Axcella Announces Program Reprioritization and Corporate Restructuring

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Move Positions Company to Best Focus on Long COVID Program

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 14, 2022-- Axcella Therapeutics (Nasdaq: AXLA), a biotechnology company pioneering a new approach to treat complex diseases using multi-targeted endogenous metabolic modulator (EMM) compositions, today announces a repositioning of its strategy to focus on Long COVID and realize value from its platform and current programs. The company has initiated a process to explore a range of strategic alternatives to maximize shareholder value and is working with an investment bank to act as a strategic advisor for this process. As part of this repositioning, and to align with its current capital constraints, the company is announcing a series of organizational and program updates, including a reprioritization of its programs for Long COVID Fatigue and Nonalcoholic Steatohepatitis (NASH) and a restructuring of operations to support its streamlined set of priorities.

“The strategic process we initiate today prioritizes efforts to support our Long COVID program and will best position us to derive value from our platform technology and its corresponding programs,” said Bill Hinshaw, CEO of Axcella. “We are in active and accelerating business development discussions and are exploring creative collaborations to bring these innovations forward.”

Organizational and Program Updates:

- Axcella will reprioritize its efforts to focus on the significant unmet need and opportunity presented by Long COVID. Axcella’s Phase 2a clinical trial results demonstrate the potential of AXA1125 to play an important role in treating patients suffering from Long COVID. Axcella’s Phase 2a trial has been the only controlled trial to demonstrate statistically and clinically relevant improvement in fatigue in patients with Long COVID. Axcella is engaged in ongoing and productive reviews with regulators in the U.S. and Europe, and the company is aiming to advance its Long COVID Fatigue program into a potential registration trial.
- Axcella will be discontinuing its ongoing Phase 2b clinical trial of AXA1125 in NASH, while keeping the option to revisit this program should resource availability change. In September, Axcella reported positive data from a preplanned interim analysis from their trial of AXA1125 in NASH. At 24 weeks, there were statistically significant and clinically relevant improvements in the liver stiffness measurement (LSM) compared to placebo in the high dose arm for all subjects and statistically significant improvements in other non-invasive tests of liver fat and stiffness. Axcella’s pre-clinical and clinical trial data for NASH demonstrated relevant activity and established a notable safety record for AXA1125, which the company applied to its clinical trial for Long COVID Fatigue.
- Axcella is realigning the organization to correspond to this shift in strategy and reprioritization of its programs, reducing its workforce by 85 percent, retaining certain employees to execute the strategic process. Among the departing employees are Bob Crane, Chief Financial Officer, and Virginia Dean, Chief People Officer.
- Axcella reached an agreement with SLR Investment Corp. (f/k/a Solar Capital Ltd.) (“SLR”) to paydown the debt obligations of the previous agreement.
- With respect to the Company’s plans, no assurances can be made as to whether a strategic transaction will be recommended by the Board of Directors, and the Company does not intend to discuss developments with respect to the evaluation process unless a transaction is approved, or disclosure otherwise becomes appropriate.

“We are incredibly proud of the work of the entire Axcella team and would like to thank our talented employees for their dedication and contributions to bringing these programs for Long COVID and NASH along on their journeys to the clinic, and to achieving recent major milestones including our promising top line trial data,” continued Hinshaw. “Repositioning the company will best enable us to accelerate the development of AXA1125. We are in active conversations with regulators in both the U.S. and Europe and are enthusiastic about the clinical pathway for AXA1125 and Long COVID Fatigue, a disease that currently has no treatment options.”

“We continue to demonstrate the power and scalability of Axcella’s underlying science, and the speed and predictability of the platform our team has built, in a consistent way,” said Margaret Koziel, M.D., Chief Medical Officer of Axcella. “We believe AXA1125 could be an important first line agent for the large and unserved patient populations with Long COVID Fatigue and NASH, and with our current capital constraints, we are realigning our efforts to best preserve the value of our programs and platform.”

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 in Phase 2 development 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.

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.

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 or NASH, the strength of the Company’s platform and comparison to traditional drug discovery methods, and the ability of the Company to realize the benefits from its strategic reprioritization and organizational restructuring. 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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Company
info@axcellatx.com

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