Anavex Life Sciences Corp.

Fact Sheet

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QUICK REFERENCE

Anavex Life Sciences Corp.

NASDAQ: AVXL

Website: **www.ANAVEX.com**

ANAVEX

BUSINESS SUMMARY

Anavex Life Sciences Corp. is a biopharmaceutical company dedicated to the development of differentiated therapeutics for the treatment of neurodegenerative and neurodevelopmental disorders including Alzheimer's disease, Parkinson's disease, Rett syndrome and other central nervous system (CNS) diseases, pain and various types of cancer. Anavex's lead drug candidate, ANAVEX®2-73 (*blarcamesine*), completed successfully a Phase 2a clinical trial for Alzheimer's disease and recently a Phase 2 proof-of-concept study in Parkinson's disease dementia and a Phase 2 study in adult patients with Rett syndrome. 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. ANAVEX®2-73 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 previously awarded Anavex a research grant, which fully funded a preclinical study to develop ANAVEX®2-73 for the treatment of Parkinson's disease. ANAVEX®3-71, which targets sigma-1 and muscarinic receptors, is a promising clinical stage drug candidate demonstrating disease-modifying activity against the major hallmarks of Alzheimer's disease in transgenic (3xTg-AD) mice, including cognitive deficits, amyloid and tau pathologies. In preclinical trials, ANAVEX®3-71 has shown beneficial effects on mitochondrial dysfunction and neuroinflammation.

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 AD1
- 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; $r = 0.7$)2 • 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 syndrome3 and Alzheimer's disease4
- Data will be submitted to the U.S. Food and Drug Administration to seek regulatory guidance

1. Mahurin, R. K., & Pirozzolo, F. J. (1993). Application of Hick's law of response speed in Alzheimer and Parkinson diseases. Perceptual and Motor Skills, 77(1), 107–113
2. Wesnes K, Edgar C, Andreasen N, Annas P, Basun H, Lannfelt L, et al. Computerized cognition assessment during acetylcholinesterase inhibitor treatment in Alzheimer's disease. Acta Neurol Scand 2010; 122:270–7
3. ClinicalTrials.gov Identifiers: NCT03758924, NCT03941444, NCT04304482
4. ClinicalTrials.gov Identifiers: NCT03790709, NCT02756858

CONTACT INFORMATION

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Recent Press Releases *(Headline and Excerpts)*

Anavex Life Sciences Announces Participation at Precision in Clinical Trials Virtual Summit

May 7, 2021 – Anavex Life Sciences Corp. announced that its President and Chief Executive Officer, Christopher U. Missling, PhD, will give a presentation titled, "Clinical Trials for Rare Diseases: Challenges and Opportunities", at the Precision in Clinical Trials Virtual Summit (East Coast) on Monday, May 10th at 9:35 a.m. EDT. The Precision in Clinical Trials Virtual Summit (East Coast) takes place May 10th – 11th 2021.

Anavex Life Sciences to Announce Fiscal 2021 Second Quarter Financial Results and Business Outlook on Thursday, May 13, 2021

Conference Call and Webcast To be Held Thursday, May 13, 2021 4:30 pm Eastern Time

May 6, 2021 – Anavex Life Sciences Corp. announced that it will issue financial results for its fiscal quarter ended March 31, 2021 on Thursday, May 13, 2021.

Management will host a conference call on Thursday, May 13, 2021 at 4:30 pm Eastern Time to review financial results and provide an update on its clinical programs and corporate highlights. Following management's formal remarks, there will be a question-and-answer session with equity analysts.

Conference Call / Webcast Information:
The live webcast of the conference call can be accessed online at https://wsw.com/webcast/cc/avxl18/1499544.
To join the conference call, live via telephone, interested parties within the U.S. should dial, toll-free, 1 (866) 866-1333 and international callers should dial 1 (404) 260-1421. Please use confirmation number 50162864, followed by the pound sign (#). A replay of the conference call will also be available on **www.anavex.com**.

Anavex Life Sciences Appoints Former FDA Officer as Senior Vice President for Nonclinical Development

May 05, 2021 – Anavex Life Sciences Corp. announced the appointment of Dr. Adebayo (Bayo) Laniyonu, as Senior Vice President for Nonclinical Development. Dr. Laniyonu has over 24 years' experience with the US Food and Drug Administration (FDA).

Prior to joining Anavex, Dr. Laniyonu served as Supervisory Pharmacologist/Toxicologist at the FDA Center for Drug Evaluation and Research (CDER). He has reviewed hundreds of NDAs, BLAs (including first in class), sNDAs, ANDAs and INDs and provided high impact regulatory and strategic recommendations to the Sponsors of these products. He organized, chaired and presented at FDA workshops and at scientific sessions of professional societies where he presented on FDA current thinking on regulatory issues, he has also presented at FDA Advisory Committee meetings. His review and Supervisory experience span several therapeutics areas including Rare Diseases and Medical Genetics, hematology, Medical Imaging, Radiation Medicine and Medical Counter Measures products. Dr. Laniyonu played pivotal roles in the development of several FDA regulatory guidance documents.

Anavex Life Sciences Reports the Results of Review by the Independent Data Safety Monitoring Board for its Phase 2/3 Trials of ANAVEX®2-73 in Patients with Rett Syndrome

April 12, 2021 – Anavex Life Sciences Corp. announced that the Independent Data Safety Monitoring Board (DSMB) for the Company's ongoing clinical trial program, including the late stage AVATAR (ANAVEX®2-73-RS-002)[1], EXCELLENCE (ANAVEX®2-73-RS-003)[2] and the U.S. Rett syndrome extension study (ANAVEX®2-73-RS-EP-001) of its investigational compound ANAVEX®2-73 (blarcamesine) has completed its recent pre-planned review of the respective interim safety data for these three separate clinical studies.
Upon review of the interim safety data, the DSMB made the following recommendation for the randomized, double-blind, placebo-controlled AVATAR (ANAVEX®2-73-RS-002) study in adult patients with Rett syndrome:

- The DSMB recommendation is to continue the studies without modification.

Upon review of the interim safety data, the DSMB made the following recommendation for the randomized, double-blind, placebo-controlled EXCELLENCE (ANAVEX®2-73-RS-003) study in pediatric patients with Rett syndrome:

- The DSMB recommendation is to continue the studies without modification.

Upon review of the interim safety data, the DSMB made the following recommendation for the open-label extension U.S. Rett syndrome (ANAVEX®2-73-RS-EP-001) study in adult patients with Rett syndrome:

- The DSMB recommendation is to continue the studies without modification.

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