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Novartis' heart failure drug receives EU approval

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Novartis has announced that the European Commission (EC) has approved Entresto (sacubitril/valsartan) for the treatment of adult patients with symptomatic chronic heart failure with reduced ejection fraction (HFrEF). Entresto is a twice a day tablet and has a unique mode of action which is thought to reduce the strain on the failing heart.

The approval is based on results from the 8,442-patient PARADIGM-HF study in patients with HFrEF, 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 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.

"We know that people living with heart failure face a high risk of death and have a worse quality of life than those with almost any other chronic condition, so it is very meaningful for HFrEF patients in Europe that we're able to offer a new first in class treatment option," said Mr David Epstein, division head, Novartis Pharmaceuticals.