FOR IMMEDIATE RELEASE

STRONG-HF study in patients admitted for acute heart failure (HF) terminated early for superior efficacy

DURHAM, NC, Sept. 28, 2022 -- Heart Initiative, the sponsor of the STRONG-HF (Safety, Tolerability and efficacy of Rapid Optimization, helped by NT-proBNP testinG, of Heart Failure therapies) study, announced today the premature termination of the trial. The decision was made after discussion with the study's executive committee, the study PI (Dr. Alexandre Mebazaa) and the Coordinating Center (Momentum Research, Durham, NC represented by Dr. Gad Cotter and Dr. Beth Davison), based on a recommendation from the Data Safety Monitoring Board (DSMB) to stop the study. The DSMB recommended to terminate the study early due to a significantly lower risk of the primary endpoint – 180-day all-cause death or heart failure (HF) readmission – in the "high intensity care" arm as compared to the "usual care" arm.

STRONG-HF is a randomized, multi-center, therapeutic strategy trial, designed to assess the safety and efficacy of early and rapid optimization of oral HF therapy supported by frequent visits and NT-proBNP measurements in patients after an acute HF admission. Guideline-recommended oral HF medications for patients in the "high intensity care" arm were up-titrated to half optimal doses at discharge and to full optimal doses at 2 weeks post-discharge with safety visits 1 week after any up-titration and follow-up visits at 6 weeks and 3 months. At each visit, patients were assessed by physical examination for congestion and blood tests including NT-proBNP measurements.(1,2)

It was planned to enroll 1,800 patients in STRONG-HF. The DSMB decision was based on examination of data of approximately 1,000 patients who had at least 90 days follow-up.

Acute HF is a major contributor to morbidity and mortality of patients with heart failure (HF).(3) Patients admitted for acute HF are at high risk of readmission and death, especially in the first months after hospital discharge.(4, 5) Recent analysis from a US registry showed that only a small percentage of patients with HF with reduced ejection fraction are treated with full doses of all guideline directed medical therapies.(6)

The study is an Investigator Initiated Study sponsored by Heart Initiative, Durham, North Carolina, USA and supported by Roche Diagnostics International Ltd. The coordinating center for the study was Momentum Research, Inc. from Durham, North Carolina, USA.

The full STRONG-HF trial results will be presented at the upcoming meeting of the American Heart Association, Nov 7th 2022 at 8:00 AM and submitted for publication shortly.

About Heart Initiative

The Heart Initiative is a non-profit organization created in 2009 whose mission is, through research, to increase public awareness and knowledge of cardiovascular diseases particularly heart failure, and to improve the early diagnosis and treatment of cardiovascular diseases through increasing usage of proven therapies and improving adherence. https://www.worldheartinitiative.org/

References:

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