**GUIDE-HF: Hemodynamic-guided management of heart failure – randomized arm primary outcomes**

**Purpose:** To evaluate whether pulmonary artery (PA) pressure-guided heart failure management leads to a clinical benefit in a broad range of heart failure patients (NYHA Class II, III, or IV), with either a recent hospitalization for heart failure or elevated natriuretic peptides.

**Trial Design:** Single blind, randomized controlled trial of PA pressure-guided therapy in NYHA class II-IV pts. (N=1000) with either HF hospitalization or elevated natriuretic peptide. Pts. received an implantable PA pressure sensor (CardioMEMS HF System) followed by randomization to either treatment group with provider remote access, or control group without provider access. Median follow-up 11.7 months.

**Primary Endpoints:** Composite of all-cause mortality and total heart failure events (heart failure hospitalizations and urgent heart failure hospital visits) at 12 months. The pre-COVID impact analysis included all primary endpoints up to March 13, 2020.

<table>
<thead>
<tr>
<th></th>
<th>Remote Hemodynamic Guided Care (n=497)</th>
<th>Standard Care (no access to PA pressures) (n=503)</th>
<th>HR (95%CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall primary endpoint analysis</td>
<td>253</td>
<td>289</td>
<td>0.88 (0.74-1.05)</td>
<td>0.16</td>
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Components of overall primary endpoint:

- HF events: 213 vs. 252, HR 0.85 (0.70-1.03), P = 0.096
- Urgent HF hospital visits: 28 vs. 27, HR 1.04 (0.61-1.77), P = 0.89
- HF hospitalizations: 185 vs. 225, HR 0.83 (0.68-1.01), P = 0.064
- Death: 40 vs. 37, HR 1.09 (0.70-1.70), P = 0.71

Pre-COVID impact analysis-primary endpoint:

- HF events: 147 vs. 199, HR 0.76(0.61-0.95), P = 0.014
- Urgent HF hospital visits: 23 vs. 23, HR 1.02 (0.57-1.82), P = 0.95
- HF hospitalizations: 124 vs. 176, HR 0.72 (0.57-0.92), P = 0.0072
- Death: 30 vs. 25, HR 1.24 (0.73-2.11), P = 0.42

**Results:**

Hemodynamic-guided management across the spectrum of ejection fraction and symptom severity was safe but did not reduce a composite of mortality and heart failure events.

COVID-19 pandemic impacted the outcomes of the trial. The pre-COVID impact analysis indicated a benefit of hemodynamic-guided management on the primary outcome in the pre-COVID-19 period, primarily driven by a lower HF hospitalization rate (28%) compared to control group.

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Results reflect the data available at the time of presentation.