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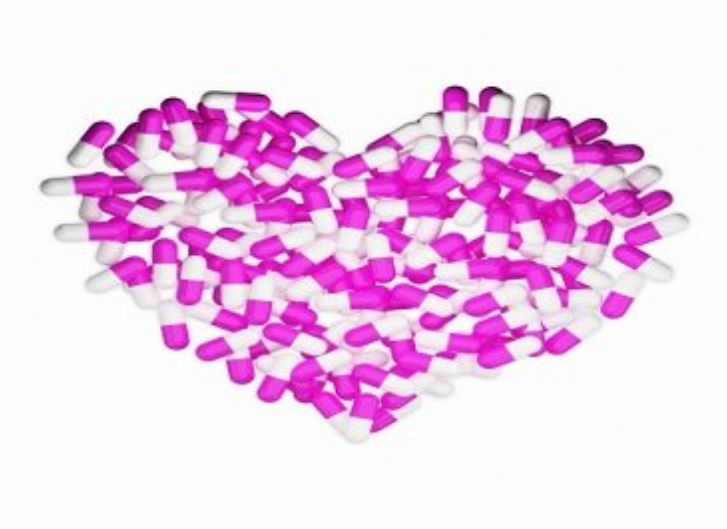

Novartis has announced that the US Food and Drug Administration (US FDA) has approved Entresto (sacubitril/valsartan) tablets, previously known as LCZ696, for the treatment of heart failure with reduced ejection fraction. Entresto will be available on prescription for patients whose condition is classified NYHA class II-IV, indicated to reduce the risk of cardiovascular death and heart failure hospitalization. It is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other angiotensin receptor blocker.

"Despite the uncertainty and high financial risk we designed the world's largest heart failure trial to compare Entresto to the previous gold standard. As a result millions of people diagnosed with reduced ejection fraction heart failure now have a much greater opportunity to live longer and stay out of hospital," said Mr David Epstein, division head, Novartis Pharmaceuticals. He added, "We recognize our responsibility to ensure Entresto reaches the US patients and prescribers as soon as possible and will begin shipping in the US in the coming week."

The FDA's decision is based on results from the 8,442-patient PARADIGM-HF study which was stopped early when it was shown Entresto significantly reduced the risk of cardiovascular death versus ACE-inhibitor enalapril. At the end of the study, patients with reduced ejection fraction who were given Entresto were more likely to be alive and less likely to have been hospitalized for heart failure than those given enalapril. Analysis of safety data showed that Entresto had a similar tolerability profile to enalapril.

Entresto is currently undergoing review by Health Authorities around the world, including in Canada, Switzerland and the EU.