# ACORAMIDIS REDUCES ALL-CAUSE MORTALITY (ACM) AND CARDIOVASCULAR-RELATED HOSPITALIZATION (CVH): INITIAL OUTCOMES FROM THE ATTRibute-CM OPEN-LABEL EXTENSION (OLE) STUDY

This is plain language information of the poster presentation by Judge DP, et al, presented at the American Heart Association Scientific Sessions 2024,
16 – 18 November 2024; Chicago, IL, US

## WHAT IS ATTR-CM ?

- Transthyretin amyloid cardiomyopathy, or ATTR-CM for short, is a type of heart disease that occurs when the transthyretin, or TTR, protein misfolds and forms amyloid fibrils. These amyloid fibrils then accumulate in the heart muscle, leading to thickening and stiffening of the heart walls, thereby reducing its ability to pump blood effectively.

## WHAT IS ACORAMIDIS?

- **Acoramidis is an investigational medicine** that is designed to stabilize the TTR protein and prevent it from misfolding and forming harmful amyloid fibrils.
- Therefore, there is reduced accumulation of amyloid fibrils in the heart (and other tissues of the body), thus slowing down the worsening of heart failure. It was studied in people with ATTR-CM in a clinical study called ATTRibute-CM.

## WHAT IS ATTRibute-CM?

- ATTRibute-CM is a clinical trial that investigated how effective and safe acoramidis is for the treatment of ATTR-CM. The study was carried out in 80 centers throughout the world and lasted for 30 months.
- In the ATTRibute-CM study, participants with heart failure due to ATTR-CM who received acoramidis showed improved clinical outcomes over 30 months compared to those who received a **placebo** (dummy pill).
- Participants who completed Month 30 in ATTRibute-CM trial were invited to enroll in the Open-Label Extension (OLE) study.

## WHAT IS THE OPEN-LABEL EXTENSION (OLE) STUDY?

- OLE is an open-label extension study, meaning both investigators and participants know which treatment is being given. All participants receive acoramidis. The study evaluates the long-term safety, tolerability and effects of acoramidis in people with ATTR-CM.

## WHAT IS THE PURPOSE OF THE OLE STUDY?

- To check how acoramidis affects death due to any cause or **all-cause mortality** (**ACM** in short) and risk of hospitalization due to **cardiovascular** issues (also known as cardiovascular-related hospitalization, or **CVH** in short) for up to 42 months in the OLE study.

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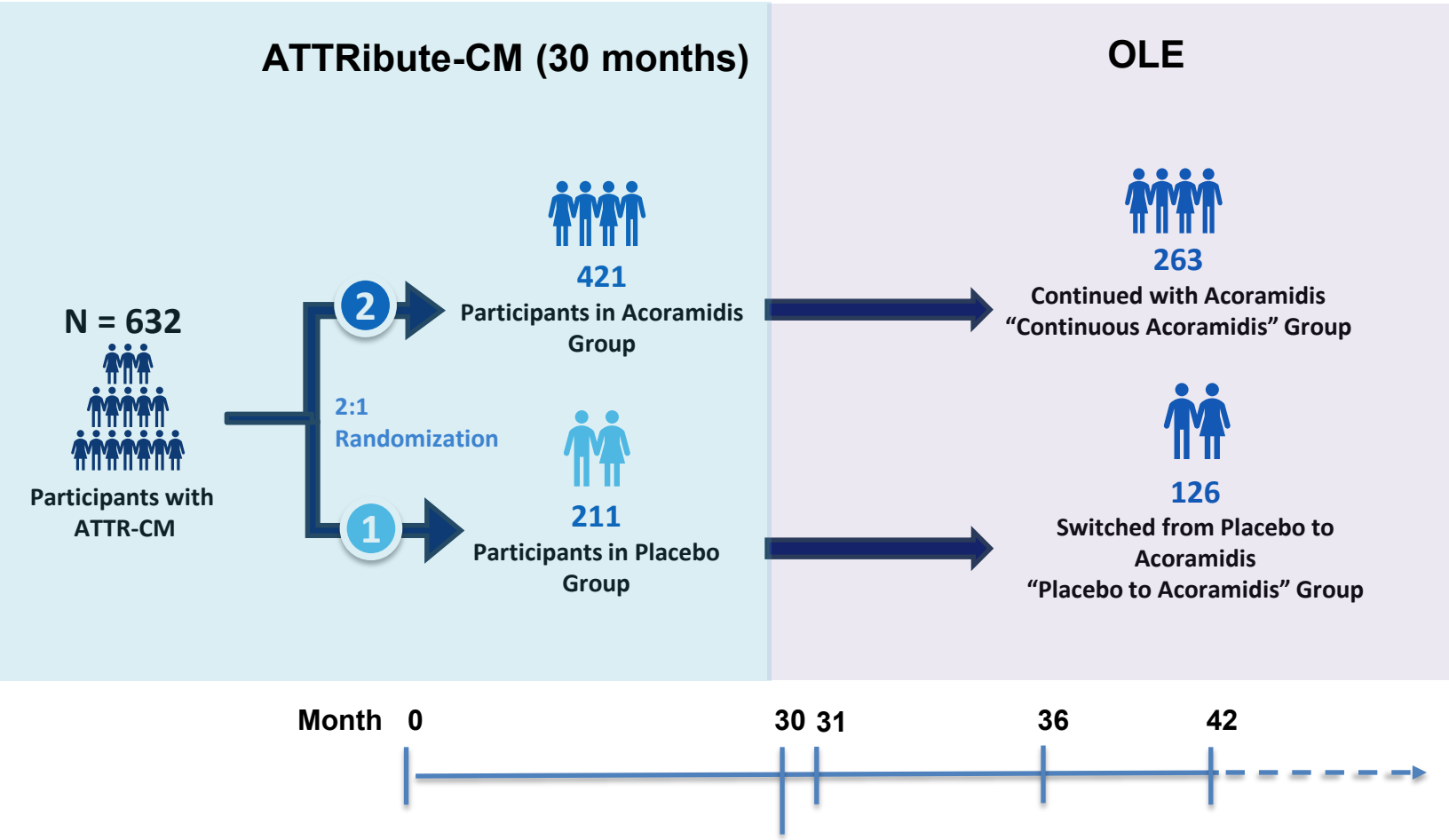
## WHO TOOK PART IN THIS STUDY?







- A total of 438 participants completed Month 30 treatment in ATTRibute-CM and were invited to join the OLE.
- Out of these, 389 participants met the criteria to join OLE, which included stopping any open-label tafamidis they were taking during ATTRibute-CM.
- Of these 389 participants,
  - 263 participants who received acoramidis in the ATTRibute-CM trial continued to receive acoramidis in the OLE; this is the continuous acoramidis arm, and
  - 126 participants who received placebo in ATTRibute-CM switched to open-label acoramidis, which is the placebo to acoramidis group in the OLE.

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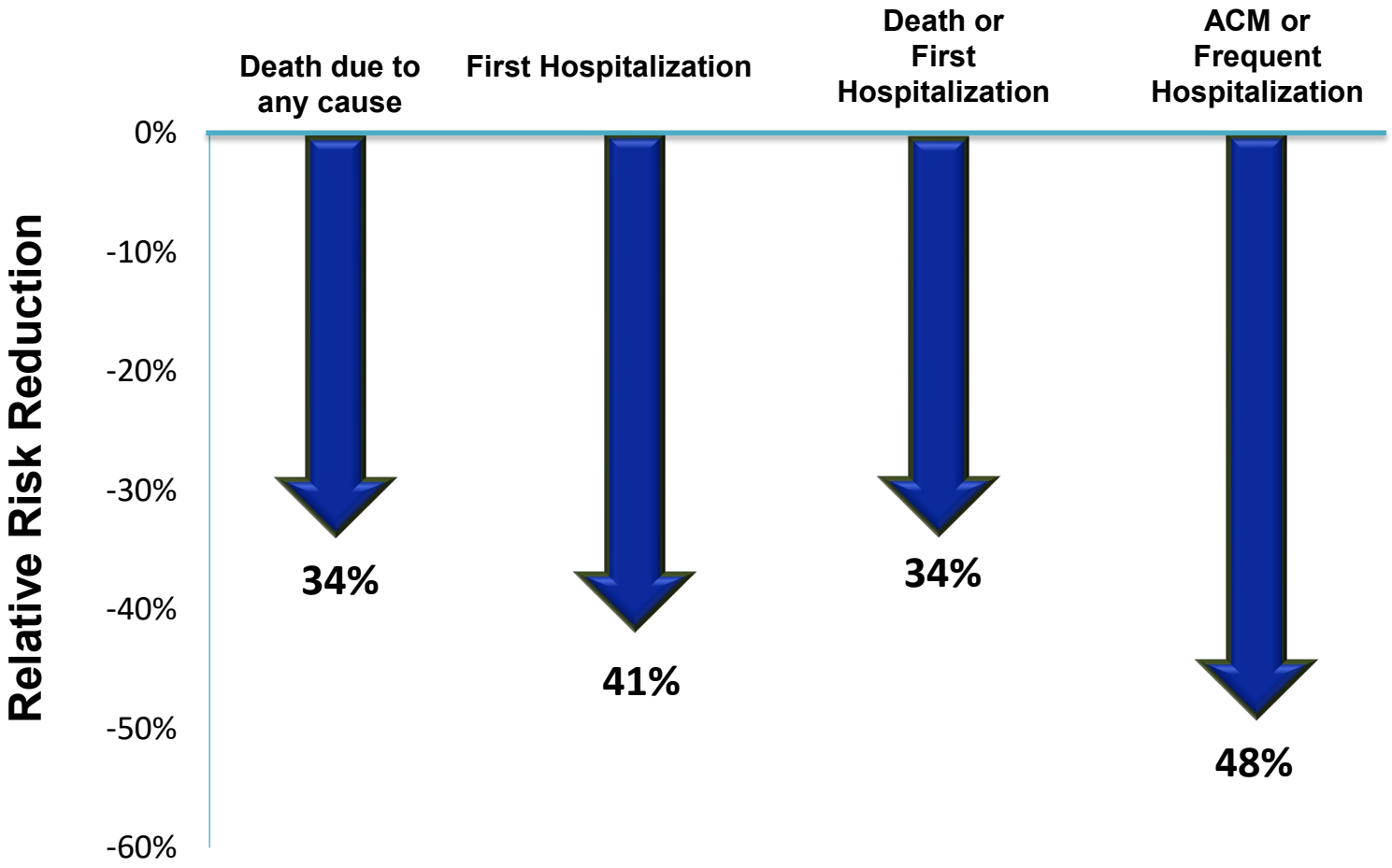
## WHAT WERE THE KEY FINDINGS?

Continuous treatment with acoramidis reduces the risk of death and hospitalizations at Month 42 in the OLE Study




## WHAT WERE THE SAFETY FINDINGS?

- No new safety signals were identified with long-term treatment of acoramidis.

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## WHAT DO THE RESULTS MEAN?

- Patients who took acoramidis continuously for 42 months had much lower risks of death, first hospitalization due to heart-related issues, death or first CVH, and death or frequent CVH.
- No new safety signals of potential clinical concerns were identified up to Month 42 with acoramidis treatment.
- This study shows how crucial it is to diagnose ATTR-CM early and start treatment quickly to improve patient outcomes.

## IS ACORAMIDIS APPROVED BY HEALTH AUTHORITIES?

- Acoramidis is an investigational drug and is not approved by any health authority.

## GLOSSARY

- **All-Cause Mortality:** Death due to any reason or all causes, including because of heart issues. It also includes participants who received heart transplant, or implantation of devices (known as cardiac mechanical assist device) in the participant's heart to improve its function.
- **Cardiovascular:** The system in the body that includes the heart (cardio-) and blood vessels (vascular).
- **Cardiovascular Hospitalization (CVH):** Hospitalization that is caused by cardiovascular-related issues.
- **Placebo:** Sugar or dummy pill without any medication.
- **Randomization:** A process wherein whether a participant gets acoramidis or placebo in a study is decided by random chance using a computer program.

*This study was funded by BridgeBio Pharma, Inc. San Francisco, CA, US.*



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