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FDA Approves Valsartan/Sacubitril (*Entresto*) Combination for Heart Failure

Michael O'Riordan | July 07, 2015

BETHESDA, MD — The US Food and Drug Administration (FDA) has now approved the combination tablet valsartan/sacubitril (*Entresto*, Novartis) for the treatment of patients with heart failure[1].

The combination drug, formerly known as LCZ696, is the first approved agent in the angiotensin receptor-neprilysin inhibitor (ARNI) class and exerts its effect within and beyond the renin-angiotensin system. Chemically, the agent consists of the angiotensin-receptor blocker valsartan affixed to the neprilysin inhibitor sacubitril.

The US approval is based on results of the Prospective Comparison of ARNI with ACE-I to Determine Impact on Global Mortality and Morbidity in Heart Failure (PARADIGM-HF) trial, a study reported by **heart*wire*** from Medscape when it was presented at the European Society of Cardiology 2014 Congress in Barcelona, Spain.

In PARADIGM-HF, a study that included more than 8000 chronic-heart-failure patients, treatment with the valsartan/sacubitril combination significantly reduced cardiovascular death or heart-failure hospitalizations — the study's primary end point — by 20% compared with treatment with the ACE inhibitor enalapril alone. All-cause mortality, a secondary end point, was also significantly reduced with the ARNI when compared with enalapril.

Entresto was reviewed under the agency's priority review program. The expedited review process is intended for new drugs developed to treat a serious disease or those that provide a significant improvement over existing therapy. In addition, the agency awarded the drug a fast-track designation, a process reserved for new drugs that treat a serious condition, such as heart failure, and filled an unmet medical need.

As reported by **heart*wire*** , heart-failure experts are enthusiastic about the prospects of the ARNI, believing it represents the future cornerstone of chronic-heart-failure therapy. The new Canadian heart failure guidelines have already been updated and include recommendations on when and how to use the new agent in clinical practice.

References

1. Food and Drug Administration. FDA approves new drug to treat heart failure [press release]. July 7, 2015. Available here.

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