Anavex Life Sciences Announces FDA Approval of IND for Phase 2 Trial of ANAVEX®2-73 in Patients with Rett Syndrome

Study will incorporate genomic precision medicine ANAVEX®2-73-specific biomarkers

NEW YORK – October 19, 2018 – 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, Rett syndrome and other central nervous system (CNS) diseases, today announced that the Company has received confirmation from the U.S. Food and Drug Administration (FDA) that its Investigational New Drug application (IND) is now open for ANAVEX®2-73 for the treatment of Rett syndrome, a rare and catastrophic neurodevelopmental disease.

ANAVEX®2-73 has already received orphan drug designation from the FDA for the treatment of Rett syndrome.

"The acceptance of this IND by the FDA is a significant milestone for ANAVEX®2-73," stated Christopher U Missling, PhD, President and Chief Executive Officer of Anavex. "This is an important step toward achieving clinical data for the third indication for ANAVEX®2-73 also incorporating genomic precision medicine biomarkers."

FDA has allowed Anavex to proceed with the Phase 2 study protocol, *ANAVEX2-73-RS-001, A Double-Blind, Randomized, Placebo-Controlled, Dose Titration Study of ANAVEX2-73 in Patients with Rett Syndrome* using experimental drug ANAVEX®2-73 for the treatment of patients with Rett syndrome. The Phase 2 study is a randomized double-blind, placebo-controlled safety, tolerability, pharmacokinetic and efficacy study of oral liquid ANAVEX®2-73 formulation to treat Rett syndrome. Pharmacokinetic and dose finding will be investigated in a total of 15 patients over a 7-week treatment period including ANAVEX®2-73-specific genomic precision medicine biomarkers. All patients who participate in the study will be eligible to receive ANAVEX®2-73 under a voluntary open label extension protocol. This study will be followed by a planned placebo-controlled safety and efficacy evaluation of ANAVEX®2-73 over a 3 month treatment period.
In addition to Rett syndrome, Anavex has clinical development programs for ANAVEX®2-73 for the treatment of Alzheimer's disease and Parkinson's disease dementia.

About Rett Syndrome

Rett syndrome is a rare, non-inherited genetic postnatal progressive neurodevelopmental disorder that occurs almost exclusively in girls and leads to severe impairments, affecting nearly every aspect of the child's life: their ability to speak, walk, eat and even breathe easily. The hallmark of Rett syndrome is near constant repetitive hand movements while awake. It is characterized by normal early growth and development (6 to 18 months) followed by a slowing of development, loss of purposeful use of the hands, distinctive hand movements, slowed brain and head growth, problems with walking, seizures and intellectual disability. There is currently no cure for Rett syndrome and treatment of the disorder is symptomatic. Management of symptoms is done through a multidisciplinary approach utilizing medication for motor difficulties, breathing irregularities and control of seizures through anticonvulsant

drugs. Rett syndrome is caused by mutations in the MECP2 gene and strikes all racial and ethnic groups and occurs worldwide in approximately one in every 10,000 to 15,000 live female births.

About ANAVEX®2-73

ANAVEX®2-73 activates the Sigma-1 receptor (S1R) protein, which serves as a molecular chaperone and functional modulator involved in restoring homeostasis. In a Phase 2a Alzheimer's disease (AD) study, ANAVEX®2-73 has shown dose dependent improvement in exploratory endpoints of cognition (MMSE) and activities of daily living (ADCS-ADL). Full genomic analysis of ANAVEX®2-73 Phase 2a AD patients was performed. The ANAVEX®2-73 Phase 2 Rett syndrome study design includes genomic biomarkers identified in the ANAVEX®2-73 Phase 2a AD study. Studies of ANAVEX®2-73 in a mouse model with a MECP2-null mutation that causes neurological symptoms that mimic Rett syndrome, ANAXEX®2-73 was evaluated in automatic visual response and respiration tests in 7-month old mice, an age at which advanced pathology is evident. Vehicle-treated methyl-CpG binding protein 2 (MECP2) mice demonstrated fewer automatic visual responses than wild-type mice. Treatment with ANAVEX®2-73 for four weeks significantly increased the automatic visual response in the MECP2 Rett syndrome disease mouse ($p<0.05$). Additionally, chronic oral dosing daily for 6.5 weeks of ANAVEX®2-73 starting at ~5.5 weeks of age was conducted in the MECP2 HET Rett syndrome disease mouse model assessed the different aspects of muscular coordination, balance, motor learning and muscular strengths, some of the core deficits observed in Rett syndrome. Administration of ANAVEX®2-73 resulted in both significant and dose related improvements in an array of these behavioral paradigms in the MECP2 HET Rett syndrome disease model. These experiments were sponsored by Rettsyndrome.org.

About Rettsyndrome.org

Rettsyndrome.org is the most comprehensive nonprofit organization dedicated to accelerating research of treatments and a cure for Rett syndrome and related disorders while providing information and family empowerment. As the world's leading private funder of Rett syndrome research, Rettsyndrome.org has funded over $44M in high-quality, peer-reviewed research grants and programs to date. The organization hosts the largest global gathering of Rett researchers and clinicians to establish research direction for the future. Rettsyndrome.org, a 501(c)(3) organization, has earned Charity Navigator's most prestigious 3 star rating year after year. To learn more about our work and Rett syndrome, visit www.rettsyndrome.org or call (800) 818-7388 (RETT).

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, 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. 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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