Arrowhead Pharmaceuticals Initiates Phase 1/2a Study of ARO-INHBE for the Treatment of Obesity

December 23, 2024

- ARO-INHBE targets a known pathway that signals the body to store fat in adipose tissue
- In preclinical studies ARO-INHBE reduced body weight and fat mass with a novel mechanism of action that may better preserve lean muscle mass compared to currently approved obesity therapies

PASADENA, Calif.--(BUSINESS WIRE)--Dec. 23, 2024-- Arrowhead Pharmaceuticals, Inc. (NASDAQ: ARWR) today announced that it has dosed the first subjects in a Phase 1/2a clinical trial of ARO-INHBE, the company's investigational RNA interference (RNAi) therapeutic being developed as a potential treatment for obesity. Arrowhead also filed recently a request for regulatory clearance to initiate a clinical trial for its second obesity candidate, ARO-ALK7. Both ARO-INHBE and ARO-ALK7 are designed to intervene in a known pathway that signals the body to store fat in adipose tissue.

"ARO-INHBE is an important program for Arrowhead that complements our strategic focus on developing and commercializing important RNAi-based therapies for cardiometabolic diseases. Further, our preclinical studies have yielded promising results for this novel mechanism to reduce body weight and potentially preserve lean muscle mass resulting in improved body composition," said James Hamilton, M.D., Chief of Discovery and Translational Medicine at Arrowhead. "The Phase 1/2 study will evaluate ARO-INHBE as a monotherapy in part 1 and as a combination therapy with tirzepatide in part 2, with both parts enrolling patients with obesity."

About ARO-INHBE

ARO-INHBE is designed to reduce the hepatic expression of the INHBE gene and its secreted gene product, Activin E. INHBE is a promising genetically validated target in which loss-of-function INHBE variants in humans are associated with improved fat distribution and lower risk of metabolic diseases, such as type 2 diabetes. Activin E acts as a ligand in a pathway that regulates energy homeostasis in adipose tissue. Inhibiting this pathway with investigational ARO-INHBE treatment has the potential to increase lipolysis, and reduce adipose hypertrophy and dysfunction, visceral adiposity, and insulin resistance.

About the AROINHBE-1001 Phase 1/2 Study

AROINHBE-1001 (NCT06700538) is a Phase 1/2a dose-escalating study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of ARO-INHBE in up to 78 adult volunteers with obesity. Part 1 of the study is designed to assess single and multiple doses of ARO-INHBE monotherapy, and Part 2 of the study is designed to assess ARO-INHBE in combination with tirzepatide, a subcutaneously administered GLP-1/GIP receptor co-agonist that has been approved in the United States and the European Union for management of type 2 diabetes mellitus since 2022 and weight management since 2023/2024 respectively.

About Arrowhead Pharmaceuticals

Arrowhead Pharmaceuticals develops medicines that treat intractable diseases by silencing the genes that cause them. Using a broad portfolio of RNA chemistries and efficient modes of delivery, Arrowhead therapies trigger the RNA interference mechanism to induce rapid, deep, and durable knockdown of target genes. RNA interference, or RNAi, is a mechanism present in living cells that inhibits the expression of a specific gene, thereby affecting the production of a specific protein. Arrowhead's RNAi-based therapeutics leverage this natural pathway of gene silencing.

For more information, please visit www.arrowheadpharma.com, or follow us on X (formerly Twitter) at @ArrowheadPharma, LinkedIn, Facebook, and Instagram. To be added to the Company's email list and receive news directly, please visit http://ir.arrowheadpharma.com/email-alerts.

Safe Harbor Statement under the Private Securities Litigation Reform Act:

This news release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Any statements contained in this release except for historical information may be deemed to be forward-looking statements. Without limiting the generality of the foregoing, words such as "may," "will," "expect," "believe," "anticipate," "hope," "intend," "plan," "project," "could," "estimate," "continue," "target," "forecast" or "continue" or the negative of these words or other variations thereof or comparable terminology are intended to identify such forward-looking statements. In addition, any statements that refer to projections of our future financial performance, trends in our business, expectations for our product pipeline or product candidates, including anticipated regulatory submissions and clinical program results, prospects or benefits of our collaborations with other companies, or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements include, but are not limited to, statements about the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; our expectations regarding the potential benefits of the partnership, licensing and/or collaboration arrangements and other strategic arrangements and transactions we have entered into or may enter into in the future; our beliefs and expectations regarding milestone, royalty or other payments that could be due to or from third parties under existing agreements; and our estimates regarding future revenues, research and development expenses, capital requirements and payments to third parties. These statements are based upon our current expectations and speak only as of the date hereof. Our actual results may differ materially and adversely from those expressed in any forward-looking statements as a result of numerous factors and uncertainties, including the impact of the ongoing COVID-19 pandemic on our business, the safety and efficacy of our product candidates, decisions of regulatory authorities and the timing thereof, the duration and impact of regulatory delays in our clinical programs, our ability to finance our operations, the likelihood and timing of the receipt of future milestone and licensing fees, the future success of our scientific studies, our ability to successfully develop and commercialize drug candidates, the timing for starting and completing clinical trials, rapid technological change in our markets, the enforcement of our intellectual property rights, and the other risks and uncertainties described in our most recent Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and other documents filed with the Securities and Exchange Commission from time to time. We assume no obligation to update or revise forward-looking statements to reflect new events or circumstances.

Source: Arrowhead Pharmaceuticals, Inc.

View source version on businesswire.com: https://www.businesswire.com/news/home/20241223983257/en/

Arrowhead Pharmaceuticals, Inc.
Vince Anzalone, CFA
626-304-3400
ir@arrowheadpharma.com

Investors:
LifeSci Advisors, LLC
Brian Ritchie
212-915-2578
britchie@lifesciadvisors.com

Media:
LifeSci Communications, LLC
Kendy Guarinoni, Ph.D.
724-910-9389
kguarinoni@lifescicomms.com

Source: Arrowhead Pharmaceuticals, Inc.