Arrowhead Subsidiary Visirna Sells Rights to Hypertriglyceridemia Candidate Plozasiran in Greater China to Sanofi

August 1, 2025

- Sanofi to pay $130 million upfront and up to $265 million in potential regulatory milestones to Visirna Therapeutics, a majority-owned subsidiary of Arrowhead, which was previously granted rights to investigational plozasiran in Greater China

- Sanofi will receive an exclusive license to develop and commercialize investigational plozasiran in Greater China from Visirna Therapeutics, offering potential treatment to people living with elevated triglycerides

PASADENA, Calif.--(BUSINESS WIRE)--Aug. 1, 2025-- Arrowhead Pharmaceuticals, Inc. (NASDAQ: ARWR) today announced the signing of an asset purchase agreement between Sanofi and Visirna Therapeutics, a majority-owned subsidiary of Arrowhead created to develop and commercialize four of Arrowhead's investigational cardiometabolic candidates in Greater China. Under the terms, Sanofi will acquire rights to develop and commercialize investigational plozasiran, Arrowhead's first-in-class RNA interference (RNAi) therapeutic candidate designed to reduce production of apolipoprotein C-III (APOC3) as a potential treatment for familial chylomicronemia syndrome (FCS) and severe hypertriglyceridemia (SHTG), in Greater China.

Visirna has completed a Phase 3 clinical trial (CTR20231418/NCT05902598) of investigational plozasiran in Chinese patients with familial chylomicronemia syndrome (FCS), which successfully met its primary efficacy endpoint and all key secondary endpoints. Visirna subsequently submitted a New Drug Application (NDA) for plozasiran to the National Medical Products Administration (NMPA) in China for the treatment of FCS and received official acceptance in January 2025. Plozasiran has also been granted Breakthrough Therapy Designation in the treatment of patients with FCS and Priority Review Designation by the China NMPA.

"When we founded Visirna in 2022, we believed that Greater China represented an important potential future market for multiple programs in Arrowhead's pipeline of investigational RNAi-based candidates for cardiometabolic diseases," said Christopher Anzalone, Ph.D., Arrowhead's President and CEO. "The team at Visirna understand the intricacies of China's clinical, regulatory, and commercial environment and have done impressive work moving plozasiran through clinical studies and into the regulatory submission and review process. We now look forward to working with Sanofi and believe they are extremely well positioned as a global company with a strong presence in China."

Wayne Shi, President, Sanofi Greater China, added, "We are pleased to have concluded this agreement to enable us to advance plozasiran in Greater China where Sanofi has deep roots and a proud heritage of serving people living with a wide range of diseases. Plozasiran has shown considerable potential in studies across diverse patient populations where serious illness is caused by elevated triglycerides. With our strong presence in China's cardiometabolic field, we now look forward to bringing it forward to address unmet need."

Upon closing of the Asset Purchase Agreement, Visirna will receive an upfront payment of $130 million from Sanofi. In addition, Visirna will be eligible to receive further milestone payments of up to $265 million upon approval of plozasiran across various indications in mainland China. Arrowhead is further eligible to receive royalties on net commercial product sales in Greater China as part of the Arrowhead-Visirna license which was assigned in part to Sanofi.

Gibson, Dunn & Crutcher LLP and Sidley Austin LLP are serving as legal advisors to Arrowhead.

About Plozasiran

Plozasiran, previously called ARO-APOC3, is a first-in-class investigational RNA interference (RNAi) therapeutic designed to reduce production of apolipoprotein C-III (APOC3) which is a component of triglyceride rich lipoproteins (TRLs) and a key regulator of triglyceride metabolism. APOC3 increases triglyceride levels in the blood by inhibiting breakdown of TRLs by lipoprotein lipase and uptake of TRL remnants by receptors in the liver. The goal of treatment with plozasiran is to reduce the level of APOC3, thereby reducing triglycerides and restoring lipids to more normal levels.

In multiple clinical studies, investigational plozasiran has demonstrated reductions in triglycerides and multiple atherogenic lipoproteins in patients with familial chylomicronemia syndrome (FCS), severe hypertriglyceridemia (SHTG), and mixed hyperlipidemia. Plozasiran has been generally well tolerated to date with treatment emergent adverse events reported that generally reflect the comorbidities and underlying conditions of the study populations. Across clinical studies and study populations, the most frequently reported treatment emergent adverse events for the 25 mg dose that is proposed for marketing approval were COVID-19, upper respiratory tract infection, headache, Type 2 diabetes mellitus, and abdominal pain.

Plozasiran is being investigated in the SUMMIT program of clinical studies, which includes the PALISADE Phase 3 study in patients with FCS, the SHASTA Phase 2 and Phase 3 studies in patients with SHTG, and the MUIR Phase 2 and Phase 3 studies in patients with mixed hyperlipidemia.

Plozasiran in the treatment of patients with FCS has been granted Breakthrough Therapy Designation, Orphan Drug Designation, and Fast Track Designation by the U.S. Food and Drug Administration and Orphan Medicinal Product Designation by the European Medicines Agency. Investigational plozasiran has been submitted for marketing authorization in treatment of FCS to multiple global regulatory authorities but has not been reviewed or approved to treat any disease.

About Visirna Therapeutics

Visirna Therapeutics was founded in 2022 as a majority owned subsidiary of Arrowhead Pharmaceuticals. Headquartered in China with a global perspective, Visirna strives to emerge as a frontrunner in the advancement of siRNA therapeutics. The existing product portfolio comprises clinical stage siRNA candidates with a focus on cardiovascular/metabolic, and auto-immune ailments.

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.

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