Analysis of ANAVEX™2-73
Phase 2a Data
October 2017

Developing targeted therapies for neurodevelopmental and neurodegenerative diseases
Safe Harbor

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Executive Summary

- ANAVEX2-73 focuses on a new target relevant to Alzheimer’s disease and other neurological diseases
- Sophisticated design of ANAVEX 2-73-002 trial with multiple dosing and availability of longitudinal PK/PD data enables detailed responder analysis
- Initial study and in depth data analysis using ARIANA technology demonstrates
  - Relationship between ANAVEX2-73 measured exposure and dose (PK) are consistent across study periods
  - Strong drug concentration / response relationship revealed for key Alzheimer’s disease trial endpoints cognition and function, MMSE and ADCS-ADL (PK/PD). This relationship is consistent across multiple time periods
  - Same applies for the brain activity biomarker ERP (PK/PD)
  - Systematic analysis using KEM® identifies actionable parameters enabling a precision medicine approach to include best responders in follow-up Phase 2/3 study
- Additional data to be incorporated
  - DNA, RNA and gut microbiota
  - Advanced data analytics will enable “targeted therapy” design for new trial
The Sigma-1 Receptor (S1R): From Gene to Therapeutic Target

Sigma-1 Receptor is an integral membrane protein involved in cellular homeostasis which targets restoration of neuroplasticity and cellular stress response²,³

*Endogenous* S1R agonists activate the Sigma-1 Receptor under conditions with cellular stress⁴,⁵,⁶

**ANADEX2-73** is a S1R agonist and activates the Sigma-1 Receptor

Enhancing Activation of endogenous S1R with ANAVEX2-73 improves disease symptoms and underlying pathophysiology

Lack of S1R exacerbates disease progression¹

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Sigma-1 Receptor Activation of ANAVEX2-73 Extended with Active Metabolite

- ANAVEX2-73 is metabolized into the pharmacologically active metabolite, ANAVEX19-144
- Metabolite also acts as sigma-1 receptor agonist with neuroprotective action like ANAVEX2-73, restoring homeostasis and neuroplasticity
- The apparent elimination half-life of the metabolite (21.45 hr) is approximately twice that of ANAVEX2-73 (10.71 hr) hence the active metabolite result in extended activation of the sigma-1 receptor
ANA VEX 2-73 Phase 2a Alzheimer’s Disease

Randomized, Crossover Assignment, Open Label Study of ANAVEX 2-73 (ANA VEX™2-73-002 Study#)

Baseline

N = 32
- Mild-to-moderate AD patients
- Baseline MMSE: 16-28

Initial screen

Randomized to 1 of 2 arms

36 Days (5 Weeks)
Two-period, cross-over treatment
✓ Safety, MTD
✓ Bioavailability of ANAVEX 2-73
✓ Dose-effect relationship
✓ PK/PD modeling

PART A

NCT02244541

52 Weeks
Voluntary open label extension
✓ Safety
✓ Multiple doses of ANAVEX 2-73
✓ Dose-effect relationship
✓ PK/PD modeling

PART B

ClinicalTrials.gov Identifier: NCT02244541

* ClinicalTrials.gov Identifier: NCT02244541
Design and Exploratory Endpoints of the Phase 2a

PART A
Establish safety and PK of ANAVEX2-73
Explore a dose-effect relationship

PART B
Establish continued safety and tolerability
Explore a dose-effect relationship

- 1st Period
- wash out Period
- 2nd Period

intravenous

oral

all patients on oral daily treatment

0 weeks
52 weeks
5 weeks

0 days
12 days
36 days
Pre-specified Stated PK Time Points of the Phase 2a

Part A: IV (3/5 mg), Oral (30/50 mg)

- Measures (hours): 0, 1, 2, 6, 8, 12, 18, 24, 48, 72, 120, 192, 264
- Daily intake: [Graph showing intake periods]
- Period 1
- Wash out
- Period 2

Part B: Oral (10 to 50 mg)

- Measures (hours): 0, 1, 2, 6, 8, 12, 18, 24, 48, 72, 120, 192, 264
- Daily intake: [Graph showing intake periods]
- Period 1
- Wash out
- Period 2

Baseline: [Graph showing baseline levels]

Day 12

Day 24

Day 36 (Week 5)

Week 12

Week 26

Week 36

Week 48

Week 57

C°
Part A: Analysis of Distinct Timeframes

- **Period 1**: 0-24h
- **Wash out**: 24-264h
- **Period 2**: 264-264h

**Baseline**
- Day 12
- Day 24
- Day 36
  - Week 5

**Part A1 [0-24h]**

**Part A2 [24-264h]**
Analysis of All Relevant Time Periods


Immediate response

Short-term response

Long-term response
ANAVEX™ 2-73 Rational Clinical Trial Execution Plan

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

ANAVEX™2-73-002 Study#: 
- Phase 2a (iv/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)

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

Initiation of subsequent randomized, double-blind, placebo-controlled ANAVEX™2-73 studies:
- Rett syndrome
- Parkinson’s disease
- Alzheimer’s disease

ClinicalTrials.gov Identifier: #NCT02244541; ##NCT02756858
Confirmed Reliable Inter-Individual Variability (Dispersion) for the ANAVEX2-73 Phase 2a Study with 32 Patient Cohort

- Evaluation of the dispersion index of all the 32 patient of the Phase 2a reveals that above 16 patients, the dispersion index is maintained at a fixed level with the narrowest confidence intervals.

- That is confirmation that the sample of 32 patients of the Phase 2a provides reliable information regarding dispersion and as such allows for meaningful predictions for larger populations.
Relation Between ANAVEX2-73 Exposure and Dose (PK) are Consistent Across Administrations

- ANAVEX2-73 (IV, 3 mg)
- ANAVEX2-73 (IV, 5 mg)
- ANAVEX2-73 (Oral, 30 mg)
- ANAVEX2-73 (Oral, 50 mg)

**Analyte**
- ANAVEX2-73 (IV, 3 mg)
- ANAVEX2-73 (IV, 5 mg)
- ANAVEX2-73 (Oral, 30 mg)
- ANAVEX2-73 (Oral, 50 mg)

**Period**
- Period 1
- Period 2
High Dose of ANAVEX2-73 Correlates with Exposure

Total average drug exposure over time
$\text{AUC}_{(0 \text{ to } \infty)}$
Area Under the Curve, 0-24h

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Dose</th>
<th>IV/Orgal</th>
<th>AUC (ng/mL h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: 3 mg, iv</td>
<td></td>
<td></td>
<td>44.55</td>
</tr>
<tr>
<td>B: 5 mg, iv</td>
<td></td>
<td></td>
<td>66.58</td>
</tr>
<tr>
<td>C: 30 mg, oral</td>
<td></td>
<td></td>
<td>127.34</td>
</tr>
<tr>
<td>D: 50 mg, oral</td>
<td></td>
<td></td>
<td>185.75</td>
</tr>
</tbody>
</table>

$\frac{127.34}{185.75} = 0.68$

$\frac{44.55}{66.58} = 0.67$
Measured Concentration of ANAVEX2-73 is Reproducible over Time


\[ R^2 = 0.285 \]
\[ p = 0.0019 \]

Part A vs Part B

\[ R^2 = 0.318 \]
\[ p = 0.0021 \]
Metabolite of ANAVEX2-73 Extends Activation of Sigma-1 Receptor Activity

- A typical concentration-time for ANAVEX2-73 and metabolite for a subject administered orally 60 mg ANAVEX2-73
- ANAVEX2-73 is rapidly absorbed with an absorption half-life of 30 min and an apparent elimination half-life of 10.71 hr
- The active metabolite is slowly eliminated with an apparent elimination half-life that is approx. twice that of the parent (21.45 hr)
P300 ERP Biomarker Measuring Direct Brain Activity

P3a and P3b are Subcomponents of P300 ERP Biomarker

- Non-invasive biomarker ERP\(^\#\) measures cortical network performance in the brain
- Demonstrated sensitivity to Alzheimer’s disease and other neurological disorders
- Real-time physiological biomarker measure of cognitive processes
- More proximal to disease pathology and pharmacological intervention than psychometric measures

Polich and Criado, Int J Psychophysiol. 2006

doi:10.1007/978-1-4615-0294-4

\(^\#\) ERP = Event-Related Potential
P3a Amplitude Correlates With Verbal Memory Performance

- 20 subjects: P3a amplitude is associated with verbal memory performance
- Scatterplot of P3a amplitude and CVLT-II total recall (r = 0.72, p < 0.001)
- Topography of the correlation plotted across electrode sites
- Red and black indicate significant correlations at fronto-central electrodes

ERP Biomarker Shows Significant Drug Response: P3a Amplitude Increases with ANAVEX2-73

P3a Amplitude in PART A

- Oral / IV dosing
- Wash out
- Oral / IV dosing

1st Period: 12d
2nd Period: 12d
5 week

**Significant drug response effect**

ERP Biomarker Shows Significant Drug Response: P3a Amplitude Increases with ANAVEX2-73
Ariana’s KEM® Platform

Advanced Artificial Intelligence Platform Supporting Clinical Trial Design

- **KEM®**: a Formal Concept Analysis (FCA) Artificial Intelligence framework

- Comprehensively analyzes complex datasets by measuring all logical relations within a dataset, exploring all combinations of parameters and End-Points

- Identifies most relevant and powerful causal relations, revealing hidden relationships and deriving new hypothesis

- Validated by a large selection of clients and partners including Sanofi, Ipsen, Pierre Fabre, Chemo, ValiRx, Harvard Medical School and the FDA (www.arianapharma.com/about/our-customers/)
Precision Medicine Paradigm in Oncology

- Cancer seen as a collection of heterogeneous diseases
- Characterized by molecular features of the tumor
- Molecular test performed prior to treatment decision
- ~40% of new drugs have a companion marker

Large number of biomarkers characterize patient tumors, dominated by genomic data from Next Generation Sequencing (NGS)
Precision Medicine in Alzheimer’s Disease

- Current Alzheimer’s disease drug development paradigms continue to fail in Phase 3 clinical trials
- Deconstructing Alzheimer’s disease into multiple biological and genetic subsets within this heterogeneous target population
- Transposing the Oncology Precision Medicine Paradigm to the Neurological disease area requires:
  - Collecting the right data
  - Enabling effective Data Analytics Tools
  - Executing more rigorous clinical trials

An effective Precision Medicine strategy for treating individual patients with agents that are likely to work most effectively based on the specific individual’s biological make-up
Comprehensive Phase 2a Patient Characterization to Identify Actionable Phase 2/3 Clinical Trial Parameters

Ariana’s KEM® data analytics:
- Systematic integrated analysis of all combined parameters
- Identification of actionable parameters
- Design of an optimized Phase 2/3 clinical trial
Ariana’s KEM® platform enables a systematic and exhaustive search of all possible relations across variables, endpoints, PK parameters and time.

71,172 relations

83 rules

Exploration & pruning

3 Periods (A1, A2, B)
12 Endpoints and 3 molecules’ PK
4 Transformations
80 Baseline variables
2 or 3 Categories per variables

97% of them showing coherent dose-response relation
Robust Dose (Concentration) / Response Effect of ANAVEX2-73

KEM® analysis: Consistency for 6 main exploratory endpoints cognition, function and biomarker (MMSE, ADCS-ADL & EEG/ERPs) demonstrated through systematic exploration of the full data matrix.

- 97% Consistency: MMSE, ADCS-ADL and EEG/ERPs: Identified relations show that high dose (concentration) is linked to improved response and low dose (concentration) to poor response.

- High dose -> Improved response (54%)
- Low dose -> Poor response (43%)
- High dose -> Poor response or Low dose -> Improved response (3%)

97% Consistency: MMSE, ADCS-ADL and EEG/ERPs: Identified relations show that high dose (concentration) is linked to improved response and low dose (concentration) to poor response.
Relation between ANAVEX2-73 Concentration and MMSE

KEM® explores all possible relations

- Increasing
- Decreasing

High Concentration → MMSE increases

Low Concentration → MMSE decreases
Relation between ANAVEX2-73 concentration and MMSE

KEM® characterizes all identified relations

<table>
<thead>
<tr>
<th>Concentration</th>
<th>MMSE.SlopeFromBL</th>
<th>SupportRatio</th>
<th>Confidence</th>
<th>Lift</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANAVEX2-73 partB Medium</td>
<td>Decreasing</td>
<td>33.3%</td>
<td>1.00</td>
<td>1.35</td>
</tr>
<tr>
<td>ANAVEX2-73 partB Low</td>
<td>Decreasing</td>
<td>25.9%</td>
<td>0.78</td>
<td>1.05</td>
</tr>
<tr>
<td>ANAVEX2-73 partB High</td>
<td>Increasing</td>
<td>28.5%</td>
<td>0.56</td>
<td>2.14</td>
</tr>
</tbody>
</table>
The relationship between ANAVEX2-73 concentration and MMSE is being explored by KEM®. Increasing MMSE concentrations are rare events. A patient receiving a higher concentration of ANAVEX2-73 has a +110% (2.1-fold) chance of improving its MMSE during 57 weeks. This is a significant finding in the study of Alzheimer's disease treatment.
KEM® Identifies Strong non linear Relations Linking Concentration with Response for both MMSE and ADCS-ADL

<table>
<thead>
<tr>
<th>Dose</th>
<th>Response</th>
<th>SupportRatio</th>
<th>Confidence</th>
<th>Lift</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>MMSE.SlopeFromBL.Increasing</td>
<td>18,50%</td>
<td>0,556</td>
<td>2,143</td>
</tr>
<tr>
<td>ANAVEX2-73</td>
<td>partB__High</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dose</th>
<th>Response</th>
<th>SupportRatio</th>
<th>Confidence</th>
<th>Lift</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>ADCS-ADL.DeltaFromBL.High</td>
<td>18,50%</td>
<td>0,625</td>
<td>1,667</td>
</tr>
<tr>
<td>ANAVEX2-73</td>
<td>partB__High</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
High ANAVEX2-73 Concentration linked to Improved Response Consistently Across All Analytes and Periods

Both ANAVEX2-73 and metabolite show a consistent response across the 3 different times frames:

- **Part A1 [0-24h]** Immediate response
- **Part A2 [24-264h]** Short-term response
- **Part B [52 weeks]** Long-term response

ANAEXV2-73 and metabolite concentration

Implies

MMSE Improvement

ADCS-ADL Improvement
Correlation of MMSE with ADAS-Cog

1 MMSE ≈ 3.7 ADAS-Cog

MMSE range for linear equivalence: 20 to 30
KEM® analysis has identified exclusion / inclusion criteria. Each criterion has the potential to improve MMSE / ADAS-Cog for mild-to-moderate Alzheimer’s patients treated with ANAVEX2-73.

These criteria will be incorporated into the upcoming ANAVEX2-73 Phase 2/3 trial.
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- Additional data to be incorporated
  - DNA, RNA and gut microbiota
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Anavex Highlights

**FDA granted Orphan status to ANAVEX™ 2-73 for Rett syndrome; Clinical trial Q4 2017**

- Orally available novel sigma-1 receptor (S1R) agonist with strong IP (COM to 2033)
- S1R linked to cellular homeostasis and plasticity relevant to CNS disorders

**Safety with signals of efficacy established in Phase 2a Alzheimer’s Disease trial**

- 54 subjects treated with ANAVEX 2-73 (Phase 1 and Phase 2a)

**Preclinical validation in other orphan and larger CNS diseases**

- Portfolio of clinical and preclinical compounds varying in S1R and muscarinic binding kinetics

**Partnerships with RettSyndrome.org, Michael J. Fox Foundation, FRAXA, and FAST**

- Clinical studies focused on pursuing fastest path to market

**Near term clinical advancements**

- 4Q 2017 Phase 2a Alzheimer’s disease – PK/PD data
- 4Q 2017 Phase 2 clinical trial in Rett syndrome
- 4Q 2017 Phase 2 clinical trial in Parkinson’s disease
- 4Q 2017 Phase 2/3 clinical trial in Alzheimer’s disease

**Cash to fund operations over the next 2 years**
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ANAVEX is a trademark of Anavex Life Sciences Corp.
Alzheimer’s Disease Progression:
Comparative cognitive decline in open-label studies as in placebo-controlled studies

Progressive decline in cognition:
Open-label study with SoC#

Progressive decline in cognition:
Double-blind placebo-controlled study with SoC##

- Open-label and double-blind controlled studies equivalent for long-term cognition changes

## Figure adapted from Doody RS et al (2013) N Engl J Med; 369:341-350 (SoC = Ach inhibitors and/or memantine)
MMSE Δ and ADCS-ADL Δ Significantly Different to SoC AD
Bootstrap test for difference between ANAVEX 2-73 and SoC AD

1.8 MMSE points improvement to historical control (SoC)\# at week 57 (p=0.0164)

4 ADCS-ADL points improvement to historical control (SoC)\# at week 57 (p=0.0186)


SoC (Standard of Care AD): Comparison to historical control subjects with mild-to-moderate AD with comparable MMSE baseline, assigned to the placebo arm from pooled cohort study conducted by the Alzheimer Disease Cooperative Study Group, age adjusted\#
Examples of Continued Improvements and Reported Events ‘Therapeutic Response’ during 57 Weeks

<table>
<thead>
<tr>
<th>PATIENT</th>
<th>EVENTS: THERAPEUTIC RESPONSE UNEXPECTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>101001</td>
<td>MORE ALERT REGARDING SURROUNDINGS</td>
</tr>
<tr>
<td>101002</td>
<td>FEELS MUCH HAPPIER MAKING JOKES</td>
</tr>
<tr>
<td>101003</td>
<td>MUCH HAPPIER WHEN ATTENDING CLINIC APPTS AND ENJOYS MAKING JOKES AND ENGAGES WELL IN CONVERSATION</td>
</tr>
<tr>
<td>101004</td>
<td>BETTER HAND COORDINATION. CALMER AND MORE COMMUNICATIVE</td>
</tr>
<tr>
<td>101006</td>
<td>IMPROVING MOODS. READING MORE BOOKS</td>
</tr>
<tr>
<td>101007</td>
<td>ABILITY TO PLAY THE PIANO AND READ MUSIC NOTES AT ABOUT 9 MONTHS INTO TRIAL. SHE USED TO PLAY THE PIANO AT AGE 5 AND LOST HER ABILITY PRE-ALZHEIMER TRIAL</td>
</tr>
<tr>
<td>101010</td>
<td>ABLE TO FOLLOW PLOT WHEN WATCHING MOVIES WHEREAS PREVIOUSLY COULD NOT</td>
</tr>
<tr>
<td>101010</td>
<td>MORE COMPASSION FOR CHILDREN</td>
</tr>
<tr>
<td>101011</td>
<td>WIFE THINKS PATIENT IS A BIT MORE CHEERFUL</td>
</tr>
<tr>
<td>101013</td>
<td>ABLE TO DO MUCH MORE HOUSEWORK THAN BEFORE</td>
</tr>
<tr>
<td>101013</td>
<td>MORE DRIVEN AND UPBEAT LESS ANXIOUS ACCORDING TO CARER</td>
</tr>
<tr>
<td>101014</td>
<td>AN INTERNATIONAL ARTIST WHO RESUMED HER PAINTING ABILITIES AND NOW HAVING AN EXHIBITION IN NOV 2016. WRITTEN A 3 PAGE LETTER TO LONG LOST BROTHER</td>
</tr>
<tr>
<td>101015</td>
<td>PLAYING MORE GOLF NOW BY HIMSELF. MORE CONFIDENT AT GOING OUT BY HIMSELF</td>
</tr>
<tr>
<td>101017</td>
<td>ENJOYED HER TRIP TO BELGIUM - TALKS ABOUT SOME BITS OF HER TRIP</td>
</tr>
<tr>
<td>102001</td>
<td>IMPROVED ENGAGEMENT WITH FAMILY/FRIENDS/OUTSIDE WORLD</td>
</tr>
<tr>
<td>102008</td>
<td>IMPROVEMENT IN MOOD</td>
</tr>
<tr>
<td>102010</td>
<td>FEELING GREAT - IMPROVEMENT IN COGNITION AND MOOD, BALANCE AND GAIT HAS IMPROVED</td>
</tr>
<tr>
<td>103001</td>
<td>PATIENT REMEMBERING SOMETHING HE WOULDN'T HAVE PREVIOUSLY</td>
</tr>
</tbody>
</table>
ANAVEX™ 2-73 Shown to be Safe in Phase 2a Clinical Trial of Mild-to-Moderate Alzheimer’s Patients

- Phase 2a results demonstrate a favorable safety, bioavailability, dose-response curve and tolerability/risk profile at doses between 10mg and 50mg of oral daily ANAVEX 2-73

- Primary endpoints met with favorable safety and tolerability

- Secondary endpoints met with supportive exploratory biomarker, cognition and functional measures correlating
  - Low-High dose was statistically significant to affect MMSE-Δ and EEG/ERP-Δ scores with $\text{MMSE-Δ (}p=0.0285\text{)}$ and $\text{EEG/ERP-Δ (}p=0.0168\text{)},$ respectively
Valuable feature of Sigma-1R agonists are their favorable safety profiles, particularly in humans due to the modulatory action of Sigma-1R.

Selectively only under pathological conditions while sparing normal physiological activity, thus limiting adverse side effects.


Later expansion of indication scope with disease modification or prevention trial – ANAVEX 2-73 has already demonstrated preclinically to prevent symptoms of Alzheimer’s.

Comprehensive Phase 2a Patient Characterization to Identify Actionable Phase 2/3 Clinical Trial Parameters

**Scores**
- **Baseline**
- **Evolution**

**Population PK**

**Scores**
- MMSE
- ADCS-ADL
- COGSTATE
- EEG/ERP
- HAM-D

**Clinical Assessment**
- Vital signs
- Co-medication

**New**

**FGS: Full Genomic Sequencing**

**DNA FGS**

**RNA FGS**

**Advanced Data Analytics using KEM®**

**Systematic Responders Hypothesis**

**Actionable optimized Phase 2/3 clinical trial parameters**
57 Week Longitudinal Cognition MMSE and Function ADCS-ADL

- 57 week longitudinal MMSE and ADCS-ADL without dose optimization
- Cognition MMSE and Quality of life score ADCS-ADL (Activities of Daily Living) maintained close to baseline through week 57