

FDA approves new heart failure pill from Novartis

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Government regulators have approved a new pill from Novartis to treat heart failure, a deadly chronic disease that affects millions of U.S. patients.

The Food and Drug Administration approved the combination drug, Entresto, based on studies showing it reduced rates of heart-related death and hospitalization compared with older drugs.

More than 5 million Americans and more than 25 million people worldwide have heart failure, a disease that causes the heart to gradually lose its pumping power. It kills up to half of patients within five years, despite numerous generic pills and other treatments available.

It costs the global economy an estimated \$108 billion annually, so prevention is a key goal for health care providers.

For most patients, heart failure is a chronic condition, caused by high blood pressure or other factors damaging heart muscle. Symptoms include breathlessness, fatigue and fluid retention. That keeps many patients homebound and causes repeated emergency department visits, often in the middle of the night, due to infections or just straying from a low-salt diet.

The FDA approved the drug under its priority review program, which accelerates review for drugs that treat serious diseases or offer a significant improvement over older drugs. The agency approved another

heart failure from Amgen Inc. in April. That drug, Corlanor, was the first new FDA-approved medication for heart failure to launch in the U.S. in a dozen years.

Entresto combines Novartis' off-patent, blood pressure treatment Diovan with a new drug that decreases certain heart-damaging proteins in the blood.

Novartis-based Basel studied its drug in more than 8,000 patients with reduced heart pumping ability. Patients taking the drug experienced fewer hospitalizations for heart failure and death from heart disease than patients taking an older heart drug, known as an ACE inhibitor.

The most common side effects reported by study patients included low blood pressure and kidney problems. Some patients also experienced an allergic reaction that causes swelling of the face or lips.

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