DARE-19: Effects Of Dapagliflozin On Prevention Of Major Clinical Events And Recovery In Patients With Respiratory Failure Due To COVID-19

Purpose: This is an international, multicenter, parallel-group, randomized, double-blind, placebo controlled, study in hospitalized adult patients with COVID-19 in the US, Brazil, Mexico, Argentina, India, Canada, and UK. The study evaluates the effect of dapagliflozin 10 mg versus placebo, given once daily for 30 days in addition to background local standard of care therapy, on reducing complications and all-cause mortality, or improving clinical recovery.

Trial Design: N = 1250, Phase III randomized, double-blind trial to evaluate efficacy and safety of once daily dapagliflozin 10 mg compared to placebo.

Primary Endpoints: Prevention of COVID-19 Complications or death (during the 30-day treatment period, time to first occurrence of new/worsened organ dysfunction during index hospitalization or death from any cause); and improving clinical recovery.

Secondary Endpoints: Time to hospital discharge, the number of days alive and free from respiratory decompensation, time to composite of acute kidney injury or initiation of renal replacement therapy, time to death from any cause.

Outcome, n	Dapagliflozin 10mg (N=625)	Placebo (N=625)	Hazard Ratio (95% CI)
	Number of events (%)	Number of events (%)	
Primary composite outcome	70 (11.2%)	86 (13.7%)	0.80 (0.58 – 1.10)
New or worsening organ dysfunction	64 (10.2%)	80 (12.8%)	0.80 (0.57 -1.11)
Respiratory decompensation	58 (9.3%)	70 (11.2%)	0.85(0.60 1.20)
Cardiac decompensation	47 (7.5%)	58 (9.3%)	0.81 (0.55 1.19)
Kidney decompensation	24 (3.8%)	35 (5.6%)	0.65 (0.381.10)
Death from any cause	41 (6.6%)	54 (8.6%)	0.77 (0.52 -1.16)
Composite Kidney Endpoint	48 (7.7%)	65 (10.4%)	0.74 (0.50 – 1.07)
All-cause Mortality	41 (6.6%)	54 (8.6%)	0.77 (0.52 – 1.16)

Conclusion: DARE-19 failed to capture enough events to achieve statistical significance on its primary endpoints, reducing the risk of organ failure and death and improving recovery, but the data suggests that dapagliflozin is safe and well-tolerated in hospitalized patients in an acute setting.

Results reflect the data available at the time of presentation.

Presented by: Mikhail Kosiborod MD, Saint Luke's Mid-America Heart Institute