

# Anavex Life Sciences Presents New Clinical Data of Investigational Alzheimer's Disease Treatment ANAVEX<sup>®</sup>2-73 at 2017 Clinical Trials on Alzheimer's Disease Meeting

*Presentation Includes New Data from Phase 2a Long-Term Extension Cohort*

**NEW YORK**, November 4, 2017 – Anavex Life Sciences Corp. (Anavex or the Company) (Nasdaq: AVXL), a clinical-stage biopharmaceutical company developing differentiated therapeutics for the treatment of neurodegenerative and neurodevelopmental diseases including Alzheimer's disease, other central nervous system (CNS) diseases, pain and various types of cancer, today presented new clinical pharmacokinetic (PK) and pharmacodynamic (PD) data for ANAVEX2-73 in a late-breaking oral presentation at the 2017 Clinical Trials on Alzheimer's Disease (CTAD) Meeting.

Data presented include new results from the Phase 1 study (ANAVEX<sup>®</sup>2-73-001), the Phase 2a study (ANAVEX<sup>®</sup>2-73-002), and data from the first year of the Phase 2a long-term extension study (ANAVEX<sup>®</sup>2-73-003).

At 109 weeks and halfway into the long-term extension Phase 2a study ANAVEX<sup>®</sup>2-73-003, data from the cohort of patients with the highest ANAVEX2-73 concentrations point towards the continued ability of the medication to stop the decline in the exploratory secondary endpoints cognition (MMSE) and function (ADCS-ADL). At 57 weeks, this cohort had demonstrated improvement of the measures MMSE and ADCS-ADL compared to baseline. For the primary endpoint, ANAVEX2-73 demonstrated continued favorable safety and tolerability through 109 weeks.

"We are cautiously optimistic about the promising results of ANAVEX2-73 observed in patients who have received the drug for over two years," said Christopher U Missling, PhD, President and Chief Executive Officer of Anavex. "We are committed to advancing ANAVEX2-73, utilizing all relevant scientific knowledge we can learn, in hopes of helping those affected by the disease."

Additionally, clinical data from 54 subjects from the Phase 1 (ANAVEX<sup>®</sup>2-73-001) and the Phase 2a (ANAVEX<sup>®</sup>2-73-002) trials were analyzed including using formal concept analysis (FCA), non-linear mixed effect (NLME) modeling and non-compartmental analysis methods.

Data analysis demonstrates:

- Strong drug concentration / response relationship for exploratory secondary endpoints cognition (MMSE) and function (ADCS-ADL). Drug concentration in the upper tertile increased the probability of improved MMSE score 2.1-fold (110%) during 57 weeks. Also, higher drug concentration increased the probability of improved ADCS-ADL score 1.6-fold (67%) during the same period.

- Alzheimer's patients with milder disease stage (baseline MMSE >20) tended to respond better to ANAVEX2-73 than patients with more advanced disease stage (baseline MMSE <20).
- No difference in the pharmacokinetics of ANAVEX2-73 was observed between women and men.
- ANAVEX2-73 administration does not prolong QTc interval.

This data provide support to proceed with the clinical development of ANAVEX2-73 for Alzheimer's disease in a focused Phase 2/3 study using the precision medicine paradigm, including DNA whole exome, RNA expression and gut microbiome characterization. Further clinical studies in other indications, such as Rett syndrome and Parkinson's disease are under development utilizing the translational potential of precision medicine approach of ANAVEX2-73.

ANAVEX2-73 is a novel, orally available sigma-1 receptor agonist. Sigma-1 receptor, an emerging therapeutic target in Alzheimer's disease and other central nervous system disorders, has been shown to reduce cellular stress and regulate neuroplasticity and cellular homeostasis. The Company previously reported that the Phase 2a (ANAVEX<sup>®</sup>2-73-002) trial successfully achieved both primary and secondary endpoints.

#### Presentation Details:

Title: Clinical Pharmacokinetics and Pharmacodynamics Characterization of ANAVEX2-73 for Designing a Phase 2/3 Study in Mild-to-Moderate Alzheimer's Disease

Date and Time: Saturday November 4th, 2017 at 3:30 pm ET

The slides are accessible through the investor relations section of the Company's website at [www.anavex.com](http://www.anavex.com).

#### **About ANAVEX<sup>®</sup>2-73-002 Phase 2a Clinical Study (ClinicalTrials.gov NCT02244541)**

The multicenter Phase 2a clinical trial of ANAVEX 2-73 consisted of two parts and a total of 32 mild-to-moderate Alzheimer's patients. PART A was a randomized, open-label, two-period, cross-over between oral (30mg/50mg) and IV (3mg/5mg) administration, adaptive trial lasting up to 5 weeks for each patient. PART B was an open-label extension for an additional 52 weeks. Initially planned for 26 weeks, PART B was extended to 52 weeks as a result of requests from patients and caregivers.

The primary endpoint of the Phase 2a trial was safety, tolerability and maximum tolerated dose (MTD) of ANAVEX2-73, which had shown potential in preclinical studies to prevent, halt and/or reverse the course of the disease. Secondary endpoints included dose response, bioavailability, and exploratory cognitive as well as functional measures using the Mini Mental State Examination (MMSE) and evaluation of Alzheimer's Disease Co-operative Study – Activities of Daily Living Inventory (ADCS-ADL), as well as Cogstate test battery and biomarker EEG/ERP.

### **About ANAVEX®2-73-003 Phase 2a Clinical Study (ClinicalTrials.gov NCT02756858)**

The multi-center Phase 2a clinical trial of ANAVEX 2-73 consists of an open-label extension for an additional 104 weeks, allowing for the collection of potential safety data for ANAVEX 2-73 cumulatively over three years.

The new 104-week (two-year) extension of the multi-center Phase 2a clinical trial of ANAVEX 2-73 will follow mild-to-moderate Alzheimer's patients who have already completed 52 weeks in PART B of the study. Every three months, patients will be scheduled for physician visits to assess primary and secondary endpoints.

The primary endpoint of the new Phase 2a trial is to establish continued safety and tolerability of ANAVEX 2-73. Secondary endpoints are exploratory cognitive as well as functional measures using the Mini Mental State Examination (MMSE) and evaluation of Alzheimer's Disease Co-operative Study – Activities of Daily Living Inventory (ADCS-ADL), respectively.

### **About Anavex Life Sciences Corp.**

Anavex Life Sciences Corp. (Nasdaq: AVXL) is a publicly traded biopharmaceutical company dedicated to the development of differentiated therapeutics for the treatment of neurodegenerative and neurodevelopmental diseases including Alzheimer's disease, other central nervous system (CNS) diseases, pain and various types of cancer. Anavex's lead drug candidate, ANAVEX®2-73, recently completed a successful Phase 2a clinical trial for Alzheimer's disease. ANAVEX®2-73 is an orally available drug candidate that restores cellular homeostasis by targeting sigma-1 and muscarinic receptors. Preclinical studies demonstrated its potential to halt and/or reverse the course of Alzheimer's disease. It has also exhibited anticonvulsant, anti-amnesic, neuroprotective and anti-depressant properties in animal models, indicating its potential to treat additional CNS disorders, including epilepsy. The Michael J. Fox Foundation for Parkinson's Research has awarded Anavex a research grant to develop ANAVEX®2-73 for the treatment of Parkinson's disease. The grant fully funds a preclinical study, which could justify moving ANAVEX®2-73 into a Parkinson's disease clinical trial. ANAVEX®3-71, also targeting sigma-1 and M1 muscarinic receptors, is a promising preclinical drug candidate demonstrating disease modifications against the major Alzheimer's hallmarks in transgenic (3xTg-AD) mice, including cognitive deficits, amyloid and tau pathologies, and also with beneficial effects on neuroinflammation and mitochondrial dysfunctions. Further information is available at [www.anavex.com](http://www.anavex.com). You can also connect with the company on [Twitter](#), [Facebook](#) and [LinkedIn](#).

### **Forward Looking Statements**

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks set forth in the Company's most recent Annual Report on Form 10-K filed with the SEC. Readers are cautioned not to place undue reliance on these forward-looking

statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and Anavex Life Sciences Corp. undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof.

**For Further Information:**

Anavex Life Sciences Corp.

Research & Business Development

Toll-free: 1-844-689-3939

Email: [info@anavex.com](mailto:info@anavex.com)

Investors & Media:

Clayton Robertson

The Trout Group

(646) 378-2900

[crobertson@troutgroup.com](mailto:crobertson@troutgroup.com)

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