Statistical analysis plan for

# ANGIOTENSIN–NEPRILYSIN INHIBITION IN DIASTOLIC DYSFUNCTION AFTER AMI

# the ARNiAMI study

## 1 Data analysis

Data required by the protocol will be entered into an internet based Electronic Case Report Form using fully validated RedCap software. Data storage will be managed by Odense Patient data Explorative Network (OPEN). The full analysis set will consist of all randomized patients. Following the intent to treat principle, patients will be analyzed according to the treatment to which they were assigned at randomization, and efficacy variables will be analyzed based on the full analysis set.

### 1.1 Baseline characteristics

Summary statistics will be provided by treatment group for demographics and baseline characteristics. Continuous variables will be summarized using n, mean, standard deviation or median, 25'th and 75' percentile depending on distribution of data. Categorical variables will be summarized using frequency and percentage. The difference between treatment groups will be compared using the Chi-square test, t-test or Mann-Whitney, as appropriate. A p value <0.05 will be considered statistically significant.

### 1.2 Analysis of primary endpoint

Primary endpoint, PCWP/CI ratio, will be analyzed using ANCOVA or mixed effects models with treatment as fixed effect factor with the intention-to-treat priciple. Additionally, the baseline value of the corresponding variable may be included as a covariate if appropriate. The estimated treatment effect and the corresponding two-sided 95% confidence interval will be provided.

### 1.3 Analysis of secondary endpoints

The secondary hypotheses will be tested and statistical inferences will be made only if the primary hypothesis is rejected. The five secondary efficacy variables will be tested for superiority of LCZ696 to placebo for all randomized patients following the intent-totreat principle.

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