

Axcella, Now Axcella Therapeutics, to Host Virtual R&D Day on October 26, 2021

October 19, 2021

Event to feature an unveiling of Axcella's next clinical program, ongoing OHE and NASH programs, and platform

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 19, 2021-- Axcella Therapeutics (Nasdaq: AXLA), a clinical-stage biotechnology company pioneering a new approach to treat complex diseases using endogenous metabolic modulator (EMM) compositions, today announced that it will host a virtual R&D Day on Tuesday, October 26, 2021, at 10:00 a.m. ET. The event will feature presentations from multiple key opinion leaders (KOLs) as well as Axcella's management team. Topics will include the company's next clinical program (to be announced the day of the event), its ongoing programs in overt hepatic encephalopathy (OHE) and non-alcoholic steatohepatitis (NASH), and its platform.

Additionally, the company announced today that it will now operate as "Axcella Therapeutics." The addition of "Therapeutics" to the Axcella name reflects the company's current clinical stage and its ultimate aspiration, which is to develop therapies with multi-targeted mechanisms that address substantial unmet needs for patients with a range of complex conditions.

"We have made considerable progress over the past three years and have demonstrated that we can profoundly impact targeted biologies using candidates that work *with* the body's systems and are composed of safe, endogenous molecules," said Axcella President and CEO Bill Hinshaw. "We look forward to showcasing our platform and progress, demonstrating the need for and value of our product candidates, and sharing details of our newest program during R&D Day."

R&D Day presenters will include:

- Stephen Harrison, MD, Medical Director of Pinnacle Clinical Research in San Antonio, TX, and Visiting Professor of Hepatology at the University of Oxford, UK
- Eric Lawitz, MD, Medical Director and VP of Research and Development, Texas Liver Institute and Professor of Medicine, University of Texas Health San Antonio
- Elliot Tapper, MD, Associate Professor at the University of Michigan and Director of the Michigan Cirrhosis Program
- An additional external expert, who will provide context about Axcella's new clinical program
- Bill Hinshaw, Axcella President and CEO
- Alison Schecter, MD, Axcella President of Research & Development
- Karim Azer, PhD, Axcella VP of Systems Biology & Discovery

A live audio webcast of this event will be available on the "Investors & News" section of the company's website, www.axcellatx.com. A replay will also be available on Axcella's website for 90 days following the presentation.

Internet Posting of Information

Axcella uses its website, www.axcellatx.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 & News" section. Accordingly, investors should monitor this portion of the company's website, in addition to its press releases, SEC filings and public conference calls and webcasts.

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 reset multiple biological pathways, improve cellular energetics, and restore homeostasis. Axcella's pipeline includes lead therapeutic candidates in Phase 2/2b development for the reduction in risk of overt hepatic encephalopathy (OHE) recurrence 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 company's ability to develop therapies with multi-targeted mechanisms that profoundly impact targeted biologies and address substantial unmet needs for patients with a range of complex conditions. 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 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 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20211019005179/en/

Jason Fredette <u>ifredette@axcellatx.com</u> 857.320.2236

Source: Axcella Therapeutics