Arrowhead Receives FDA Fast Track Designation for ARO-APOC3

March 20, 2023

PASADENA, Calif.--(BUSINESS WIRE)--Mar. 20, 2023-- Arrowhead Pharmaceuticals Inc. (NASDAQ: ARWR) today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ARO-APOC3 for reducing triglycerides in adult patients with familial chylomicronemia syndrome (FCS). ARO-APOC3 was previously granted Orphan Drug designation by the FDA and the European Union.

ARO-APOC3 is Arrowhead's investigational RNAi therapeutic targeting apolipoprotein C-III (APOC3) being developed as a treatment for patients with severe hypertriglyceridemia (SHTG), mixed dyslipidemia (MD), and FCS. FCS is a rare genetic disorder that causes severely elevated triglyceride levels, which can result in acute and potentially fatal pancreatitis. There are currently no FDA approved therapies to treat FCS.

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fulfill an unmet medical need. The purpose is to get important new drugs to patients earlier. This designation makes Arrowhead eligible for multiple potential benefits including more frequent interactions with FDA, eligibility for accelerated approval and priority review, and rolling review of the new drug application (NDA).

ARO-APOC3 is being investigated in the Phase 3 PALISADE clinical study (NCT05089084) in patients with FCS, the Phase 2 SHASTA-2 clinical study (NCT04720534) in patients with SHTG, and the Phase 2 MUIR clinical study (NCT04998201) in patients with MD.

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

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

Media:
LifeSci Communications, LLC
Josephine Belluardo, Ph.D.

646-751-4361
jo@lifescicomms.com
www.lifescicommunications.com

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