Uploaded to the VFC Website

2016

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

If Veterans don't help Veterans, who will?

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members & subscribers.

Anavex reports safety and efficacy data of ANAVEX 2-73 Phase 2a trial in Alzheimer's patients

Published on November 11, 2015 at 1:34 AM

Positive Safety Data, Statistically Significant Improvements on Exploratory Clinical Endpoints

Anavex Life Sciences Corp. ("Anavex" or the "Company") (Nasdaq: AVXL). On Saturday, investigators presented positive safety and cognitive efficacy data for ANAVEX 2-73, the Company's lead investigational oral treatment for Alzheimer's disease targeting sigma-1 and muscarinic receptors, which are believed to reduce protein misfolding including reduction of beta amyloid, tau protein and inflammation at the international CTAD 2015 conference in Barcelona, Spain.

Initial analysis of Phase 2a data demonstrated that the study met the primary objective of safety as ANAVEX 2-73 was well tolerated and results were consistent with prior Phase 1 clinical trial data. The secondary objectives were also met, with ANAVEX 2-73 showing cognitive improvement across all doses in all exploratory cognitive measurements, including the Cogstate battery, Mini Mental State Examination (MMSE), event-related potentials (ERP) and P300 tests, which consistently demonstrated improvements from baseline in the completed PART A portion of the study in 32 mild-to-moderate Alzheimer's patients. Even though PART A was designed as a 5 week bioavailability trial that included a built-in wash-out period of 12 days and without an optimized dosing regimen, several Cogstate tests demonstrated highly statistically significant improvements. This finding was supported by a trend towards improvement in median MMSE score, which increased by +1.5 over baseline at week 5.

Positive effects on cognition were further supported by highly statistically significant biomarker effects of treatment at week 5 on one event-related potential (ERP) measure with a p-value of $p<0.0007$ and improvement in the P300 signal. The ERP biomarker scores improved compared to the initial data presented at AAIC in Washington, DC in July 2015, by which time not all patients had yet completed PART A.

All patients who completed PART A volunteered to continue in the longitudinal PART B extension study.

In the interim analysis of the first 14 patients at week 12, the PART B portion of the study demonstrated a positive trend towards improvement over 12 weeks of ANAVEX 2-73 treatment on the secondary functional outcome measure, the Alzheimer's Disease Co-operative Study - Activities of Daily Living Inventory (ADCS-ADL) by +3.21 points.

"While it is of prime importance to have confirmed that both the primary and secondary endpoints of the trial have been met, it is extremely encouraging to see the emergence of such strong cognitive signals after only 5 weeks of treatment. Such an outcome in a trial such as this is unprecedented in my experience, and the current results suggest that ANAVEX 2-73 could potentially make a significant difference in patients' lives," said Associate Professor Stephen Macfarlane, FRANZCP, Director of Aged Psychiatry at Alfred Health, who conducted the study. "We continue to receive extremely positive feedback about the effects of the drug from our study participants and their caregivers. The results justify a prospective comparison with current standard of care in a larger clinical trial."

Professor Paul Maruff, Chief Scientific Officer of Cogstate commented:

> The Cogstate tests measure people's ability to store and use information. The results of the Phase 2a study demonstrate that ANAVEX 2-73 improves psychomotor function, attention and working memory. For attention and working memory these improvements were statistically significant with a p-value of $p<0.05$ and $p<0.001$, respectively and their magnitude clinically important. To my knowledge, we have not yet seen a drug that has improved quantitatively working memory to such an extent as seen with ANAVEX 2-73.

Professor Harald Hampel, member of Anavex's Scientific Advisory Board, and AXA Research Fund Chair at Sorbonne Universities' Pierre and Marie Curie University (UPMC) in Paris, France, commented:

> The collective data from this Phase 2a trial supports the concept of targeting the sigma-1 receptor with ANAVEX 2-73 with a degree of confidence that we did not foresee. Sigma-1 receptor presents an innovative interventional upstream approach to impact key cellular events believed to contribute to

Alzheimer's disease pathophysiology. The presented Phase 2a data underlines the importance of rigorously investigating a potential efficacy signal on co-primary outcomes such as cognition and function in larger and well-powered trials.

"We are encouraged by the preliminary safety and efficacy data. We look forward to continuing with PART B of the Phase 2a trial and expect to provide data updates at 12 week, 26 week, 38 week and 52 week time points," said Christopher U. Missling, PhD, President and Chief Executive Officer of Anavex. "While we remain focused on Alzheimer's, the remarkably fast onset of clinical effect of ANAVEX 2-73 increases our options to potentially pursue additional indications for diseases characterized by working memory impairment and may enable clinical trials to be completed within shorter time frames."

The presentation entitled "New Exploratory Alzheimer's Drug ANAVEX 2-73: Assessment of Safety and Cognitive Performance in a Phase 2a Study in mild-to-moderate Alzheimer's Patients" was presented by Professor Steve Macfarlane at CTAD in a late-breaking oral session and is available on the publications page of the Anavex website.

Source:
http://www.anavex.com/