Akero Therapeutics and InSphero partner to evaluate AKR-001 using InSphero’s 3D InSight™ Human Liver Disease platform

3D InSight™ Human Liver Disease Platform will be used to screen effects of Akero lead program AKR-001 on underlying metabolic and fibrotic drivers of NAFLD and NASH.

Schlieren, Switzerland and San Francisco, CA, USA – October 3, 2019 – Akero Therapeutics (Nasdaq: AKRO) and InSphero AG today announced that Akero has selected InSphero’s 3D InSight™ Human Liver Disease Platform to characterize the physiological effects of AKR-001 in different types of liver cells. AKR-001 is designed to be a novel, long-acting FGF21 analog, currently being evaluated in a Phase 2a clinical trial for the treatment of non-alcoholic steatohepatitis (NASH).

“We believe AKR-001 has unique potential among investigational NASH therapies to restore whole-body metabolic balance while also acting directly to reduce inflammation and fibrotic scarring in the liver,” said Tim Rolph, D.Phil., Akero Therapeutics Chief Scientific Officer and Co-founder. “With InSphero’s human in vitro liver disease platform, we will evaluate AKR-001’s effects on human liver cells to help contextualize results from our ongoing Phase 2a clinical trial.”

Akero will leverage InSphero’s 3D InSight™ Human Liver NASH Model to investigate the effects of AKR-001 on: (a) liver metabolism, (b) pathways that induce stress and death of hepatocytes, the primary functional cells of liver, (c) sentinel immune effector Kupffer cells, (d) collagen-synthesizing hepatic stellate cells, and (e) NASH-induced fibrosis of the liver.

“Our research partnership with Akero Therapeutics highlights the rapid adoption of our novel in vitro discovery platform for NASH and non-alcoholic fatty liver disease,” said Jan Lichtenberg, Ph.D., InSphero Chief Executive Officer and Co-founder. “AKR-001 shows great promise as a NASH therapy, and we are excited to be working with Akero as they perform rigorous efficacy and safety testing on their lead program.”

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About NASH

A leading cause of liver-related disease, NASH is the most severe form of non-alcoholic fatty liver disease (NAFLD). The prevalence of NASH is growing rapidly, driven by the epidemic of obesity and type 2 diabetes. NASH is characterized by damage to hepatocytes leading to liver inflammation and fibrosis that can ultimately progress to liver failure, cancer and death.
About InSphero

InSphero is the pioneer of industrial-grade, 3D-cell-based assay solutions and scalable, scaffold-free microtissue technology. Through partnerships, InSphero supports pharmaceutical and biotechnology researchers in successful decision-making by recapitulating human physiology in vitro. Its robust and precisely engineered suite of 3D InSight™ human tissue platforms for liver toxicology, metabolic diseases, and immuno-oncology, are used by major pharmaceutical companies worldwide to increase efficiency in drug discovery and safety testing. Underlying these platforms, InSphero’s Akura™ technology, which includes 96- and 384-well plate formats as well as the Akura™ Flow organ-on-a-chip system, drives drive efficient innovation throughout all phases of drug development.

About Akero Therapeutics

Akero Therapeutics is a clinical-stage biotechnology company focused on the development and commercialization of transformative treatments for patients with serious metabolic disease with high unmet medical need.

About AKR-001

AKR-001 is an Fc-FGF21 fusion protein that has been engineered to mimic the biological activity profile of native FGF21, an endogenous hormone that regulates lipid and energy metabolism, and is secreted throughout the body to alleviate cellular stress. Observations from clinical trials of AKR-001 and other FGF analogs point to AKR-001’s potential to reduce liver fat, cellular stress, inflammation and fibrosis in people with non-alcoholic steatohepatitis (NASH), as well as to improve risk factors of cardiovascular disease, the principal cause of death among NASH patients.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: the potential objectives and expectations for Akero’s partnership with InSphero, including expectations regarding its implementation, timing and success; Akero’s guidance regarding its business plans and objectives for AKR-001, including the therapeutic potential and clinical benefits thereof, as well as the potential patient population that may be addressed by AKR-001; Akero’s ongoing Phase 2a clinical trial and planned clinical trials of AKR-001 including the design, implementation, timing and success of its current and planned clinical trials.

Any forward-looking statements in this statement are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the risk that Akero’s partnership with InSphero will not be successful; the success, cost, and timing of the company’s product candidate development activities and clinical trials; the company's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States; and risks related to the competitive landscape. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Akero’s actual results to differ from those contained in the forward-looking
statements, see the section entitled "Risk Factors" in the final prospectus dated June 19, 2019 and filed pursuant to Rule 424(b) under the Securities Act of 1933, as amended, with the United States Securities and Exchange Commission (SEC) and quarterly reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in Akero’s other filings with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Akero undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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