Axcella Therapeutics Details Clinical and Operational Milestones for 2022

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- *Long COVID Phase 2a top-line data anticipated in mid-2022*
- *EMMPACT℠ Phase 2b interim data in nonalcoholic steatohepatitis (NASH) anticipated in mid-2022*

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jan. 6, 2022-- Axcella Therapeutics (Nasdaq: AXLA), a clinical-stage biotechnology company pioneering a new approach to treat complex diseases using multi-targeted endogenous metabolic modulator (EMM) compositions, today outlined key clinical and operational milestones that are expected for the company in 2022.

“The year 2021 was a foundational time for Axcella Therapeutics that was highlighted by the clearance of our first investigational new drug (IND) filings and the initiation of three Phase 2 clinical trials,” said Axcella President and Chief Executive Officer Bill Hinshaw. “These accomplishments set the stage for what we expect to be an exciting and transformative 2022 as we continue to enhance our platform, build on our science and leverage important new clinical insights for additional potential applications. With patient screening well underway in our Long COVID Phase 2a trial, we remain at the forefront of the therapeutic development landscape for this debilitating condition and are on track for a top-line data readout mid-year. Shortly thereafter, we plan to conduct an interim analysis from our EMMPACT Phase 2b clinical trial that will provide the most robust data to date about AXA1125’s potential in NASH.”

AXA1125 for Long COVID

AXA1125, a multi-targeted oral EMM composition that has shown the potential to improve mitochondrial energetics and reduce inflammation, is being investigated in a Phase 2a clinical trial enrolling approximately 40 patients with Long COVID. In 2022, Axcella expects to:

- Complete enrollment in the Phase 2a trial (first half of 2022);
- Report top-line data (mid-2022);
- Assuming positive data, engage with regulatory authorities to discuss the potential for a registrational clinical trial of AXA1125 in Long COVID; and
- Assuming positive data, consider AXA1125’s potential to address mitochondrial dysfunction in conditions other than Long COVID.

AXA1125 for NASH

In past clinical studies, AXA1125 has demonstrated its potential to reduce well-established markers of liver fat, inflammation and fibrosis. This candidate is currently being investigated in the EMMPACT Phase 2b clinical trial enrolling approximately 270 patients with biopsy-confirmed F2/F3 NASH. In 2022, Axcella expects to:

- Report interim data (mid-2022); and
- Complete patient enrollment in EMMPACT.

AXA1665 for OHE

AXA1665 is a multi-targeted oral EMM composition that has shown the potential to improve amino acid balance, ammonia metabolism, muscle function and neurocognition in past clinical studies. This candidate is currently being investigated in the EMMPOWER℠ Phase 2 clinical trial enrolling approximately 150 patients with a history of overt hepatic encephalopathy (OHE). In 2022, Axcella expects to:

- Provide an enrollment update for EMMPOWER.

About Axcella Therapeutics (Nasdaq: AXLA)

Axcella is a clinical-stage biotechnology company pioneering a new approach to treat complex diseases using endogenous metabolic modulator (EMM) compositions. The company’s product candidates are comprised of EMMs and derivatives that are engineered in distinct combinations and ratios to restore cellular homeostasis in multiple key biological pathways and improve cellular energetic efficiency. Axcella’s pipeline includes lead therapeutic candidates in Phase 2 development for the reduction in risk of overt hepatic encephalopathy (OHE) recurrence, the treatment of Long COVID, and the treatment of non-alcoholic steatohepatitis (NASH). 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 timing of development plan disclosures, regulatory interactions, enrollment updates and clinical trial readouts. 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 AXA1665 and AXA1125, other potential impacts 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 AXA1665 and AXA1125, the clinical development and safety profile of AXA1665 and AXA1125 and their 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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