



Axcella Receives Fourth Patent Covering EMM Compositions

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Newly issued U.S. patent covers elements of Axcella's muscle program

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Apr. 7, 2020-- Axcella (Nasdaq: AXLA), a clinical-stage biotechnology company focused on leveraging endogenous metabolic modulators (EMMs) to pioneer a new approach for treating complex diseases and improving health, today announced the issuance of U.S. Patent 10,596,136. This patent broadly covers the use of the company's initial muscle product candidate, AXA2678, and related EMM compositions for the reduction of fat infiltration in muscle.

"This patent is the first to cover key elements of Axcella's muscle program, including an important use of our initial muscle candidate," said Paul F. Fehlner, J.D., Ph.D., Senior Vice President and Chief Intellectual Property Officer of Axcella. "This issuance is key for Axcella as it broadens our patent portfolio to cover additional areas and assets outside of the liver space. It also further solidifies Axcella's position as we seek to demonstrate the ability for EMM compositions to address metabolic dysregulations across a wide range of organ systems."

Over the course of the past several years, Axcella has worked aggressively to establish a first-mover advantage in the use of EMMs to treat complex diseases and conditions. In addition to Axcella's four granted U.S. patents, the company has established 18 patent families and more than 125 additional worldwide patents pending.

"We believe EMM combinations have the unique ability to target and impact multiple biological pathways simultaneously," said Shreeram Aradhye, M.D., Executive Vice President and Chief Development Officer at Axcella. "This issuance focuses on specific EMM combinations that are intended to modulate key metabolic pathways in skeletal muscles. In an initial clinical study, we saw attenuation of immobilization related muscle atrophy and reduced intramuscular fat infiltration in healthy subjects receiving our product candidate, AXA2678."

About Endogenous Metabolic Modulators (EMMs)

EMMs are a broad family of molecules, including amino acids, that regulate human metabolism. Axcella is developing a range of novel product candidates that are comprised of multiple EMMs engineered in distinct combinations and ratios to simultaneously impact multiple metabolic pathways to modify the root causes of various complex diseases and improve health.

About Axcella's Clinical Studies

Each of the company's ongoing clinical studies are being conducted as non-investigational new drug (IND) application clinical studies under U.S. Food and Drug Administration regulations and guidance supporting research with food. These studies evaluate product candidates for safety, tolerability and effects on the normal structures and functions in humans, including in individuals with disease. They are not designed or intended to evaluate a product candidate's ability to diagnose, cure, mitigate, treat or prevent a disease. If Axcella decides to further develop a product candidate as a potential therapeutic, as is the case with AXA1665 and AXA1125/1957, subsequent studies will be conducted under an IND.

Internet Posting of Information

Axcella uses its website, www.axcellahealth.com, as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD. Such disclosures will be included on the company's website in the "Investors and News" section. Accordingly, investors should monitor such portions of the company's website, in addition to following its press releases, SEC filings and public conference calls and webcasts.

About Axcella

Axcella is a clinical-stage biotechnology company focused on leveraging endogenous metabolic modulators (EMMs) to pioneer a new approach for treating complex diseases and improving health. The company's product candidates are comprised of EMMs and their derivatives that are engineered in distinct combinations and ratios to simultaneously impact multiple biological pathways. Axcella's pipeline includes lead therapeutic candidates for non-alcoholic steatohepatitis (NASH) and the reduction in risk of overt hepatic encephalopathy (OHE) recurrence. Additional muscle- and blood-related programs are in earlier-stage development. For more information, please visit www.axcellahealth.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 development potential of the Company's product candidates, including AXA2678, potential expansion into new health or therapeutic fields, the ability of endogenous metabolic modulators to target and impact dysregulated metabolism and health, including key metabolic pathways in skeletal muscles, and the potential protection that granted patents provide for the Company's product candidates, including AXA2678. 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 breadth of the company's pipeline of product candidates, the strength of the development platform, the efficiency of the company's

discovery and development approach, the clinical development and safety profile of product candidates and their health or therapeutic potential, whether and when, if at all, product candidates will receive approval from the U.S. Food and Drug Administration and for which, if any, indications, competition from other biotechnology companies, the company's liquidity, its ability to successfully develop product candidates through current and future milestones on the anticipated timeline, if at all, past results from Clinical Studies not being representative of future results, and other risks identified in the company's SEC filings, including Axcella's Annual Report on form 10-K and Quarterly Reports on Form 10-Q and other 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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