



Anavex Life Sciences Presents New Clinical Data Identifying Gut Microbiota Biomarkers Associated with Improved Clinical Response in Patients Treated with ANAVEX@2-73 at 2019 Alzheimer's Association International Conference (AAIC)

- *High-Levels of Two Gut Microbiota Families Linked to Improved Responses with ANAVEX@2-73*
- *ANAVEX@2-73 May Have Beneficial Homeostatic Effect on Brain-Gut Microbiota Axis*

NEW YORK – July 17, 2019 – 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, Parkinson’s disease, Rett syndrome and other central nervous system (CNS) diseases, today reported results from a study evaluating the gut microbiota of patients in the ongoing ANAVEX@2-73 Phase 2a extension study of ANAVEX@2-73, a selective sigma-1 receptor agonist.

“This is the first gut microbiota DNA sequencing analysis of Alzheimer’s disease patients treated with ANAVEX@2-73, which might help to identify potential biomarkers of response for ANAVEX@2-73,” said Christopher U. Missling, PhD, President and Chief Executive Officer of Anavex. “We continue to advance the ANAVEX@2-73 Alzheimer’s disease program through the ongoing Phase 2b/3 Alzheimer’s disease clinical study^[1] and in other ongoing ANAVEX@2-73 clinical trials focused on serious neurology diseases with high unmet needs, including Rett syndrome^[2] and Parkinson’s disease dementia^[3].”

The analysis was conducted using Ariana Pharma’s KEM® Artificial Intelligence, an FDA-tested technology to systematically explore combinations of biomarkers. Results revealed that patients treated with ANAVEX@2-73 had high levels of two gut microbiota families, *Ruminococcaceae* and *Porphyromonadaceae*, which were associated with improved activities of daily living (ADCS-ADL) at week 148 ($p < 0.01$ and $p < 0.04$, respectively).

Communication between gut microbiota and the brain has been shown to be a critical requirement of a healthy brain function. The reduction in gut microbiota diversity has become one of the hallmarks of aging, and disturbances in its composition are associated with several age-related neurological conditions, including Alzheimer’s disease. These changes in the gut microbiota composition induce increased permeability of the gut barrier and immune activation leading to systemic inflammation, which in turn may impair the blood-brain barrier and promote neuroinflammation, neuronal injury, and ultimately neurodegeneration.^[4]



Numerous pre-clinical studies demonstrate beneficial effects of SIGMAR1 (S1R) agonists on neuroinflammation, including with ANAVEX@2-73[5]. The effect might potentially be reversal of the microbiota imbalances and might have a homeostatic effect on the brain-gut-microbiota axis.

The oral presentation at AAIC 2019, titled, *Exploring gut microbiota as a source of potential biomarkers: Initial results from the ANAVEX@2-73 Alzheimer's disease clinical study*[O4-02-04][6] will be presented by the lead author of the study, Mohammad Afshar, MD, PhD, CEO of Ariana Pharma, and will be available at www.anavex.com.

About ANAVEX@2-73-003 Phase 2a Clinical Study Gut Microbiota Protocol

The multicenter Phase 2a clinical trial of ANAVEX@2-73 open-label 208-week study (ClinicalTrials.gov NCT02756858) was extended after the previous 57-week 32 mild-to-moderate Alzheimer's disease patients' study (ClinicalTrials.gov NCT02244541) was completed. A total of 16 patients consented to the stool sampling, which took place between week 77 and 109. Abundance of each gut microbiota genus/family/phylum was assessed using 16S meta-sequencing, resulting in the analysis of 32,875 operational taxonomic units (OTU) i.e. microbial species in the human's gut. A dedicated bioinformatics pipeline was used for taxonomic classification of sequences; relative abundances measurement of operational taxonomic units (OTU) were mapped to phyla, families and genera of gut microbiota. The full integrated knowledge base, including omic and clinical parameters, was analyzed using Ariana Pharma's Artificial Intelligence platform KEM@. KEM@ enables identification and ranking of biomarkers relating to outcome derived from a small number of samples, while avoiding overfitting and bias.

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, 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, recently completed a successful Phase 2a clinical trial for Alzheimer's disease and is currently in clinical studies in Phase 2b/3 Alzheimer's disease, Phase 2 Parkinson's disease dementia and two Phase 2 studies in 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 M1 muscarinic receptors, is a promising preclinical 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 neuroinflammation and mitochondrial dysfunction. Further information is available at 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.

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[1] ClinicalTrials.gov Identifier: NCT03790709

[2] ClinicalTrials.gov Identifier: NCT03758924; ClinicalTrials.gov Identifier: NCT03941444

[3] ClinicalTrials.gov Identifier: NCT03774459

[4] Giau, V.V.; Wu, S.Y.; Jamerlan, A.; An, S.S.A.; Kim, S.; Hulme, J. Gut Microbiota and Their Neuroinflammatory Implications in Alzheimer's Disease. *Nutrients* 2018, 10, 1765

[5] 1) Jia J et al 2018. *Front Cell Neurosci.* 2018 Sep 20;12:314; 2) Zhao J et al 2014. *Invest. Ophthalmol. Vis. Sci.* 55, 3375–3384; 3) Behensky AA et al 2013. *J. Pharmacol. Exp. Ther.* 347, 458–467; 4) Cenci A et al 2016. Presented at World Parkinson Congress; 5) Hall H et al 2018. *Alzheimers Dement.* Jun;14(6):811-823; 6) Allahtavakoli M et al 2011. *Brain Res Bull.* May 30;85(3-4):219-24; 7) Cogram P et al 2016. Presented at Gordon Research Conference; 8) Lisak RP et al 2016. Poster presentation at ACTRIMS; 9) Lisak RP et al 2017. Oral presentation at ECTRIMS

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