Arrowhead Pharmaceuticals to Advance Two New RNAi-Based Obesity Candidates, ARO-INHBE and ARO-ALK7, Into Clinical Studies

August 14, 2024

- Company hosting an obesity/metabolic R&D webinar today, August 14, 2024, at 2:00 pm ET as Part IV of the 2024 Summer Series of R&D Webinars

PASADENA, Calif.--(BUSINESS WIRE)--Aug. 14, 2024-- Arrowhead Pharmaceuticals, Inc. (NASDAQ: ARWR) today presented preclinical data and detailed its plans to advance two next generation RNAi-based candidates, ARO-INHBE and ARO-ALK7, into upcoming clinical studies for the treatment of obesity and metabolic diseases. In preclinical studies to date, these candidates demonstrated the potential to reduce body weight and fat mass with a novel mechanism of action that may lead to improved preservation of lean muscle mass compared to currently approved obesity therapies. Arrowhead plans to submit clinical trial applications with regulatory authorities for both programs by the end of 2024 with the goal of initiating clinical studies in volunteers with obesity in early 2025.

“Arrowhead believes that targeting the hepatic expression of the INHBE gene and the production of the Activin E ligand, and the adipose tissue expression of the ALK7 gene and the receptor it encodes, represent promising novel mechanisms to treat obesity and associated metabolic diseases. When studied as mono therapy and in combination with tirzepatide in diet induced obesity mouse models, ARO-INHBE and ARO-ALK7 both resulted in suppression of body weight and fat mass and, importantly, preservation of lean mass leading to improved body composition,” said James Hamilton, M.D., Chief of Discovery and Translational Medicine at Arrowhead. “Following the approval and positive clinical impact of new agents for obesity over the last few years, new therapeutic strategies with novel mechanisms of action are emerging that may represent the future in successful treatment and management of patients with obesity and associated diseases. We are in the final stages of preclinical development of ARO-INHBE and ARO-ALK7 and we are eager to engage with regulators by the end of this year to begin clinical studies of these exciting new medicines.”

ARO-INHBE is designed to reduce the hepatic expression of the INHBE gene and its secreted gene product, Activin E. ARO-ALK7 is designed to reduce the adipose expression of Activin receptor-like kinase 7 (ALK7). INHBE and ALK7 are both genetically validated targets with loss of function variants being associated with lower risk of obesity and metabolic diseases, such as type 2 diabetes. Both targets are involved in the same pathway that regulates energy homeostasis in adipose tissue, with Activin E acting as a circulating ligand and ALK7 as a receptor on adipocytes. Intervening in this pathway with ARO-INHBE and ARO-ALK7 is believed to result in increased lipolysis, and reductions in adipose hypertrophy and dysfunction, visceral adiposity, and insulin resistance.

To learn more about ARO-INHBE and ARO-ALK7, please join Part IV of Arrowhead’s 2024 Summer Series of R&D Webinars, being held today, August 14, 2024, at 2:00 PM ET. The event will feature Arrowhead management and Carel le Roux, M.D., Ph.D., from University College Dublin. The live event and an archived webcast may be accessed on the Events and Presentations page in the Investors section of the Arrowhead website.

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 or on LinkedIn. 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.

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