



Arrowhead Pharmaceuticals Granted Entry in the FDA STAR Pilot Program for Plozasiran in Severe Hypertriglyceridemia

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- FDA STAR pilot program aims to shorten the time from complete supplement submission to the action date to allow earlier patient access to therapies that address an unmet medical need

PASADENA, Calif.--(BUSINESS WIRE)--Oct. 7, 2026-- [Arrowhead Pharmaceuticals, Inc.](#) (NASDAQ: ARWR) today announced that the United States Food and Drug Administration (FDA) has granted plozasiran entry in the Split Real Time Application Review (STAR) pilot program in connection with Arrowhead's upcoming supplemental new drug application (sNDA) for severe hypertriglyceridemia (sHTG). sHTG is a condition that significantly increases the risk of acute pancreatitis, which is associated with repeated hospital admissions and can be fatal.

The FDA STAR pilot program aims to shorten the time from the date of a complete sNDA submission to the action date for certain supplemental indications for already-approved drugs. To be granted entry in the STAR program, FDA must determine that clinical evidence from adequate and well-controlled investigation(s) indicates that the drug may demonstrate substantial improvement on a clinically relevant endpoint(s) over available therapies.

Once accepted into the STAR program, a supplemental application qualifies for a 6-month Priority Review compared to a 10-month standard review. In addition, FDA will generally target an "expedited review" for efficacy supplements in the STAR program, meaning an action at least 1 month before the Priority Review goal date is possible. The use of a Priority Review Voucher (PRV) is not necessary for programs that are granted entry in the STAR program, so Arrowhead retains the PRV previously purchased in August 2026.

"We are committed to pursuing every potential opportunity to accelerate the process of bringing plozasiran to patients, and the FDA STAR Pilot program provides important benefits to sponsors with efficacy supplements," said Christopher Anzalone, Ph.D., President and CEO at Arrowhead. "In addition, earning Priority Review for plozasiran without the need to use a PRV gives us the option to redeploy our voucher for a future application or monetize it."

Arrowhead is on schedule to submit a sNDA for plozasiran in sHTG to the FDA by year-end 2026 and plans to seek regulatory approval with additional global regulatory authorities thereafter. Plozasiran has received regulatory approval, as REDEMPLO[®], in the United States, the European Union, China, Australia, and Canada as an adjunct to diet to reduce triglycerides in adults with genetically confirmed or clinically diagnosed familial chylomicronemia syndrome (FCS), which is the most severe form of sHTG.

About Severe Hypertriglyceridemia

Severe hypertriglyceridemia (sHTG) is characterized by triglyceride (TG) levels greater than 500 mg/dL, with the most severe form being familial chylomicronemia syndrome (FCS) where TGs typically exceed 880 mg/dL. sHTG significantly increases the risk of acute pancreatitis (AP), which can often include recurrent attacks requiring repeat hospital admissions and worsening outcomes. AP risk is proportional to the number, characteristics, and concentration of triglyceride rich lipoproteins (TRLs), particularly chylomicrons, and increases as TGs rise. Elevated TGs can also increase the risk of atherosclerotic cardiovascular disease (ASCVD). Limited treatment options exist to sustainably reduce TGs below guideline directed risk thresholds.

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 and was also granted Breakthrough Therapy designation by the U.S. FDA in severe hypertriglyceridemia.

Sanofi acquired the rights to develop and commercialize REDEMPLO in Greater China, with Arrowhead retaining rights to REDEMPLO in all geographies, outside of Greater China.

For more information about REDEMPLO, visit [Our Medicines](#).

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 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 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 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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