Arrowhead Pharmaceuticals Announces NMPA Approval of REDEMPLO® (plozasiran) for Familial Chylomicronemia Syndrome (FCS) in China

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- REDEMPLO is being launched in China by Sanofi

- NMPA approval triggers $10 million milestone payment to be paid by Sanofi to Arrowhead subsidiary Visirna Therapeutics

PASADENA, Calif.--(BUSINESS WIRE)--Jan. 7, 2026-- Arrowhead Pharmaceuticals, Inc. (NASDAQ: ARWR) today announced that the Chinese National Medical Products Administration (NMPA) has approved REDEMPLO® (plozasiran) for the reduction of triglyceride levels in adult patients with familial chylomicronemia syndrome (FCS). FCS is a severe, rare disease characterized by triglyceride levels that can be 10 to 100 times higher than normal leading to a substantially higher risk of developing acute, recurrent, and potentially fatal pancreatitis.

REDEMPLO will be marketed in Greater China by Sanofi under an agreement between Sanofi and Arrowhead. In 2025, Sanofi purchased those rights from Visirna, a majority-owned subsidiary of Arrowhead created to develop and commercialize four of Arrowhead's investigational cardiometabolic candidates in Greater China.

Approval in China marks the third regulatory approval for REDEMPLO, following recent approvals by U.S. Food and Drug Administration (FDA) and Health Canada, as an adjunct to diet to reduce triglycerides in adults with FCS. REDEMPLO is also in review for marketing authorization by additional global regulatory authorities.

REDEMPLO is the first and only U.S. FDA-approved, Health Canada-approved, and China NMPA-approved siRNA medicine for people living with FCS and can be self-administered at home with a simple subcutaneous injection once every three months.

"NMPA approval of REDEMPLO for FCS in China is another positive step and continues the strong momentum since launching in the U.S. in November 2025. We look forward to working with Sanofi, an innovative global company with an established presence in China," said Christopher Anzalone, Ph.D., President and CEO at Arrowhead Pharmaceuticals. "We are happy to report encouraging initial response from physicians and patients following FDA approval and launch in the U.S. last month. We intend to continue building on this rapid progress and anticipate additional commercial launches in 2026, pending regulatory review and approval."

About FCS

Familial chylomicronemia syndrome (FCS) is a severe and rare disease leading to extremely high triglyceride (TG) levels, typically over 880 mg/dL. Such severe elevations can lead to various serious signs and symptoms including acute and potentially fatal pancreatitis, chronic abdominal pain, diabetes, hepatic steatosis, and cognitive issues. Currently, there are limited therapeutic options to adequately treat FCS.

About REDEMPLO® (plozasiran)

REDEMPLO (plozasiran) is approved by the U.S. Food and Drug Administration, Health Canada, and the Chinese National Medical Products Administration as an adjunct to diet to reduce triglycerides for adults with Familial Chylomicronemia Syndrome (FCS). REDEMPLO is an siRNA therapeutic designed to suppress the production of apoC-III, a protein produced in the liver that raises triglyceride levels by slowing their breakdown and clearance. By targeting apoC-III with sustained silencing, REDEMPLO delivers significant reductions in triglyceride levels. REDEMPLO is the first and only siRNA FDA-approved treatment studied in both genetically confirmed and clinically diagnosed patients living with FCS.

For more information about REDEMPLO, visit Our Medicines.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

None.

ADVERSE REACTIONS

Most common adverse reactions in REDEMPLO treated patients (incidence ≥10% of patients treated with REDEMPLO and >5% more frequently than with placebo) are hyperglycemia, headache, nausea, and injection site reaction.

Please see full Prescribing Information for REDEMPLO®.

About Plozasiran

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

In addition to the FDA approval of REDEMPLO as an adjunct to diet to reduce triglycerides for adults with Familial Chylomicronemia Syndrome, plozasiran has been submitted to additional global regulatory authorities for review and marketing authorization. Plozasiran is also being investigated in the SHASTA-3, SHASTA-4, and SHASTA-5 Phase 3 studies in patients with severe hypertriglyceridemia and the MUIR Phase 3 study in patients with mixed hyperlipidemia.

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, products or product candidate or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements include, but are not limited to, statements about our beliefs and expectations regarding the long-term impacts of REDEMPLO (plozasiran) on patient health and the health care system; our beliefs and expectations regarding the pricing, value, or expected timing for availability of our drugs and drug candidates; and our believes and expectations around the potential uses and value of the TRiM™ platform. These statements are based upon our current expectations and speak only as of the date hereof. Actual results or outcomes may differ materially and adversely from those expressed in any forward-looking statements as a result of numerous factors and uncertainties the safety and efficacy of our products and product candidates, pricing and reimbursement decisions related to our products, demand for our products, 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, 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

Media:
HAVAS PR
Erick Edwing
941-468-7534
Erick.edwing@havasred.com

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