Axcella Presents Mechanistic Data Demonstrating that AXA1125 Modulated Liver Metabolic, Inflammatory and Fibrotic Pathways

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- In vitro data showed AXA1125 impacted multifactorial liver biology in primary human cells
- Consistent effects of AXA1125 have been observed across humans, rodents and primary human cells
- Data further support compositions of Endogenous Metabolic Modulators (EMM) as novel multifactorial assets with the potential to support health or become therapeutically relevant

CAMBRIDGE, Mass., January 24, 2019 – Axcella Health, a biotechnology company pioneering a new approach to address metabolic dysregulation and health, presented new data on the company’s AXA1125 program at the Integrated Pathways of Disease in NASH and NAFLD Keystone Symposium. The new data were introduced in an oral presentation by Svetlana Marukian, Ph.D., Senior Director, Discovery at Axcella.

AXA1125 is a novel composition of EMMs designed to simultaneously support metabolic, inflammatory and fibrotic pathways associated with liver health. Results from in vitro primary human single and multicellular systems were consistent with previously presented Non-IND, IRB Approved Clinical Studies human and in vivo rodent studies, and showed that AXA1125:

- Lowered triglycerides in human hepatocyte cells;
- Suppressed aerobic glycolysis while preserving total ATP levels in human macrophage cells; and
- Reduced ProC3 and other key fibrogenic markers, including reducing the activation and proliferation of human stellate cells.

“We’re thrilled to discuss our findings with the scientific community. We believe these data provide compelling new insights and mechanistic support for the effects of AXA1125 we observed on key structural and functional liver parameters (metabolism, inflammation and fibrosis) in Type 2 Diabetic patients with NAFLD which were recently presented at AASLD,” said Manu Chakravarthy, M.D., Ph.D., Senior Vice President, Clinical Development and Chief Medical Officer of Axcella.

“These data demonstrate the ability of our platform and development paradigm to rapidly obtain a significant depth and breadth of information,” said Bill Hinshaw, President and Chief Executive of Axcella. “The results from our liver program support our belief that our EMM compositions represent a new and exciting approach to potentially address health and complex diseases and demonstrate the strength of our growing pipeline.”

About Endogenous Metabolic Modulators

Endogenous metabolic modulators are a broad family of molecules, including amino acids, which fundamentally impact and regulate human metabolism. Our AXA Candidates are comprised of EMMs that individually, as part of food products, and in other forms, have a history of safe use in or as foods and dietary supplements. We believe that unlike conventional targeted interventions currently used to address dysregulated metabolism, EMM compositions have the potential to directly and simultaneously modulate multiple critical biologies and pathways implicated both in health and complex diseases, including across a broad spectrum of severity in healthy and diseased populations.

About Non-IND, IRB Approved Clinical Studies

Axcella conducts Institutional Review Board-approved clinical studies in humans, including individuals with disease, with its AXA candidates under U.S. Food and Drug Administration regulations and guidance supporting research with food outside of an investigational new drug application, or IND. In these studies, Axcella evaluates AXA Candidates for safety, tolerability, and effects on the normal structures and functions of the body. Non-IND IRB Approved Clinical Studies are not designed or intended to evaluate an AXA Candidate’s ability to diagnose, cure, mitigate, treat, or prevent a disease. If Axcella decides to further develop an AXA Candidate as a potential therapeutic instead of a food product, subsequent studies for such candidate will be conducted under an IND.

About Axcella Health

Axcella is designing and developing AXA candidates, compositions of EMMs matched to biologies and engineered in distinct ratios, with the aim of maximizing the vital role that EMMs play in regulating multiple metabolic functions. Our aspiration is to identify biologies and generate AXA Candidates that can support health and have therapeutic effects. We believe our leading expertise and capabilities in EMMs position us to become a preeminent company modulating dysregulated metabolism and providing health solutions where highly targeted pathway interventions have not been successful. Our platform has already produced a pipeline of product candidates in programs targeting liver, muscle, and CNS. We were founded by
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