Axcella Announces Two Oral Presentations on AXA1125 for Long COVID Fatigue at ECCMID 2023

April 17, 2023

Dr. Lucy E.M. Finnigan will present on the Phase 2a clinical trial of AXA1125 in Long COVID Fatigue on April 18

Dr. Finnigan will also report on AXA1125 treatment effects on biomarkers of mitochondrial energetics and vascular endothelial function on April 17

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 17, 2023-- Axcella Therapeutics (Nasdaq: AXLA), a clinical-stage biotechnology company pioneering novel approaches to treating complex diseases using multi-targeted endogenous metabolic modulator (EMM) compositions, today announced two oral presentations of results from the Phase 2a clinical trial of AXA1125 in the treatment of Long COVID Fatigue at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID), as a hybrid event both online and in Copenhagen, Denmark on April 15-18, 2023.

Lucy E.M. Finnigan, Ph.D., M.Res., B.Sc. (Hons.), AFHEA, Oxford Centre for Clinical Magnetic Resonance Research (OCMR), Division of Cardiovascular Medicine, Radcliffe Department of Medicine, University of Oxford, will present efficacy results from the Axcella-sponsored Phase 2a clinical trial. This was a randomized, double-blind, placebo-controlled investigation to evaluate the efficacy and safety of AXA1125 in patients with fatigue related to Long COVID. The study found that subjects who received AXA1125 (n=21) experienced clinically and statistically significant improvement in mental (p=0.0097) and physical (p=0.0097) fatigue scores compared to placebo subjects (n=20). Lancet eClinical Medicine published the trial results on April 14, 2023 (eClinicalMedicine 2023; April 14: 101946, Published Online).

Dr. Finnigan will also present biomarker findings from the Phase 2a trial as part of a session entitled “Novel strategies for anti-COVID treatment: still a challenge.” In conjunction with the reduction in fatigue in patients who received AXA1125, fatigue responders showed significantly greater (p=0.0024) improvement in phosphocreatine recovery time, a marker of mitochondrial function, and a trend towards reductions in plasma FGF-21 (p=0.083) and serum lactate (p=0.073) at day 28 compared with placebo-treated patients.

Axcella’s Phase 2b/3 study design for possible registration of AXA1125 in the treatment of Long COVID Fatigue now has acceptance from the U.S. Food and Drug Administration (FDA) and The Medicines and Healthcare products Regulatory Agency (MHRA), the U.K.’s regulatory agency. The MHRA provided regulatory guidance supporting a single trial that could serve as the registration trial for patients with Long COVID Fatigue. Consistent with the Ph2a trial, the Ph2b/3 trial will enroll participants who have had fatigue for at least 12 weeks after COVID-19 infection. The primary endpoint will utilize the same patient reported outcome tool, the Chalder Fatigue Questionnaire (CFQ-11), to measure improvements in fatigue. Additional endpoints will evaluate improvements in physical function, quality of life, and ability to return to work. Participants will receive either placebo or AXA1125 for three months.

“We are excited to see two oral presentations of abstracts from our Phase 2a clinical study of AXA1125 in Long COVID fatigue at ECCMID, along with publication of the results in the Lancet, one of the premier medical journals,” said Margaret Koziel, M.D., Chief Medical Officer of Axcella. “This scientific recognition reinforces the potential for AXA1125 to provide relief for the millions of people suffering from Long COVID Fatigue, which has a devastating effect on patients and their families, impacting their ability to work and be part of society. Through our work, we are contributing to the scientific understanding of Long COVID, as well as working toward a potential treatment for this condition.”

“There remains an urgent need for treatment developed specifically for the millions of patients suffering from Long COVID Fatigue, a disease that is having a devastating health and economic impact,” said Oved Amitay, Chief Executive Officer of Solve M.E. Amitay, who also is the co-founder of the Long COVID Alliance, a network of patient-advocates, scientists, disease experts, and drug developers focused on educating policy makers and accelerating research into post-viral illnesses. Dr. Amitay added, “We hope this scientific recognition of the study results translates into urgent action by both Axcella and the FDA to progress this promising candidate as quickly as possible. Patients, families, and our entire society are desperate for treatments, and Axcella has a potential therapeutic ready to go into a clinical study. Furthermore, this approach – if successful – may be helpful for people with other similar conditions such as myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS).”

Long COVID is a persistent and growing long-term consequence of the pandemic, affecting an estimated one hundred million patients worldwide, with fatigue as the most commonly reported symptom. Recent estimates indicate that 15-20% of Americans with COVID have persisting health issues,[i] up to four million Americans are out of work due to Long COVID symptoms, and that Long COVID has contributed to approximately $1 trillion in lost earnings and $544 billion in increased medical spending.[ii]

About Axcella Therapeutics (Nasdaq: AXLA)

Axcella is a clinical-stage biotechnology company pioneering a new approach to treat complex diseases using compositions of endogenous metabolic modulators (EMMs). The company’s product candidates are comprised of EMMs and derivatives that are engineered in distinct combinations and ratios to reset multiple biological pathways, improve cellular energetics, and restore homeostasis. Axcella’s pipeline includes lead therapeutic candidates for the treatment of Long COVID, NASH, and the reduction in risk of OHE recurrence. The company’s unique model allows for the evaluation of its EMM compositions through non-IND clinical studies or IND clinical trials. For more information, please visit www.axcellatx.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the potential utility of AXA1125 as a treatment of Long COVID and the Company’s anticipated regulatory pathway for AXA1125 and the timing and potential success thereof. The words “may,” “will,” “could,” “would,” “should,” “expect,” “plan,” “anticipate,” “intend,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “target” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release

are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those related to the potential impact of COVID-19 on the company's ability to conduct and complete its ongoing or planned clinical studies and clinical trials in a timely manner or at all due to patient or principal investigator recruitment or availability challenges, clinical trial site shutdowns or other interruptions and potential limitations on the quality, completeness and interpretability of data the company is able to collect in its clinical trials of AXA1125, other potential impacts of COVID-19 on the company's business and financial results, including with respect to its ability to raise additional capital and operational disruptions or delays, changes in law, regulations, or interpretations and enforcement of regulatory guidance, whether data readouts support the company's clinical trial plans and timing, clinical trial design and target indications for AXA1125, the clinical development and safety profile of AXA1125 and its therapeutic potential, whether and when, if at all, the company's product candidates will receive approval from the FDA or other comparable regulatory authorities, potential competition from other biopharma companies in the company's target indications, and other risks identified in the company's SEC filings, including Axcella's Annual Report on Form 10-K, Quarterly Report on Form 10-Q and subsequent filings with the SEC. The company cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Axcella disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent the company's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. The company explicitly disclaims any obligation to update any forward-looking statements.

[i] Bull-Otterson L, Baca S, Saydah S, et al. Post–COVID Conditions Among Adult COVID-19 Survivors Aged 18–64 and ≥65 Years — United States, March 2020–November 2021. MMWR Morb Mortal Wkly Rep 2022;71:713–717. DOI: http://dx.doi.org/10.15585/mmwr.mm7121e1external icon

[ii] Bach K. New data shows long Covid is keeping as many as 4 million people out of work. Brookings Institute. August 24, 2022. https://www.brookings.edu/research/new-data-shows-long-covid-is-keeping-as-many-as-4-million-people-out-of-work/#footnote-3

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