Anavex Life Sciences Corp.

Fact Sheet

AVXL

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NASDAQ

ANAVEX

QUICK REFERENCE

Anavex Life Sciences Corp.

NASDAQ: AVXL

Outstanding Shares: **62,045,198**

Website: **www.ANAVEX.com**

BUSINESS SUMMARY

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 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*), recently completed successfully a Phase 2a clinical trials for Alzheimer's disease and 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.

TRANSFORMATIVE EVENTS

- Rett Syndrome Program Received Fast Track Designation and is 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 Parkinson's Disease Dementia, 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

Continued Significant Value-creating Events with Several Clinical Readouts in 2020/2021:

- Two Phase 2 Adult Rett Syndrome Trials (ClinicalTrials.govIdentifier: NCT03758924, NCT03941444)
- Phase 2/3 Pediatric Rett Syndrome Trial (ClinicalTrials.govIdentifier: NCT04304482)
- Phase 2b/3 Alzheimer's Disease Trial (ClinicalTrials.govIdentifier: NCT03790709)
- Phase 1 of ANAVEX®3-71 with focus on Frontotemporal Dementia (ClinicalTrials.govIdentifier: NCT04442945)

CONTACT INFORMATION

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Recent Press Releases *(Headline and Excerpts)*

Anavex Life Sciences Receives Michael J. Fox Foundation Grant for Clinical Study of ANAVEX®2-73 (blarcamesine) in People with Parkinson's Disease

January 11, 2021 – Anavex Life Sciences Corp. announced that it has been awarded a research grant of $995,862.51 from The Michael J. Fox Foundation for Parkinson's Research (MJFF) to develop ANAVEX®2-73 (blarcamesine) for the treatment of Parkinson's disease. The award will explore utilization of PET imaging biomarkers to enable measurement of target engagement and pathway activation of the sigma-1 receptor (SIGMAR1) with clinically relevant doses in people with Parkinson's disease.

MJFF previously awarded Anavex a research grant, which fully funded a preclinical study that established ANAVEX®2-73 as a potentially disease-modifying treatment for Parkinson's disease. Anavex is working toward the goal of confirming ANAVEX®2-73 as a disease-modifying intervention for Parkinson's disease in clinical trials.

Anavex Life Sciences Reports Fiscal 2020 Year End Financial Results And Clinical Program Updates

December 28, 2020 – Anavex Life Sciences Corp. reported financial results for its fiscal year ended September 30, 2020.

Key Clinical Updates:

- Plan to advance the AVATAR adult Rett syndrome study into a pivotal Phase 2/3 clinical trial.
- Pipeline expansion for ANAVEX®2-73 using gene biomarkers of response, applying precision medicine for neurological disorders with unmet medical need:
  -Planned initiation of a pivotal Phase 2/3 study in Fragile X Syndrome, the most frequent genetic cause of autism spectrum disorder.
  -Planned initiation of a Phase 2/3 clinical trial for the treatment of a new, rare-disease indication.
- Phase 2b/3 ANAVEX®2-73 Alzheimer's disease (AD) study currently over 80% enrolled with complete enrollment expected in early 2021.
- Planned initiation of ANAVEX®2-73 imaging-focused Parkinson's disease clinical study.

Recent Business Highlights:

- In December 2020, Anavex announced top-line results from a U.S. Phase 2 controlled trial of ANAVEX®2-73 in adult female patients with Rett syndrome. Primary safety, pharmacokinetics and secondary efficacy endpoints were met, with statistically significant and clinically meaningful consistent improvements in Rett Syndrome Behaviour Questionnaire (RSBQ) and Clinical Global Impression Improvement (CGI-I) scores. Improvements in RSBQ Total scores were correlated with decreases (improvements) in plasma glutamate. Based on the results, Anavex is planning to meet with the FDA to discuss an accelerated approval pathway.
- In November 2020, Anavex presented data at the 13th Clinical Trials on Alzheimer's Disease (CTAD) 2020 Conference, reporting top-line results from the proof-of-concept Phase 2 placebo-controlled trial with primary objectives of safety, tolerability, and efficacy in cognition of ANAVEX®2-73 in patients in Parkinson's disease dementia (PDD) compared to placebo. Both primary objectives of the study were met. The results show clinically meaningful, dose-dependent, and statistically significant improvements in the Cognitive Drug Research (CDR) computerized assessment system analysis. The study confirmed the precision medicine approach of targeting SIGMAR1 as a genetic biomarker in response to ANAVEX®2-73 supporting progression to further development in upcoming Phase 2/3 studies.
- In November 2020, Anavex received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for its patent application number 16/717,921 expected to remain in force at least until 2037, expanding coverage of treatment methods using its lead drug candidate, ANAVEX®2-73, as well as drug candidate ANAVEX®1-41 for treating a range neurodevelopmental disorders including Rett syndrome, autism spectrum disorder, Angelman syndrome, cerebral palsy and multiple sclerosis, among other indications.

Anavex Life Sciences Announces ANAVEX®2-73 (Blarcamesine) Meets Primary and Secondary Endpoints in Placebo-Controlled U.S. Phase 2 Clinical Trial for the Treatment of Adult Patients with Rett Syndrome

Primary safety, pharmacokinetics and secondary efficacy endpoints met, with consistent improvements in RSBQ Total scores and CGI-I

Efficacy endpoints demonstrated statistically significant and clinically meaningful reductions in Rett syndrome symptoms and correlated with changes in biomarker (glutamate) of disease pathology

Key milestone met to advance regulatory approval pathway for adult patients with Rett syndrome

December 15, 2020 – Anavex Life Sciences Corp. reported top-line results from a U.S. Phase 2 randomized, double-blind, placebo-controlled trial of ANAVEX®2-73 (blarcamesine) in adult female patients with Rett syndrome.

The primary endpoint of the trial was safety. The convenient oral liquid once-daily dosing of 5 mg ANAVEX®2-73 was well-tolerated and demonstrated dose-proportional PK (pharmacokinetics). Adverse events related to study drug were similar between ANAVEX®2-73 (13.3%) and placebo (10%), with no reported serious adverse events (SAEs). The safety profile of ANAVEX®2-73 in this trial is consistent with prior clinical trial data.

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