Arrowhead Pharmaceuticals Receives Marketing Authorization in the European Union for REDEMPLO® (plozasiran) to Reduce Triglycerides in Adults with Familial Chylomicronemia Syndrome (FCS)

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- REDEMPLO is the first and only authorised treatment for adults with FCS that does not require genetic confirmation of the condition
- People living with FCS have extremely high triglyceride levels and a substantially higher risk of acute pancreatitis and related long-term complications, reducing their quality of life
- Marketing authorisation is supported by positive Phase 3 PALISADE study data, in which 25 mg REDEMPLO demonstrated an 80% reduction in triglycerides from baseline and an 83% reduction in the incidence of acute pancreatitis in a pooled analysis of patients using all doses of REDEMPLO compared with placebo

PASADENA, Calif.--(BUSINESS WIRE)--Jun. 22, 2026--

Arrowhead Pharmaceuticals, Inc. (NASDAQ: ARWR) today announced that the European Commission (EC) has formally granted marketing authorization for REDEMPLO® (plozasiran), a small interfering RNA (siRNA) medicine, as an adjunct to diet to reduce triglyceride levels in adult patients with familial chylomicronemia syndrome (FCS). REDEMPLO is the first and only siRNA medicine authorized by the EC for adults with FCS, diagnosed either by the presence of clinical criteria or genetic testing.

“FCS drives an elevated risk of recurrent and potentially fatal episodes of acute pancreatitis. Results from the PALISADE study demonstrate that plozasiran can achieve significant and sustained reductions in triglycerides for these patients,” said Professor Børge Nordestgaard, Department of Clinical Medicine, University of Copenhagen and President, European Atherosclerosis Society. “Importantly, the ability to diagnose and treat without requiring a genetic test could enable earlier treatment, which is particularly relevant in rare diseases such as FCS.”

Announcing its recommendation for the approval of REDEMPLO, the European Medicines Agency noted, "Although other authorised medicines can help people with FCS confirmed by genetic testing, REDEMPLO does not require genetic confirmation of the condition, thus providing a treatment option for more adults with FCS and addressing the unmet medical need in these patients."

“Today's approval marks a pivotal moment for people living with familial chylomicronemia syndrome. As a patient myself and having spoken with countless others living with FCS through leading our organization, I know firsthand how devastating the burden of FCS is on every dimension of daily life. The constant uncertainty, the worry, the fear of acute pancreatitis, the chronic pain and fatigue are challenges the FCS community faces every single day, on top of the long and often frustrating journey to receiving a diagnosis,” added Rosa Pérez Jiménez, President of Familial Chylomicronemia Association (Asociación de Quilomicronemia Familiar) Spain. “This new therapeutic option gives renewed hope to patients who have waited far too long to be seen, understood, and treated.”

Harnessing Arrowhead’s proprietary Targeted RNAi Molecule (TRiM™) platform, REDEMPLO is designed to suppress production of apolipoprotein C-III (APOC3), a protein produced in the liver that raises triglyceride levels by inhibiting their breakdown and clearance.

“We are pleased to have received EC approval for REDEMPLO as a new treatment option for people living with genetically or clinically confirmed FCS. With this approval secured, we are engaging with relevant national authorities and healthcare communities across the European Union to bring REDEMPLO to people living with FCS as quickly and efficiently as possible,” said Christopher Anzalone, Ph.D., President and CEO at Arrowhead Pharmaceuticals. “This ongoing cadence of regulatory approvals around the world reflects the strength of our clinical data and the real progress being made across our diverse pipeline of siRNA-based therapies that leverage our proprietary TRiM™ platform.”

EC regulatory approval was supported by clinical data from the Phase 3 PALISADE study, a randomized, double-blind, placebo-controlled trial in 75 adults with clinically diagnosed or genetically confirmed FCS.[1,2] The PALISADE study met its primary endpoint and all multiplicity-controlled key secondary endpoints. In PALISADE, 25 mg REDEMPLO reduced triglycerides by a median of 80% from baseline versus a 17% reduction with placebo. Additionally, the combined doses of 25 mg and 50 mg plozasiran significantly reduced the incidence of acute pancreatitis (odds ratio, 0.169; p=0.0292). The odds of acute pancreatitis were 83% lower in the pooled plozasiran groups compared with the placebo group. The most common adverse reactions were hyperglycaemia (12.8%), headache (6.8%), nausea (4.7%), and injection site reaction (4.7%).[1,2]

About Familial Chylomicronemia Syndrome (FCS)

Familial chylomicronemia syndrome is a severe and rare disease leading to extremely high triglyceride (TG) levels, typically over 10 mmol/L (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 currently approved by the U.S. Food and Drug Administration, Health Canada, China's National Medical Products Administration, the Australian Therapeutic Goods Administration, and by the European Commission as an adjunct to diet to reduce triglycerides for adults with FCS. REDEMPLO is the first and only siRNA treatment approved in these countries to be studied in both clinically diagnosed and genetically confirmed patients living with FCS.

REDEMPLO is designed to suppress the production of apolipoprotein C-III (APOC3), a protein produced in the liver that raises triglyceride levels by slowing their breakdown and clearance. By targeting APOC3 with sustained silencing, REDEMPLO delivers significant reductions in triglyceride levels. REDEMPLO is self-administered via subcutaneous injection once every three months.

REDEMPLO has been granted Orphan Medicinal Product Designation by the EMA for the treatment of patients with FCS, and Breakthrough Therapy

Designation, Fast Track Designation, and Orphan Drug Designation by the U.S. FDA for the treatment of patients with FCS. In December 2025, plozasiran was also granted Breakthrough Therapy designation by the U.S. FDA in severe hypertriglyceridemia.

Plozasiran is also being investigated in the SHASTA-3 (NCT06347003), SHASTA-4 (NCT06347016), and SHASTA-5 (NCT06880770) Phase 3 studies in adults with severe hypertriglyceridemia and the MUIR-3 (NCT06347133) Phase 3 study in adults with hypertriglyceridemia.

About Arrowhead Pharmaceuticals

Arrowhead Pharmaceuticals (NASDAQ: ARWR) is a commercial-stage pharmaceutical company developing medicines that treat intractable diseases by silencing the genes that cause them, harnessing the natural RNA interference (RNAi) mechanism. The company has built a broad portfolio of clinical and commercial RNAi therapeutics through its industry-leading targeted RNAi molecule (TRiM™) platform, which can precisely silence genes in a wide range of cell types, including liver, lung, muscle, adipose, and central nervous system tissue. At Arrowhead, we rapidly advance potential best- and first-in-class RNAi treatments for diseases with significant unmet medical need, because every day matters to the patients we serve.

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 candidates 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 if approved; 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 the safety and efficacy of our products and product candidates, pricing and reimbursement decisions related to our products if approved, 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.

References

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2. Watts GF, Hegele RA, Rosenson RS et al. Temporal Effects of Plozasiran on Lipids and Lipoproteins in Persistent Chylomicronemia. Circulation. 2025:151(10); 733-736; https://doi.org/10.1161/CIRCULATIONAHA.124.072860 PMID:39549263.

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