases Hallmark Pathologies in 3xTg-Alzheimer’s Disease Model

- 10 month-old 3xTg-AD and WT mice
- administered i.p. with tap water or ANAVEX 3-71 (10 mcg/kg/day) for 2 months

**P < 0.01 versus 3xTg-AD (vehicle); *P < 0.05 versus 3xTg-AD (vehicle)**

Reduced Abeta pathology
{Abeta1-40, Abeta1-42 and Abeta plaques}

Reduced neuroinflammation
{activated astrocytes (GFAP) and microglia (Iba-1)}

Source: Fisher et al., Neurodegenerative Diseases 2015 DOI: 10.1159/000440864
FDA Guidelines for Adaptive Trial and Population PK Design

- Fewer patients needed
- Shorter duration required
- More likely to demonstrate an effect of the drug (if one exists)
- More informative on the treatment’s effects
- Broader and better dose-response information and subgroup effects

Leads to more efficient study than conventional studies, Optimizing trial parameters for Phase 3 success

Source: U.S. Department of Health and Human Services Food and Drug Administration February 2010
ANAVEX™ 2-73 Efficient Clinical Trial Execution Plan

ANAVEX™2-73-001 Study:
- Phase 1 (oral)
- Single Ascending Dose (SAD)
- Healthy subjects

Completed

ANAVEX™2-73-002 Study:
- Phase 2a (oral)
- Mild-to-moderate AD patients
- Adaptive trial with Population PK
- Bioavailability, dose finding (PART A), and exploratory efficacy with 52 week open-label extension (PART B)

PART A: Preliminary Data CTAD 2015
PART A: Dose-Response
PART B 52 weeks: Ongoing

ANAVEX™2-73-003 Study:
- 104-week extension study after PART B

ANAVEX™2-73-00X Study:
- Phase 2 (oral)
- Rett syndrome patients
- Double-blind, placebo controlled study
- <3 month efficacy

Preparation underway

ANAVEX™2-73-00Y Study:
- Phase 2/3 (oral)
- Mild-to-moderate AD patients
- Double-blind, placebo controlled study
- 6/12 month efficacy
# ANAVEX 2-73: Phase 2a with Adaptive Trial Design

**Mild-Mod AD patients**

- ANAVEX 2-73 starting dose 30mg/50mg (oral) or 3mg, 5mg (IV)
- ANAVEX 2-73 starting dose 30mg/50mg (oral) or 3mg, 5mg (IV) + Donepezil
- Healthy control, Donepezil/ AchEI

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<th>No. of Pts:</th>
<th>32 mild-moderate AD patients (MMSE 16-28), M/F = 19/13</th>
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<tr>
<td>Sites:</td>
<td>5</td>
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<tr>
<td>Allocation:</td>
<td>Randomized</td>
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<tr>
<td>Duration:</td>
<td>PART A: 5 weeks; PART B: 52 weeks plus 104-week extension</td>
</tr>
<tr>
<td>Endpoints:</td>
<td>Safety, tolerability, bioavailability (PK study)</td>
</tr>
<tr>
<td></td>
<td>Exploratory cognitive measures (EEG/ERP, MMSE, Cogstate) and ADCS-ADL</td>
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<tr>
<td></td>
<td>Exploratory add-on therapy to AD standard of care</td>
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</table>

- Design embraces both adaptive trial features and population pharmacokinetics
- Captures all relevant information required for a larger Phase 2/3 study

# Comparison to published data (AIBL)
Positive Phase 2a Results

- Phase 2a (PART A) results demonstrate a favorable safety, bioavailability, dose-response curve and tolerability/risk profile.

- Despite the relative small sample size of this proof-of-concept randomized open-label study, dose-response analysis seem to indicate a cognitive benefit associated with ANAVEX 2-73 (Cogstate, MMSE, EEG/ERP improved significantly at 5 weeks of treatment):
  - Low-High dose was statistically significant to affect MMSE-Δ and ERP-Δ scores with
    MMSE-Δ \( (p=0.0285) \) and ERP-Δ \( (p=0.0168) \), respectively.
  - Results were confirmed by Bayesian and bootstrap analyses.

- A minimum dose of 14 mg ANAVEX 2-73 required to achieve a therapeutic effect and to keep MMSE score unchanged.

- Similar positive MMSE score effect and no notable difference between ANAVEX 2-73 alone and ANAVEX 2-73 with donepezil observed.
PART A: Bioavailability Adaptive Cross-Over Design

PART B: 52 Wk Open-Label Extension and New 104 Week Study

- **PART A** is 5 week with on-off-on dosing of ANAVEX 2-73 starting dose of 30mg/50mg (oral) and 3mg, 5mg (IV)
- **PART B** is 52 week orally daily dosing regimen without any dose optimization
ANAVEX™ 2-73 Safety from Phase 2a

- Safety profile
  - The most common AE was dizziness followed by headache
    - Events were mild or moderate and reversible with 80% being grade 1
    - There were no drug related AEs Grade 3, 4 and 5
    - Most (94.4%) observed within first 8 days
  - AE profile similar to that of healthy volunteer Phase 1 data
  - No differences in blood pressure or resting heart rate
  - Clinical laboratory parameters, vital signs, and 12-lead ECG did not show any clinically relevant or dose-dependent changes

Voges et al., presented at CNS Summit 2014; Macfarlane et al., presented at CTAD 2015
Efficacy Data Measurements Cognition and Function

- Exploratory cognitive measures (Cogstate battery); (MMSE)
- Functional measures (ADCS-ADL)

Supportive Biomarker Measurements

- ERP (P300): fundamental measures of synaptic network performance and target engagement
- ERP target detection task measures: direct measure of attention, speed of brain processing, and simple functional performance
Comparable Baseline of SoC (AIBL-AD) and ANAVEX 2-73 Trial

SoC (Standard of Care) data from *Australian Imaging Biomarkers and Lifestyle (AIBL-AD*) study testing Cogstate battery in Alzheimer’s disease patients

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<th>Baseline data:</th>
<th>SoC (AIBL-AD)</th>
<th>AV 2-73</th>
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<tr>
<td>Participants (n)</td>
<td>43</td>
<td>32</td>
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<tr>
<td>Age (mean)</td>
<td>79.6</td>
<td>71</td>
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<tr>
<td>MMSE (mean)</td>
<td>22.16</td>
<td>20.5</td>
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<tr>
<td>ApoE4 carrier</td>
<td>70.27%</td>
<td>53%</td>
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<tr>
<td>AchEI and/or memantine##</td>
<td>100%</td>
<td>78%</td>
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ANAVEX 2-73 Improves Components of Cogstate Tasks at Week 5

- ANAVEX 2-73 improved 5 of 6 Cogstate tasks
- ANAVEX 2-73 treatment is associated with improvement in psychomotor function (detection), attention (Identification) and working memory (One back). This improvement is greater than that with comparable AD patients under standard of care, AChEIs (AIBL-ROCS)

* p<0.05, ** p<0.001

Macfarlane et al., presented at CTAD 2015

# Source: aibl.csiro.au/publications/
ANAVEX 2-73 Positive Trend in Interim ADCS-ADL Data

At week 12

Δ = +3.21 points

ANAVEX 2-73 improved ADCS-ADL signal in 11 out of 14 (78.6%) patients at week 12

Macfarlane et al., presented at CTAD 2015
EEG/P300/ERP Highlights Target Engagement of ANAVEX 2-73 and Potential Correlation with Cognitive Effect on a Cellular Level

<table>
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<tr>
<th></th>
<th>P300 Amplitude (µV)</th>
<th>Task Accuracy (%)</th>
<th>False Alarms (%)</th>
<th>Reaction Time (ms)</th>
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<tr>
<td>Baseline</td>
<td>5.99 ± 0.58</td>
<td>83.8 ± 3.9</td>
<td>3.4 ± 1.0</td>
<td>559.0 ± 24.0</td>
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<tr>
<td>Week 5</td>
<td>7.09 ± 0.72</td>
<td>92.6 ± 2.4</td>
<td>1.0 ± 0.5</td>
<td>492.6 ± 23.8*</td>
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<tr>
<td>Healthy Control#</td>
<td>7.36 ± 0.39</td>
<td>94.1 ± 1.1</td>
<td>1.1 ± 0.2</td>
<td>458.6 ± 11.4</td>
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Data are mean ± SEM *p<0.0007

Cacchi et al. Alzheimer’s & Dementia DADM 2015 Dec 1; 1(4):387-394
## Financial Summary

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<th><strong>Symbol:</strong></th>
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<td><strong>Shares Outstanding:</strong></td>
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<td><strong>52-Week Stock Price Range:</strong></td>
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<td><strong>Average Daily Volume:</strong></td>
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<td><strong>Cash @ 3/31/2016:</strong></td>
<td>$12 million</td>
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<td><strong>Cash Burn (est.):</strong></td>
<td>~$600K/month</td>
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- Well-capitalized to achieve key clinical readouts
- No debt
Experienced Management Team with Strong Track Record in the CNS Space

Management and Directors

Christopher U. Missling, PhD, MBA
Tasos Zografidis, PhD
Uli Elben, PhD
Kristina Capiak
Bernd Metzner, PhD
Elliot Favus, MD
Steffen Thomas, PhD
Tom Skarpelos

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Corinne Lasmézas, DVM, PhD
John Harrison, PhD
Ottavio Arancio, MD, PhD
Tanguí Maurice, PhD
Key Achievements to Date and Expected Catalysts in 2016

- New 104 week extension study of Phase 2a after PART B
- Preparation for Phase 2 study in Rett syndrome
  - Double-blinded, randomized, placebo-controlled
- Preparation for Phase 2/3 study in Alzheimer’s disease
  - Double-blinded, randomized, placebo-controlled, Potential for first registration study
- Present at three scientific meetings in 2016
- Phase 2a – Report PART B data at scientific meetings once data available
- Phase 2a – Report PK/PD data once data available
- File IND for non-disclosed indication
- Complement current pipeline through in-licensing – ongoing
Contact Us

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