Axcella to Present Late-Breaker Data on Lead AXA™ Candidate, AXA1665 at EASL, the International Liver Congress™

March 27, 2019

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Axcella Health, a biotechnology company pioneering the research and development of novel multifactorial interventions to address dysregulated metabolism and support health, today announced a late-breaker poster presentation for their novel endogenous metabolic modulator (EMM) composition, AXA1665 in subjects with mild and moderate hepatic insufficiency. These data from a Non-IND, IRB-Approved Clinical Study will be presented at the European Association for the Study of the Liver (EASL), The International Liver Congress™ 2019 taking place April 10-14 in Vienna, Austria, by Arun J. Sanyal, M.B.B.S., M.D., Professor, Department of Internal Medicine, Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University School of Medicine.

Additional details of the presentation are as follows:

Title: AXA1665, a novel composition of amino acids restores the dysregulated amino acid profile, lowers ammonia, and improves body composition and function in Child-Pugh class A and B subjects

Abstract Number: 5217

Identifier: LBP-31

Presenter: Arun J. Sanyal, M.B.B.S., M.D., Professor, Department of Internal Medicine, Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University School of Medicine

Session: Late breaker poster

Date/Time: Thursday, April 11, 2019 at 9am CET until Saturday, April 13, 2019 at 5pm CET

About Endogenous Metabolic Modulators
Endogenous metabolic modulators, or EMMs, are a broad family of molecules, including amino acids, which fundamentally impact and regulate human metabolism. Our AXA Candidates are anchored by EMMs that have a history of safe use as food. We believe that, unlike conventional targeted interventions currently used to address dysregulated metabolism, EMM compositions have the potential to directly and simultaneously support and modulate multiple metabolic pathways implicated both in complex diseases and overall health.

About Non-IND, IRB-Approved Clinical Studies
Axcella conducts non-investigational new drug application (Non-IND), Institutional Review Board (IRB)-approved clinical studies in humans with its AXA Candidates under U.S. Food and Drug Administration regulations and guidance supporting research with food outside of an IND. In these studies, Axcella evaluates in humans, including in individuals with disease, 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, subsequent studies will be conducted under an IND.

About Axcella Health
Axcella is designing and developing AXA candidates, compositions of EMMs engineered in distinct ratios, designed to target and maximize the fundamental role that EMMs play in regulating multiple metabolic functions. Our AXA Candidates are generated from our proprietary, human-focused AXA Development Platform. We believe our expertise and capabilities in EMMs position us to become a preeminent biotechnology company reprogramming metabolism to address a diverse set of complex diseases and support health. Our AXA Development Platform has already produced a pipeline of product candidates in programs targeting liver, muscle and central nervous system. We were founded by Flagship Pioneering.

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