

Clinical trial investigates new treatment for systolic heart failure patients

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The academic partners in the VeriCiguaT GLObal Study in Subjects with Heart Failure with Reduced Ejection FrAction (VICTORIA) are pleased to announce that patient enrollment has begun. The study will explore a novel treatment pathway in patients suffering from chronic heart failure with reduced ejection fraction (HFrEF), by investigating the clinical impact of the drug vericiguat. VICTORIA is a pivotal Phase III clinical study conducted in collaboration with Merck (known as MSD outside the U.S. and Canada) and Bayer.

Heart failure (HF) is a serious debilitating condition that is characterized by the progressive decline in the heart's ability to pump enough blood through the body. The global burden of HF is increasing, and the mortality rate remains high. According to the American Heart Association, HF mortality is worse than some cancers, with approximately one third of patients dying within one year of hospitalization for an acute HF event.

"Despite available treatment options, the prognosis for HFrEF patients remains poor and we need new treatment options," said Paul W. Armstrong, MD, founding director of the Canadian VIGOUR Centre and Distinguished Professor at the University of Alberta, and chair of the study's Executive Committee. "The VICTORIA study is designed to assess whether the addition of vericiguat on top of standard of care HF therapy can help improve heart and vascular function, and reduce the risk of cardiovascular death or HF hospitalization in patients with deteriorating chronic HF with reduced ejection fraction."

"Currently, one in five people worldwide are expected to develop HF in their lifetime. Hence a critical unmet need exists for new treatments in patients with deteriorating HFrEF. Retarding or reversing the progression of disease and improving the current standard of care is a top priority," said Dr. Chris O'Connor, co-primary investigator of VICTORIA and Chief Executive Officer and Executive Director of Inova Heart and Vascular Institute. "The VICTORIA Phase III program will help us determine if vericiguat could have a role in the future of HF treatment in this high-risk population."

The event-driven Phase III VICTORIA study will assess the efficacy and safety of vericiguat, administered at a dose of 10 mg, once daily, as compared to placebo (on background standard of care treatment) in reducing the risk of cardiovascular death or HF hospitalization in patients with HFrEF following HF hospitalization or receiving an intravenous diuretic without hospitalization. The primary efficacy outcome is the time to first occurrence of cardiovascular mortality or HF hospitalization, which is the composite endpoint of the trial. VICTORIA has a global reach and will enroll approximately 4,900 patients at more than 500 centres across 40 countries. It is anticipated that the study will take 39 months to complete. VICTORIA is conducted by Merck in partnership with the Canadian VIGOUR Centre (CVC) at the University of Alberta and the Duke Clinical Research Institute (DCRI).

The design and dosing of the phase III VICTORIA study was informed by results from the SOCRATES-REDUCED phase II trial in 456 patients with HFrEF, presented at the 2015 American Heart Association (AHA) meeting in Orlando, Florida, and published in the Journal of the American Medical Association (JAMA). Dr. Burkert Pieske, co-chair of the phase II investigation and Co-Principal investigator of VICTORIA, Director of the Department of Internal Medicine and Cardiology, German Heart Institute and the Department of Internal Medicine and Cardiology at the Charité University Hospital in Berlin, said "We are

excited that enrollment in our trial has now begun and we have the opportunity to evaluate vericiguat, the first sGC stimulator to be evaluated in patients with chronic HF. We can now carry forward our early promising results into this definitive phase III trial conducted around the globe."

Provided by University of Alberta Faculty of Medicine & Dentistry

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