CLINICAL PROTOCOL SYNOPSIS

# STUDY TITLE

A Registry-based, Randomised, Double-blind, Placebo-Controlled Cardiovascular Outcomes Trial to Evaluate the Effect of Dapagliflozin on Cardiometabolic Outcomes in Patients without Diabetes with Acute Myocardial Infarction at Increased Risk for Subsequent Development of Heart Failure

# CLINICAL PHASE

Phase 3

# STUDY OBJECTIVES

primarysecondaryexploratory

# STUDY RATIONALE

Approximately 7 million individuals suffer myocardial infarction annually, with survivors at high risk for new cardiovascular events and heart failure development. Dapagliflozin has shown cardioprotective effects in previous studies, potentially preventing heart failure and reducing cardiovascular risk.

# STUDY POPULATION

Non-diabetic patients presenting with myocardial infarction (STEMI or NSTEMI) and impaired left ventricular systolic function

# MAIN INCLUSION/EXCLUSION CRITERIA

Inclusion: Age ≥18, confirmed MI within 7-10 days, impaired LV systolic function. Exclusion: Known diabetes, chronic symptomatic heart failure, severe renal disease, active malignancy

# PRIMARY ENDPOINT(S)

Hierarchical composite endpoint including death, heart failure hospitalization, non-fatal MI, AF/flutter, new onset T2DM, NYHA class, and body weight decrease

# SECONDARY & EXPLORATORY ENDPOINTS

CV death, MI, stroke, hospitalizations, new onset diabetes, body weight changes

# STUDY DESIGN

Multicentre, parallel group, randomized, double-blind, placebo-controlled registry-based trial in Sweden and UK

# SUBJECT NUMBER

Approximately 4000 patients

# TREATMENT DURATION

Minimum 3 months follow-up for each patient

# DURATION OF FOLLOW UP

Minimum 3 months per patient

# DOSE LEVEL(S) AND DOSE JUSTIFICATION

Dapagliflozin 10 mg once daily

# ROUTE OF DELIVERY

Oral

# DATA AND SAFETY MONITORING PLAN (DSMP)

Independent Data Monitoring Committee will review safety and conduct oversight

# STOPPING RULES

Study may be terminated early if clear beneficial or harmful effect is detected

# IMMUNE MONITORING & IMMUNOSUPPRESSION

Not specified

# SUPPORTING STUDIES

DECLARE-TIMI 58 and DAPA-HF trials

# ASSAYS/METHODOLOGIES

Registry-based data collection, clinical endpoint adjudication

# STATISTICAL ANALYSIS PLAN

Win-ratio method for primary endpoint, intention-to-treat analysis

# OUTCOME CRITERIA

Hierarchical composite of cardiovascular and cardiometabolic outcomes

# RISKS

Potential hypotension, volume depletion

# CLINICAL SITES

Hospitals in Sweden and United Kingdom

# CLINICAL OPERATIONS

Integrated with national clinical registries SWEDEHEART and MINAP

# ENROLLMENT

Consecutive screening of MI patients in coronary care units

# LONG TERM FOLLOW UP

Visits every 10 months until study closure

# TIMELINE

Approximately 30 months total study duration