Arrowhead Pharmaceuticals Announces Health Canada Approval of REDEMPLO™ (plozasiran) to Reduce Triglycerides in Adults with Familial Chylomicronemia Syndrome (FCS)

January 5, 2026

– REDEMPLO is the first and only Health Canada-approved siRNA medicine to be studied in patients with genetically confirmed and clinically diagnosed FCS

– People living with FCS have extremely high triglyceride levels and a substantially higher risk of acute pancreatitis and related long-term complications, often resulting in a reduced quality of life

– The Health Canada approval is based on positive results from the Phase 3 PALISADE study where REDEMPLO significantly reduced triglycerides from baseline and lowered the numerical incidence of acute pancreatitis compared to placebo

PASADENA, Calif.--(BUSINESS WIRE)--Jan. 5, 2026-- Arrowhead Pharmaceuticals, Inc. (NASDAQ: ARWR) today announced that Health Canada has issued a Notice of Compliance (NOC) authorizing REDEMPLO™ (plozasiran), a small interfering RNA (siRNA) medicine, as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS) for whom standard triglyceride lowering therapies have been inadequate. 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. FCS remains widely underdiagnosed and is estimated to affect between 1 and 13 people per million globally, though is approximately 100 times more common in parts of French Canada. REDEMPLO is the first and only Health Canada-approved siRNA medicine for people living with FCS that can be self-administered at home with a subcutaneous injection once every three months. Today's authorization follows the recent approval of REDEMPLO in the United States, as Arrowhead continues its efforts to increase global access to care for people living with FCS.

"We are thrilled to start the new year with Health Canada's approval of REDEMPLO as a new treatment option for Canadians living with genetic or clinical FCS," said Christopher Anzalone, Ph.D., President and CEO of Arrowhead Pharmaceuticals. "Arrowhead continues to drive RNAi innovation with our TRiM™ platform, which is now capable of delivering siRNA to multiple cell types throughout the body and potentially treat a growing array of diseases. As we expand our commercial capabilities, we aim to bring these new treatments to the patients who need them."

Harnessing Arrowhead's proprietary Targeted RNAi Molecule (TRiM™) platform, REDEMPLO is designed to silence the mRNA for *APOC3*, an important target for reducing triglycerides in patients with FCS. The Health Canada approval was supported by clinical data from the Phase 3 PALISADE study, a randomized, double-blind, placebo-controlled trial in adults with clinically diagnosed or genetically confirmed FCS. The clinical study was conducted across 39 global sites, including 5 study locations in Canada. The PALISADE study met its primary endpoint and all multiplicity-controlled key secondary endpoints, including demonstrating significant reductions in triglycerides and APOC3. In PALISADE, 25 mg REDEMPLO achieved deep and durable reductions in triglycerides throughout the 12-month treatment period, with a median change from baseline of -80% versus -17% in the pooled placebo group, and a lower numerical incidence of acute pancreatitis compared with placebo. The most common adverse reactions in REDEMPLO treated patients (incidence ≥15% of patients treated with REDEMPLO) are hyperglycemia, headache, nausea, and injection site reaction.

REDEMPLO is the first and only Health Canada-approved treatment studied in both clinically diagnosed and genetically confirmed patients living with FCS, giving patients, providers, and caregivers alike a convenient dosing option that can be self-administered at home with a subcutaneous injection once every three months.

Durhane Wong-Rieger, President & CEO of Canadian Organization for Rare Disorders added, "For more than two decades, we have hoped along with the FCS community the next therapy would truly help end the excruciating pain and unpredictability of this very challenging condition—and thanks to the unrelenting commitment of researchers and scientists, we believe the time has arrived. Listening to the stories of patients and family members, we share their optimism for the chance to regain control over not just their health but their lives. We are especially grateful to Arrowhead for bringing this life-changing therapy to our Canadian FCS families."

"Health Canada's approval of REDEMPLO marks an important moment for individuals and families affected by FCS, who have long faced limited treatment options for managing this often-debilitating condition," said Daniel Gaudet, M.D., Ph.D., a principal investigator in the PALISADE clinical study that supported today's approval. "The safety and efficacy of REDEMPLO, when combined with the durable and convenient at-home dosing schedule of once every three months, makes this a potential game-changer for people living with FCS, for whom traditional triglyceride-lowering medications are typically ineffective. The availability of a new therapy for treating FCS represents meaningful progress that may help improve outcomes and quality of life for this community throughout Canada."

The efficacy and safety results from the PALISADE study were presented at the European Society of Cardiology (ESC) Congress 2024 and the American Heart Association Scientific Sessions 2024 (AHA24) and simultaneously published in The New England Journal of Medicine and Circulation, respectively. ESC, AHA24, and other plozasiran presentations may be accessed on the Events and Presentations page in the Investors section of the Arrowhead website.

Underscoring the company's commitment to improving patient outcomes, ensuring access for patients, and providing value to the health system, Arrowhead is striving to develop best-in-class patient support solutions for the FCS community.

REDEMPLO was granted Breakthrough Therapy Designation, Fast Track Designation, and Orphan Drug Designation by the U.S. FDA for the treatment of patients with FCS and was granted Orphan Medicinal Product Designation by the European Medicines Agency for the treatment of patients with FCS.

About FCS

Familial chylomicronemia syndrome (FCS) is a severe and rare disease leading to extremely high triglyceride (TG) levels, typically over 880 mg/dL (9.94 mmol/L). 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 the PALISADE Phase 3 Study

The PALISADE study (NCT05089084) was a Phase 3 placebo-controlled study to evaluate the efficacy and safety of plozasiran in adults with genetically confirmed or clinically diagnosed FCS. The primary endpoint of the study was percent change from baseline in fasting TG versus placebo at Month 10. A total of 75 subjects distributed across 39 different sites in 18 countries were randomized to receive 25 mg plozasiran, 50 mg plozasiran, or matching placebo once every three months. Participants who completed the randomized period were eligible to continue in a 2-part extension period, where all participants receive plozasiran.

About REDEMPLO ™(plozasiran)

REDEMPLO (plozasiran) is approved by Health Canada and the U.S. Food and Drug Administration as an adjunct to diet to reduce triglycerides for adults with Familial Chylomicronemia Syndrome (FCS). REDEMPLO is a siRNA therapeutic drug designed to suppress the production of apoC-III, a protein produced primarily 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, see the full Product Monograph.

About Plozasiran

Plozasiran is a first-in-class investigational RNA interference (RNAi) therapeutic drug 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 approval of REDEMPLO in Canada and the U.S. 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 beliefs 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, including but not limited to 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, 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.

Source: Arrowhead Pharmaceuticals, Inc.

View source version on businesswire.com: https://www.businesswire.com/news/home/20260105004282/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:
HAVAS PR
Erick Edwing

941-468-7534
Erick.edwing@havasred.com

Source: Arrowhead Pharmaceuticals, Inc.