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Anavex Expanding Pipeline: Potential for Significant Value Creation Near and Long Term

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<th>CANDIDATE</th>
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* = Orphan Drug Designation by FDA

Fast Track, Rare Pediatric, Orphan Drug (U.S./EU)
Addressing Unmet Needs in Significant Populations

2) Marras C et al 2018. npj Parkinson’s Disease volume 4, Article number: 21
3) Based on prevalence number on orphanet
A Transformative Year for Anavex

- Rett syndrome program Fast Track Designation and eligible for Pediatric Priority Review Voucher
- Pursuing Large Markets With High Unmet Need by Applying Genetic Precision Medicine
- Novel CNS Mechanism of Action Upstream of Neurodevelopment and Neurodegeneration
- Compelling first Human Patient Data in Rett Syndrome and Alzheimer’s Disease
- Sufficient Cash for >24 months To Achieve Key Milestones — Including non-dilutive Cash from Australian Government for Alzheimer’s Trial, and from Rettsyndrome.org for Rett Syndrome Trial

We Anticipate Significant Value-creating Events with Several Clinical Readouts in 2020:

- Phase 2 Parkinson’s Disease Dementia (ClinicalTrials.gov Identifier: NCT03774459)
- Two Phase 2 Rett Syndrome Trials (ClinicalTrials.gov Identifier: NCT03758924, NCT03941444)
- Phase 2/3 Rett Syndrome Trial updates (ClinicalTrials.gov Identifier: NCT04304482)
- Phase 2b/3 Alzheimer’s Disease updates (ClinicalTrials.gov Identifier: NCT03790709)
- Phase 1 with ANAVEX®3-71 with focus on Frontotemporal Dementia
Catalysts to Drive Value

The company expects to achieve key clinical milestones

- Full enrollment Phase 2 Parkinson’s disease dementia (PDD)
- Topline data Phase 2 Parkinson’s disease dementia (PDD) – MID 2020
- FDA Fast Track designation for Rett syndrome program (RTT)
- Initiate EXCELLENCE Phase 2/3 in pediatric Rett syndrome (RTT)
- Full enrollment U.S. Phase 2 Rett syndrome (RTT)
- Full enrollment AVATAR Phase 2 Rett syndrome (RTT)
- Topline data U.S. Phase 2 Rett syndrome (RTT)
- Topline data AVATAR Phase 2 Rett syndrome (RTT)
- Initiate Phase 1 ANAVEX®3-71
- Data publications in 2020
Clinical Trials – MoA and First Clinical Data:

- Rett Syndrome (RTT)
- Alzheimer’s Disease (AD)
Neural cells suffer functional loss in neurological disorders which causes cellular stress

Pathologies include:

- Aβ, Tau and ApoE fragmentation and dysfunction
- Proteinopathy
- Microglia activation, migration, and dysregulation
- Apoptosis feedback loops that lead to neuronal degradation
- Autophagy dysfunction
- Mitochondrial Dysfunction and Oxidative Stress that leads to further neuronal degradation
- Neurodegeneration that spreads through a cascade of stress responses

S1R activates neuroprotective signals that help neurons return to homeostasis

S1R = Sigma-1 Receptor
ANAVERSE®2-73 Establishes Human Proof-of-Concept and SIGMAR1 Target Occupancy

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

ANAVERSE®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; H Hampel et al., AAIC 2018; *Alzheimer’s Disease Cooperative Study Activities of Daily Living 23-item scale (ADCS-ADL)
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**

**Article**

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

Maximilian G. Christ, Heike Huesmann, Heike Nagel, Andreas Kenn and Christian Behl *

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D-55101 Mainz, Germany; maximilian.huesmann@medizin.uni-mainz.de (M.G.C.); christ@huesmann.de (H.H.), 
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Received: 29 January 2016; Accepted: 27 February 2016; Published: 2 March 2016

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

- Daniel A. Ryskamp,
- Svetlana Korban,
- Vladimir Zhemkov,
- Nina Kraskovskaya
- and
- Ilya Bezprozvanny

Department of Physiology, UT Southwestern Medical Center, United States

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

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

Agostino Maccacaro, Filippo Caruso, Elia Bagnoletti Salorius, Tsung-Ping Su, Agnese Colognati and Giuseppe Rondoni

**SIGMAR1 Activation has been Shown to Modulate Multiple Aspects of Neurodegenerative Processes**
What is Rett Syndrome?

Devastating neuro-developmental disease in girls with both movement impairment and cognitive impairment

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

Source: https://www.rettsyndrome.org/about-rett-syndrome
Phase 2 PART A: Improvement in All Key Domains

U.S. Rett Syndrome ANAVEX®2-73-RS-001 Trial (NCT03758924)

SUMMARY
- Phase 2, safety, tolerability, efficacy for 7 weeks, oral, liquid formulation, 5 mg daily (relatively low dose)
- Part A: Intensive PK, n=6, Completed
- Part B: Randomized, double-blind, placebo-controlled, n=15, ongoing
- Females > 18 years, classic Rett w/MECP2 mutation
- Evaluations at baseline (Week 0), Week 4 & Week 7 (End of Treatment)
- Good safety and tolerability: No serious adverse events, only three grade 1-2 adverse events

EFFICACY*
- Global severity RSBQ and CGI-I
  RSBQ = Rett Syndrome Behavior Questionnaire
  CGI-I = Clinical Global Impressions – Improvements
- Secondary: Behavior (ADAMS), Sleep (CSHQ), VAS (top caregiver concerns), Seizure diary
- Response Biomarker*: Glutamate, GABA; Genetic biomarker: DNA & RNA profiles

*Preliminary evaluation of efficacy: two-tailed, nonparametric tests (conservative)
**Precision Medicine**

Patient Selection with Biomarker Increases Probability of Success

- Phase II to Phase III:
  - Without Biomarkers: 28%
  - With Patient Selection Biomarkers: 46%
- Phase III to NDA/BLA:
  - Without Biomarkers: 55%
  - With Patient Selection Biomarkers: 76%

In patients with RTT, MeCP2 deficiency leads to increased levels of Glutamate, in comparison to healthy controls\textsuperscript{1,2,3}, which results in excitatory-inhibitory imbalance and further synaptic dysfunction.

Loss of synaptic homeostasis can impair nerve cells (neurons) and their connections.

Glutamate as potential biomarker of microglia activation and synaptic dysfunction

Phase 2 PART A: Reported Improvements Correlate with Biomarkers

U.S. Rett Syndrome ANAVEX®2-73-RS-001 Trial (NCT03758924)

REPORT on PART A: INTENSIVE PK SUBCOHORT
- Plasma levels of the biomarker Glutamate decreased significantly (Week 0 vs. Week 7; 2-tailed Wilcoxon signed rank test, p = 0.046)
- Levels of Glutamate at Week 7 directly correlated with CGI-I scores at Week 7 (2-tailed Spearman’s rho = 0.837, p = 0.038)
- Greater decreases in Glutamate associated with greater improvement in these efficacy scores
- GABA changes demonstrated an inverse correlation of the magnitude of Glutamate changes (2-tailed Spearman’s rho = -0.829, p = 0.042)

Key Correlations:
- Glutamate & CGI-I
- Glutamate & Hand Behaviors
- Glutamate & Sleep

**Significant Correlations:**

**RSBQ & CGI-I**
- p = 0.003

**Glutamate & CGI-I**
- p = 0.038

**Glutamate & Hand Behaviors**
- p = 0.021

**Glutamate & Sleep**
- p = 0.005

**Glutamate decreases by over 40%**
ANAVEX®2-73 Phase 2 U.S. Rett Syndrome Study

N>21*

RTT patient population

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

Randomization 3:2

ANA VEX®2-73 Active dose#

Placebo

7 WEEK STUDY

Primary and Secondary Endpoints
- PK, Safety and tolerability of ANAVEX®2-73
- Behavioral symptoms
- Sleep function
- Seizure activity

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

* Includes a 6 patient cohort undergoing a 7-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 Phase 2 Rett Syndrome AVATAR Study

N=33* RTT patient population

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

Randomization 3:2

Primary and Secondary Endpoints
- Safety and tolerability of ANAVEX®2-73
- Behavioral symptoms
- Sleep function
- Seizure activity

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

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

WEEK STUDY

Placebo

ANAVEX®2-73 Active dose#
ANAVEX®2-73-RS-003 Rett Syndrome EXCELLENCE Study

N>69

RTT patient population

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

Randomization 2:1

ANAVENTX®2-73 Active dose#

Placebo

12 WEEK STUDY

Primary and Secondary Endpoints
- Safety and tolerability of ANAVEX®2-73
- Behavioral symptoms
- Sleep function
- Seizure activity

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

N>69 12 WEEK STUDY

* Oral liquid solution once daily; Dose restricted to maintain complete blinding
Alzheimer’s Disease (AD)

Alzheimer’s disease, progressive, irreversible neurological disease and 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


\(^1\) 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

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
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
  - 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: www.alz.org/alzheimers-dementia/what-is-dementia/types-of-dementia/parkinson-s-disease-dementia
ANAVEX®2-73 Phase 2 Parkinson’s Disease Dementia (PDD) Study

N=120

PDD patient population

- Diagnosis of probable Parkinson’s disease dementia (PDD)
- Diagnosis of idiopathic Parkinson’s disease
- Patients aged ≥ 50 years
- MoCA score 13-23
- Entire DNA and RNA sequencing

Primary Endpoints
- CDR Continuity of Attention
- Safety and tolerability of ANAVEX®2-73

Key Secondary Endpoints
- MDS-UPDRS
- Sleep function
- Actigraphy
- MoCA
- Other CDR battery measures

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

Randomization 1:1:1

ANAVERX®2-73
- High dose#
- Medium dose#
- Placebo

14 WEEK STUDY

Oral capsule once daily; Dose restricted to maintain complete blinding

# Oral capsule once daily; Dose restricted to maintain complete blinding
Primary Endpoint ‘CDR Continuity of Attention’ of PDD ANAVEX®2-73 Ph2 Study: Confirmed Beneficial Effect in Previous Ph2a AD Study

Identification (IDN) in Cogstate battery assessed in ANAVEX®2-73 Ph2a AD Study comparable to CDR Continuity of Attention (choice reaction time paradigm)

Eli Lilly and Company uses 'Continuity of Attention' as Primary Endpoint in D1PAM's dementia associated with Parkinson's disease trial (ClinicalTrials.gov Identifier: NCT03305809)
Anavex is the only Company pursuing Large Markets by Applying Precision Medicine 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 approach is needed to address the totality of CNS diseases

PRECISION MEDICINE IMPROVES CHANCE OF CLINICAL SUCCESS
Testing for biomarkers demonstrated improved clinical response to ANAVEX®-2-73 in Rett syndrome correlated with glutamate and for Alzheimer’s patients carrying wild-type (WT) SIGMAR1 and COMT genes

STRONG IP POSITION AROUND NOVEL MECHANISM OF ACTION
ANAUX®-2-73, is an orally available Sigma-1 receptor agonist that has been shown to restore homeostasis (composition of matter patent protection to 2037)

COMPELLING INITIAL HUMAN DATA
ANAUX®-2-73 undergoing Phase 2 in Rett syndrome and Phase 2a trial in Alzheimer’s disease with favorable safety and exploratory efficacy results through 148 weeks

VALUE-CREATING CATALYSTS
Clinical data readouts from two Phase 2 Rett syndrome studies and Phase 2 Parkinson’s disease dementia study anticipated in 2020. Clinical data publications and additional indications to be announced in 2020

SUFFICIENT CASH TO ACHIEVE KEY MILESTONES
Cash on hand and non-dilutive cash from Australian government for Alzheimer’s study, and from Rettsyndrome.org for Rett syndrome study
# Anavex Life Sciences Expertise

## Management Team

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<th>Position</th>
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<tbody>
<tr>
<td>Christopher U. Missling</td>
<td>PhD - President &amp; CEO</td>
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<tr>
<td>Walter E Kaufmann, MD</td>
<td>- Chief Medical Officer</td>
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<tr>
<td>Stephan Toutain, MS, MBA</td>
<td>- Chief Operating Officer</td>
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<tr>
<td>Emmanuel O Fadiran, RPh, PhD</td>
<td>- SVP of Regulatory Affairs</td>
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<tr>
<td>Daniel Klamer, PhD</td>
<td>- VP of Business Development &amp; Scientific Strategy</td>
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## Scientific Advisory Board Members

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<td>Jeffrey Cummings, MD</td>
<td>Cleveland Clinic</td>
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<tr>
<td>Corinne Lasmezas, PhD</td>
<td>Scripps Research</td>
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<td>Ottavio Arancio, MD, PhD</td>
<td>Columbia University Medical Center</td>
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<tr>
<td>Andrew Cole, MD</td>
<td>Harvard Medical School</td>
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<tr>
<td>Daniel Weintraub, MD</td>
<td>Perelman School of Medicine</td>
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