Continuous Acoramidis Treatment Significantly Reduced Risk of All-Cause Mortality and Cardiovascular-Related Hospitalization Through Month 42 in Participants with Wild-Type and Variant Transthyretin Amyloidosis Cardiomyopathy

This is a plain language information of the oral presentation by Grogan M, et al., presented at the Heart Failure Society of America (HFSA) Annual Scientific Meeting
September 26–29, 2025, Minneapolis, MN, USA

WHAT IS ATTR – CM ?

- Transthyretin amyloid cardiomyopathy, or ATTR-CM for short, is a serious heart condition caused when a protein called transthyretin (TTR for short) becomes unstable, breaks apart, and misfolds into harmful clumps called **amyloid fibrils**. These fibrils build up in the heart, making it stiff and less able to pump blood properly and can lead to heart failure
- ATTR-CM can occur because of older age, known as wild-type ATTR-CM (ATTRwt-CM for short), or when a faulty version of the *TTR* gene is passed on in families, known as variant ATTR-CM (ATTRv-CM for short)
- ATTR-CM usually starts sooner and gets worse faster in people with ATTRv-CM than in people with ATTRwt-CM

WHAT IS ACORAMIDIS?

- Acoramidis is an oral (taken by mouth) medicine that works by tightly binding and stabilizing the TTR protein, preventing it from breaking apart and depositing harmful fibrils in the heart. It works very effectively, keeping more than 90% of TTR stable
- Acoramidis is approved in the USA, Europe, Japan, and the UK for the treatment of ATTRwt-CM and ATTRv-CM in adults

WHY DID THE INVESTIGATORS CONDUCT THIS STUDY?

- In the ATTRibute-CM study, participants with ATTR-CM who received acoramidis had a lower risk of death or first hospitalization due to heart issues (also known as cardiovascular-related hospitalization, or **CVH** in short) compared with participants who received **placebo**
- In the **open-label extension** phase of ATTRibute-CM, participants who received continuous treatment with acoramidis had a lower risk of death or first CVH or both for 42 months compared with participants who switched from placebo to acoramidis
- Researchers wanted to see if acoramidis had the same effects in lowering the risk of death or CVH in participants with ATTRv-CM or ATTRwt-CM who received continuous acoramidis for 42 months compared with those who switched from placebo to acoramidis

WHAT WAS THE PURPOSE OF THIS STUDY?

- The study looked at the effect of acoramidis on the risk of death or CVH over 42 months in participants who received continuous acoramidis for 42 months and in those who received placebo for 30 months, then switched to acoramidis through Month 42

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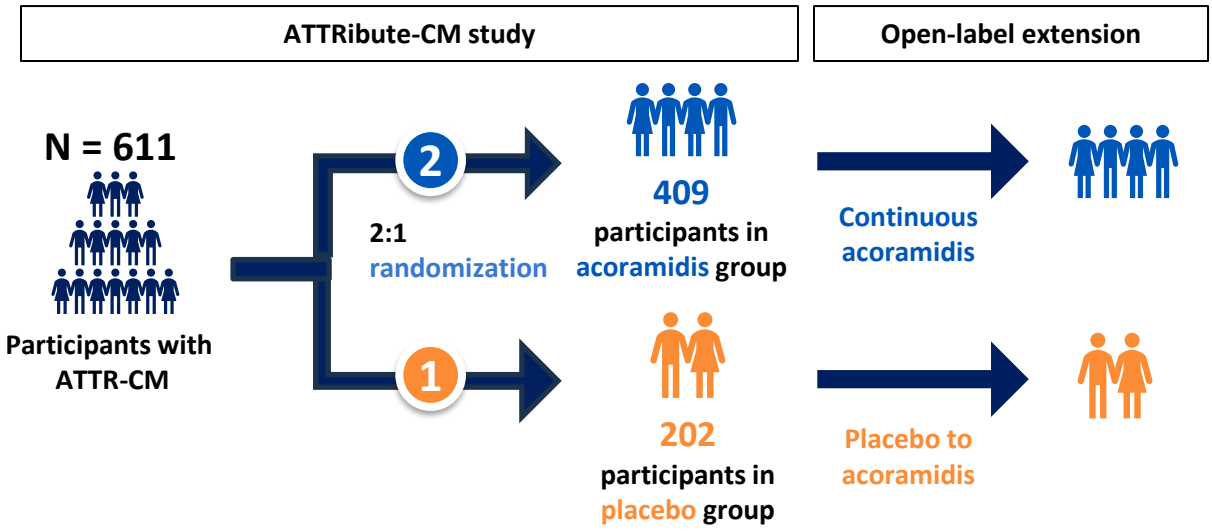
WHO TOOK PART IN THIS STUDY?



- There were 59 participants with ATTRv-CM and 552 with ATTRwt-CM at the start of the study (baseline)
- Of the 611 participants at baseline, 380 entered the open-label extension phase

WHAT WERE THE KEY FINDINGS?

- At baseline, participants in acoramidis and placebo groups had similar characteristics
- At the start of the open-label extension, the placebo-to-acoramidis group had a higher proportion of participants with a more advanced disease
- Participants who received continuous acoramidis had lower risks of death from any cause, first CVH, or a combination of both than those who switched from placebo to acoramidis
  - This effect was similar in both participants with ATTRv-CM and participants with ATTRwt-CM

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CONTINUOUS ACORAMIDIS REDUCED THE RISKS OF DEATH OR FIRST CVH COMPARED WITH PLACEBO TO ACORAMIDIS AT 42 MONTHS

	All participants	Participants with ATTRv-CM	Participants with ATTRwt-CM
Reduction in the risk of death	36%	59%	30%
Reduction in the risk of death or first CVH	43%	65%	40%
Reduction in the risk of first CVH	47%	70%	42%

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WHAT DO THE RESULTS MEAN?

- Continuous acoramidis treatment through Month 42 reduced the risks of death or first CVH compared with placebo to acoramidis in both ATTRv-CM and ATTRwt-CM
- These results highlight the benefits of taking acoramidis long term regardless of the type of ATTR-CM and the importance of starting treatment early

IS ACORAMIDIS APPROVED BY HEALTH AUTHORITIES?

- On November 22, 2024, the US Food and Drug Administration approved acoramidis to treat adults with heart problems caused by ATTR-CM. The treatment aims to lower the risk of death from heart disease and reduce hospital stays related to heart issues
- On February 10, 2025, the European Commission approved acoramidis for use in the European Union to treat adults with heart disease caused by ATTR-CM
- Acoramidis was approved by the Japanese Ministry of Health, Labour and Welfare on March 27, 2025, for the treatment of adults with ATTR-CM
- Acoramidis was approved by the UK's Medicines and Healthcare products Regulatory Agency on April 24, 2025. Patients should speak to their doctors for more information

GLOSSARY

- **Amyloid fibrils:** proteins that clump together into strands
- **Cardiovascular hospitalization (CVH):** hospitalization caused by heart-related issues
- **Placebo:** a sugar or dummy pill without any medication
- **Open-label extension:** a follow-up part of a clinical study in which all participants receive the active medicine
- **Randomization:** a process wherein whether a participant gets active medicine or placebo in a study. It is decided by random chance using a computer program

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