The Invested Trial - High Dose Versus Standard Dose Influenza Vaccine In Patients With High Risk Cardiovascular Disease: Results From The Invested Trial

Purpose: Test the efficacy of high-dose trivalent (HD-IIV3) versus standard-dose quadrivalent influenza vaccine (IIV4) in patients with a history of recent hospitalization for acute myocardial infarction (MI) or heart failure (HF).

Trial Design: • Double-blind RCT. • 157 sites in US/Canada. • Total n = 5260, • HD-IIV3 n = 2630 with 3577 vacc. • IIV4 n = 2630 with 3577 vacc. • Post-MI (1 yr.) or HF hospitalization (2 yrs.) with one additional CV risk factor • Participants followed up to four times/yr. for three influenza seasons • >90% power to detect 18% RRR (HR 0.82)

Primary Endpoints: Composite of all-cause mortality or hospitalization for a cardiovascular or pulmonary cause

Secondary Endpoints: Total hospitalizations for CV or pulmonary causes or all-cause death, • Time to first occurrence of death due to CV causes or CV hospitalization, • Time to first occurrence of all-cause death or hospitalization due to CV or pulmonary causes, • Time to first occurrence of individual components of the primary efficacy endpoint

Results: HD-IIV3 did not reduce all-cause death or hospitalizations for cardiac or pulmonary causes compared with SD-IIV4.