

**Title: HF 22: DELIVER Extends Benefits of Dapagliflozin to the Full Spectrum of Pts with HF**

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Dr Solomon:

My name is Dr. Scott Solomon. I'm Professor of Medicine at Harvard Medical School in Brigham and Women's Hospital in Boston. And today I'm going to talk about the DELIVER trial.

## DELIVER – Aims, Trial Design & Notable Features

Dr Solomon:

So, DELIVER is the largest trial that's ever been done in heart failure with mildly reduced and preserved ejection fraction. And it was designed to compare dapagliflozin 10 milligrammes once daily with placebo in patients with heart failure with evidence of structural heart disease with elevation natriuretic peptides.

We randomised 6,263 patients in DELIVER. Again, the largest trial ever been done in heart failure with preserved and mildly reduced ejection fraction. And we also enrolled patients who were either ambulatory or in hospital. They could have been enrolled while in the hospital, or recently hospitalised. Another notable feature about DELIVER in contrast to other trials in this population is that DELIVER allowed for patients who had heart failure with improved ejection fraction. In other words, patients whose ejection fraction was lower than 40% to start and then became over 40% after that.

## Trial Population

Dr Solomon:

Well, the trial population was very typical of heart failure with preserved ejection fraction. The majority of these patients were New York Heart Association class two. We had a median NT-proBNP of somewhere around a 1000. We had approximately 40% women. We had a very good geographic distribution. The study was done 350 sites and 20 countries.

## Differences in General Population Compared to Other Trials in HFpEF

Dr Solomon:

The trial was different from some of the earlier trials in heart failure with preserved ejection fraction because our LVEF cut-off went down to 40% in contrast for example to the PARAGON trial or the TOPCAT trial in which the cut-off was 45%. In addition, as I mentioned we included patients who had had recovered or improved left ventricular ejection fraction. This is a group of patients who had never been studied in any other prior trial.

## Sub-Groups of Note

Dr Solomon:

Well, the major subgroups that we've not tested in other trials or patients with heart failure with improved or recovered ejection fraction that's completely new. There have been very few trials that have also in this population that have also enrolled patients in hospital or recently hospitalised. And approximately 11% of our patients are recently hospitalised. Approximately 18% of our patients have improved or recovered ejection fraction.

## Asian Participants

Dr Solomon:

We have a very high proportion of Asian participants it's in the range of 20%. Again, one of the highest proportions of Asian participants of any clinical trial and heart failure with mildly reduced from preserved ejection fraction.

## Primary Endpoint

Dr Solomon:

DELIVER met its primary endpoint. We've announced the top line results but the full results I think will be extremely hallucinating DELIVER will really help us understand which patients we should be using SGLT2 inhibitors for.