Media & Investor Release

STRONG-HF study results demonstrate clear benefits for acute heart failure patients

- **STRONG-HF study primary outcomes showed significant reduction of all cause death or acute heart failure readmissions, at day 180, when the study strategy was implemented**
- **Rapid, simultaneous up-titration of therapies, and close follow-up, led to increased patient quality of life.**
- **The Roche Elecsys® NT-proBNP biomarker is an integral part of the treatment strategy, comprising rapid up-titration and close follow up after an acute heart failure admission.**

Basel, 08 November 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced publication of the Safety, Tolerability and Efficacy of Rapid Optimization of Heart Failure (STRONG-HF) study in patients hospitalized for acute heart failure. The study, which includes utilization of the Roche Elecsys NT-proBNP biomarker, was terminated early for superior efficacy in the active arm of the study versus the usual standard of care, as it was considered unethical to continue with usual care.

Implementing the study's strategy in routine clinical practice has the opportunity to significantly reduce all cause deaths or heart failure readmissions and increase quality of life for more heart failure patients, evaluated after six months, compared to current patient management practices. The results have been shared at the American Heart Association (AHA) Late-Breaking Scientific Session and published simultaneously in the Lancet.

"We are very excited about the positive outcome of this Investigator Initiated Study, which Roche supported, as it has the potential to bring about a paradigm shift in the management of heart failure patients," said Thomas Schinecker, CEO of Roche Diagnostics. "It also emphasizes how diagnostic solutions like NT-proBNP, embedded in a therapeutic strategy, are an integral part of improving patient care."

Acute heart failure (AHF) is a major contributor to morbidity and mortality of patients with heart failure.[1] Patients admitted for acute heart failure are at high risk of readmission and death, especially in the first months after hospital discharge.[2] A recent analysis, from the United States, showed that only 1% of patients with heart failure with a reduced ejection fraction are on the optimal dose of guideline-directed medical therapy.[3]

The STRONG-HF study outlines that guideline-recommended therapies for heart failure can be safely up-titrated at the end of an acute heart failure admission, and after discharge, under strict follow-up and assessment of signs and symptoms of congestive heart failure, renal

function, potassium and Roche Elecsys NT-proBNP. Prior to this study, there has been little data on the therapeutic approach for patients after an acute heart failure admission, including which medications should be prescribed, at which doses, and based on what follow-up the patients get. This has led clinicians to be cautious to up-titrate too quickly when they are unsure how this could affect their patients.

About STRONG-HF

STRONG-HF is a multinational, open-label, randomized, prospective clinical trial designed to assess the safety and efficacy of early and rapid up-titration of optimisation of heart failure therapies, including guideline-recommended, frequent NT-proBNP measurements and close follow-up in patients admitted to a hospital for acute heart failure.

AHF patients who were not treated with full doses of guideline-directed medical therapies (GDMT) were randomized just prior to discharge 1:1 to either usual care (UC) or high-intensity care (HIC) in which therapies were up-titrated to 100% of recommended doses within two weeks, with four outpatient visits over two months encompassing close monitoring of clinical signs and laboratory parameters, including NT-proBNP.

The study enrolled 1,078 of the initially planned 1,800 patients at the time of termination for superior efficacy, as it was considered unethical to continue with usual care.

The primary endpoint showed an absolute risk reduction of 8.1 % and a relative risk reduction of 34% in all-cause mortality or heart failure (HF) readmission 6 months after enrollment in the high-intensity care arm (ARR 8·1%, p=0·0021; NNT = 12; RR 0·66; high intensity care (HIC) vs. usual care (UC). The risk of all cause mortality or hospital readmission was 15.2 % lower in the high intensity care arm using NT-proBNP to inform titration of oral HF medications vs. 23.3% in the usual care arm without routine NT-proBNP testing and frequent visits.

Quality of life was higher in patients in the HIC arm (EQ-5D visual analog scale (VAS) 3·49 points higher in favor of HIC arm (p<0·0001)).

The number of adverse events (AEs) was increased, most notably those related to blood pressure decrease, hyperkalemia, renal impairment, and bradycardia. (HIC 41.1%, UC 29.5%). However, the increase in AEs did not translate into an increase in serious adverse events, nor fatal adverse events, especially no increase in cardiovascular AEs or SAEs. The increase in adverse events can also be explained by the higher frequency of follow-up, which may have created a bias towards more AE detection and reporting in the HIC arm.

The study is an Investigator Initiated Study sponsored by the Heart Initiative, Durham, North Carolina, United States, and supported with a research grant and diagnostic products by Roche Diagnostics.

About Elecsys NT-proBNP

Tests for NT-proBNP, a cardiac hormone that is released into the blood when the heart wall is stretched, are developed by Roche. The Roche Elecsys NT-proBNP is an objective biomarker for the aid in diagnosis in individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and congestive heart failure and as an aid in assessment of increased risk of cardiovascular events and mortality in patients at risk for heart failure who have stable coronary artery disease.[4] The Elecsys electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

References

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[4] NT-proBNP method sheet

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