

## Amvuttra® (vutrisiran) - New indication

- On March 20, 2025, <u>Alnylam announced</u> the FDA approval of <u>Amvuttra (vutrisiran)</u>, for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits.
- Amvuttra is also approved for the treatment of the polyneuropathy of hereditary transthyretinmediated amyloidosis (hATTRPN) in adults.
- The approval of Amvuttra for the new indication was based on a randomized, double-blind, placebo-controlled study (HELIOS-B) in 654 adult patients with wild-type or hereditary ATTR-CM. Patients were randomized to receive Amvuttra or placebo. The primary endpoint was the composite outcome of all-cause mortality and recurrent cardiovascular (CV) events (CV hospitalizations and urgent heart failure visits) during the double-blind treatment period of up to 36 months, evaluated in the overall population and in the monotherapy population (defined as patients not receiving tafamidis at study baseline).
  - Amvuttra led to significant reduction in the risk of all-cause mortality and recurrent CV events compared to placebo in the overall and monotherapy population of 28% (p = 0.01) and 33% (p = 0.02), respectively.
  - Both components of the primary composite endpoint individually contributed to the treatment effect in the overall and monotherapy population.
- The recommended dose of Amvuttra is 25 mg administered by subcutaneous injection once every 3 months.
  - Amvuttra should be administered by a healthcare professional.



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