Vericiguat Global Study in Subjects with Heart Failure with Reduced Ejection Fraction (VICTORIA)


Conclusions

All NYHA II
Canada
Singapore
USA
Co
EC Member
USA
Roessig
Germany
Primary outcome is the time to 1
Canada
Koglin
EC Member
Sponsor EC Member
USA
Screening phase
EC Member
S. Parikh
Elevated natriuretic Centre;
The VICTORIA trial will provide important insights
Vericiguat
Koglin
Study Chair
Secondary outcomes include:
in patients
on top
HFrEF (EF<45%)
Dose
The worsening of
Estimated
Voors
Total HF hospitalizations
sensitivity
Pieske
EC Member
Vericiguat is an oral soluble guanylate cyclase
Statistician EC Member
Co
~530 sites in 39 countries
Country
Echocardiography,
Roessig
Target enrollment of 4872 patients with the following:
Novel mechanism of action in HF augmenting on nitric
oxide pathways
• First patient enrollment date expected September 2016
• Estimated recruitment period 30 months
• Pre-specified economic and quality of life analyses
• Substudies for further phenotyping:
  • Echocardiography, Cardiac MRI, Biomarkers, Genomics

Background

• Vericiguat is an oral soluble guanylate cyclase stimulator (sGC) in development for chronic HF
• SOCRATES-REDUCED (Phase IIb): Vericiguat 10mg was well-tolerated and associated with reduced NT-proBNP in patients with HF with reduced EF (HFrEF)

Primary objective: To study the efficacy and safety of vericiguat vs. placebo on a background of usual standard care in HFrEF patients

Methods

• VICTORIA is a randomized, placebo-controlled, event-driven, multi-center, double-blind trial of vericiguat on top of standard of care vs. placebo
• Academic-industry partnership
• Target enrollment of 4872 patients with the following:
  • HFrEF (EF<45%)
  • NYHA II-IV on standard therapy
  • Prior HF hospitalization (6 months) or IV diuretic for HF without hospitalization (3 months)
  • Elevated natriuretic peptide level
  • Not taking long-acting nitrates
  • Primary outcome is the time to 1st occurrence of composite endpoint of CV mortality or HF hospitalization
• Secondary outcomes include:
  • Components of primary outcome
  • All-cause mortality
  • Total HF hospitalizations

Figure 1. Trial Organization and Executive Committee.

Figure 2. Trial diagram for VICTORIA

Study Design

• Screening phase of up to 30 days followed by dose titration (Figure)
• Dose titration will occur in a blinded fashion, based on blood pressures and symptoms at 2-week intervals

Study Highlights

• Novel mechanism of action in HF augmenting on nitric oxide pathways
• First patient enrollment date expected September 2016
• Estimated recruitment period 30 months
• Pre-specified economic and quality of life analyses
• Substudies for further phenotyping:
  • Echocardiography, Cardiac MRI, Biomarkers, Genomics

Discussion

• The worsening of chronic HF in patients with HF events despite standard care is associated with significant morbidity and mortality
• In patients with HF, endothelial dysfunction and oxidative stress may reduce nitric oxide availability
• Vericiguat offers a dual mode of action with direct stimulation of sGC as well as enhanced sensitivity to endogenous nitric oxide to increase cGMP
• The VICTORIA trial will provide important insights regarding the safety and efficacy of vericiguat in patients with chronic HFrEF

To obtain further information related to this study, contact the clinical study physician Mahesh Patel, MD (mahesh.patel1@merck.com) or any of the Executive Committee members noted above.

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