Axcella Granted Patent for Long COVID Fatigue Treatment

August 29, 2023

Claims cover methods of treating a subject presenting with fatigue from post-acute sequelae of COVID-19 (PASC), a/k/a Long COVID, with Candidate AXA1125

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 29, 2023-- Axcella Therapeutics (Nasdaq: AXLA), a clinical-stage biotechnology company focused on pioneering a new approach to address the biology of complex diseases using compositions of endogenous metabolic modulators (EMMs), today announced that the U.S. Patent and Trademark Office (USPTO) has granted U.S. Patent No. 11,737,999 with claims covering methods of use of Candidate AXA1125, for treating a subject having post-acute sequelae of COVID-19 (PASC), a/k/a Long COVID, particularly fatigue. The patent was issued on August 29, 2023, with anticipated expiration in 2042.

"Today's issuance expands our global patent portfolio and Axcella's protection of its lead candidate, AXA1125," said Paul F. Fehlner, J.D., Ph.D., Senior Vice President, Chief Legal Officer of Axcella. "These patents and our entire portfolio are fully owned by Axcella."

AXA1125 is a novel composition of EMMs designed to simultaneously support metabolic, inflammatory and fibrotic pathways associated with fatigue. Axcella was previously granted patents related to AXA1125 with claims covering methods of use and compositions. In particular, Patents Nos. 10,201,513, 10,471,034, 11,129,804, and 11,602,511 cover the AXA1125 compositions, including pharmaceuticals and nutritional supplements. These previously granted patents have an anticipated expiration date in 2037.

"In addition to further strengthening Axcella's global intellectual property position regarding its proprietary composition of amino acids in AXA1125, today's patent issuance further validates AXA1125's formulation and its tie to treating PASC or Long COVID, explicitly symptoms of fatigue," said Bill Hinshaw, President and Chief Executive Officer of Axcella. "We are pleased to have this additional designation as we pursue options to bring our investigational product forward for the benefit of the millions of people who continue to suffer from Long COVID Fatigue. The understanding of the disease continues to advance and show the importance of mitochondrial function and how a mitochondrial activator like AXA1125 has the potential to impact the issues these patients face."

About Endogenous Metabolic Modulators

Endogenous metabolic modulators, or EMMs, are a broad family of molecules, including amino acids, which fundamentally impact and regulate human metabolism. Our AXA candidates are anchored by EMMs that have a history of safe use as food. We believe that, unlike conventional targeted interventions currently used to address dysregulated metabolism, EMM compositions have the potential to directly and simultaneously support and modulate multiple metabolic pathways implicated both in complex diseases and overall health.

Internet Posting of Information

Axcella uses the "Investors and News" section of its website, www.axcellatx.com, as a means of disclosing material nonpublic information, to communicate with investors and the public, and for complying with its disclosure obligations under Regulation FD. Such disclosures include, but may not be limited to, investor presentations and FAQs, Securities and Exchange Commission filings, press releases, and public conference calls and webcasts. The information that we post on our website could be deemed to be material information. As a result, we encourage investors, the media and others interested to review the information that we post there on a regular basis. The contents of our website shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended.

About Axcella Therapeutics (Nasdaq: AXLA)

Axcella is a clinical-stage biotechnology company focused on pioneering a new approach to address the biology of complex diseases using compositions of endogenous metabolic modulators (EMMs). 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.

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