

## Eisai announces long-term cardiovascular outcomes data for anti-obesity Agent

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Eisai Inc. recently announced that results from the CAMELLIA-TIMI 61 cardiovascular (CV) outcomes trial in patients treated with BELVIQ® (lorcaserin HCl) CIV 10 mg twice-daily were presented at the European Society of Cardiology (ESC) Congress 2018 and concurrently published in the New England Journal of Medicine. As previously reported, the study met its primary safety objective and met the FDA-mandated criteria for cardiovascular safety, finding that long-term treatment with BELVIQ did not increase the incidence of major adverse cardiovascular events (MACE) in overweight and obese patients at high risk for a CV event.

With this result, BELVIQ is the first-ever weight loss medication approved for chronic weight management to achieve this objective in a dedicated CV outcomes trial. In addition, exploratory assessments of the efficacy of BELVIQ on change in weight from baseline was improved over the duration of the study, out to more than three years. Improvements in the CV and metabolic profiles of patients treated with BELVIQ were also observed in exploratory endpoints.

CAMELLIA-TIMI 61, conducted in collaboration with the Thrombolysis in Myocardial Infarction (TIMI) Study Group of Brigham and Women's Hospital, was a 12,000 patient study of BELVIQ at over 400 sites in eight countries, including the United States, and is the largest CV outcomes trial to date for a weight loss medication. The study was conducted as part of a post-marketing requirement by the U.S. Food and Drug Administration (FDA). The primary objective was evaluating long-term CV safety, by assessing the incidence of MACE in overweight and obese adults with existing CV disease or type 2 diabetes mellitus (T2DM) with CV risk factors.