Novartis heart failure medicine Entresto™ substantially cuts 30-day hospital readmissions, new post-hoc analysis shows

Nov 10, 2015

- Following a heart failure hospitalization, 44% fewer patients treated with Entresto were readmitted for heart failure, and 36% fewer patients were readmitted for any cause, within 30 days compared to those on enalapril[1]
- About one in four patients is readmitted within 30 days of a hospitalization for heart failure[2]
- Heart failure patient readmission rates are a key predictor of patient outcomes and are used by CMS as an indicator of hospital performance[3,4]
- People living with heart failure often experience debilitating symptoms and repeated hospitalizations that significantly impact quality of life[2,5,6]

EAST HANOVER, N.J., Nov. 10, 2015 /PRNewswire/ -- Novartis announced today data from a new analysis demonstrating that fewer heart failure patients with reduced ejection fraction (HFrEF) treated with Entresto™ (sacubitril/valsartan) tablets were readmitted to the hospital for heart failure or for any cause within 30 days of discharge from a heart failure hospitalization compared to patients treated with enalapril.[1] This post-hoc analysis of PARADIGM-HF data, the largest clinical trial ever conducted in heart failure,[7] was presented today at the American Heart Association Scientific Sessions 2015.

The analysis compared numbers and rates of 30-day readmissions after discharge from heart failure hospitalizations between patients who were randomized to treatment with Entresto and those who received enalapril. The primary outcome analyzed was investigator-reported readmissions for any cause within 30 days of discharge from a heart failure hospitalization.[1] Researchers found that, compared to patients taking enalapril:

- 44% fewer individual patients taking Entresto were readmitted to the hospital for heart failure within 30 days of discharge from a heart failure hospitalization, with odds of readmission (including patients who were readmitted more than once during the study) 38% lower with Entresto treatment after discharge[1]
- 36% fewer individual patients taking Entresto were readmitted to the hospital for any cause within 30 days of discharge from a heart failure hospitalization, with odds of readmission (including patients who were readmitted more than once during the study) 26% lower with Entresto treatment after discharge[1]

"In heart failure, lower readmission rates may correlate with improved patient prognosis and lower costs to the healthcare system," said Scott Solomon, MD, Director of Noninvasive Cardiology, Brigham and Women's Hospital and Professor of Medicine, Harvard Medical School, who led the analysis. "By reducing both first and subsequent hospital admissions, we can reduce the health and economic burden associated with the reduced ejection form of this condition."

Thirty-day readmission rates are a key performance metric for acute care and long-term care hospitals. To help promote high-quality, patient-centered care and accountability, the Centers for Medicare & Medicaid Services (CMS) launched the Hospital Readmissions Reduction Program in October 2012. This program reduces Medicare payments to those hospitals with comparatively high rates of 30-day readmissions for certain conditions, including heart failure.[3]

"Living with heart failure can take a significant toll on a person and their family, and repeated hospitalizations may only make things worse," said Christi Shaw, US Country Head, President of Novartis Corporation and Novartis Pharmaceuticals Corporation. "The PARADIGM-HF trial has shown that Entresto not only reduces cardiovascular death for those patients with reduced ejection fraction, but it can substantially decrease the likelihood of frequent admissions to the hospital."

Entresto received approval from the US Food and Drug Administration in July to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction. Entresto is usually administered in conjunction with other heart failure therapies, in place of an ACE inhibitor or other angiotensin receptor blocker (ARB).[8] Reduced ejection fraction means the heart does not contract with enough force, so less blood is pumped out.[9]

About Heart Failure

Heart failure represents a staggering health and economic burden in the United States.[10] It is the leading cause of hospitalization for Americans over the age of 65, as people living with the condition often experience debilitating symptoms.[5,6,11] Heart failure accounts for more than one million hospitalizations in the US each year, and hospitalizations alone account for almost 80 percent of the nearly $21 billion spent on direct medical costs of heart failure.[10,12] Nearly six million Americans have heart failure, about half of whom have the reduced ejection fraction form.[12,13]

About the PARADIGM-HF Study

The 8,442-patient PARADIGM-HF study is the largest clinical trial ever conducted in heart failure.[7] In the study, Entresto demonstrated clinically relevant and statistically significant superiority to guideline-recommended ACE-inhibitor enalapril, reducing the risk of cardiovascular death or heart failure hospitalization by 20% (the primary endpoint) at a median follow-up of 27 months. Entresto also improved overall survival by 16% versus enalapril, driven by the lower incidence of cardiovascular death.[8,14,15] The study was stopped earlier than anticipated after the Data Monitoring Committee overseeing the study found that Entresto significantly reduced the risk of cardiovascular death and that the primary endpoint had been met.[16]

About Entresto

Entresto is a twice-a-day medicine that reduces the strain on the failing heart. It does this by enhancing the protective neurohormonal systems of the heart (NP system) while simultaneously suppressing the harmful effects of the overactive renin-angiotensin-aldosterone system (RAAS).[8] Other heart failure medicines only block the harmful effects of the overactive RAAS.[15] Entresto contains the neprilysin inhibitor sacubitril, which is a new molecular entity, and the angiotensin receptor blocker (ARB) valsartan.[8]

Entresto film-coated tablets are available in three dosage strengths: 24/26 mg, 49/51 mg, and 97/103 mg (sacubitril/valsartan). These doses are referred to as 50 mg, 100 mg, and 200 mg in the clinical trial literature including the New England Journal of Medicine publication of the results of PARADIGM-HF. The target treatment dose of Entresto is 97/103 mg twice daily.[8]

Novartis is committed to providing patients with affordable access and resources through Entresto Central. For more information, please call 1-888-ENTRESTO or visit www.entresto.com.

Please visit http://www.pharma.us.novartis.com/product/pi/pdf/entresto.pdf for Entresto full Prescribing Information.

IMPORTANT SAFETY INFORMATION

Entresto can harm or cause death to an unborn baby. Patients should talk to their doctor about other ways to treat heart failure if they plan to become pregnant. If a patient gets pregnant while taking Entresto, she should tell her doctor right away.

Patients are not to take Entresto if they are allergic to sacubitril or valsartan or any of the ingredients in Entresto; have had an allergic reaction including swelling of the face, lips, tongue, throat or trouble breathing while taking a type of medicine called angiotensin-converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB); or take an ACE inhibitor medicine. Patients are not to take Entresto for at least 36 hours before or after they take an ACE inhibitor medicine. Patients should talk with their doctor or pharmacist before taking Entresto if they are not sure if they take an ACE inhibitor medicine. Patients are not to take Entresto if they have diabetes and take a medicine that contains aliskiren.

Before they take Entresto, patients should tell their doctor about all of their medical conditions, including if they have kidney or liver problems; are pregnant or plan to become pregnant; are breastfeeding or plan to breastfeed. Patients should either take Entresto or breastfeed. They should not do both.

Patients should tell their doctor about all the medicines they take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. They should especially tell their doctor if they take potassium supplements or a salt substitute; nonsteroidal anti-inflammatory drugs (NSAIDs); lithium; or other medicines for high blood pressure or heart problems such as an ACE inhibitor, ARB, or aliskiren.

Entresto may cause serious side effects including serious allergic reactions causing swelling of the face, lips, tongue, and throat (angioedema) that may cause trouble breathing and death. Patients are to get emergency medical help right away if they have symptoms of angioedema or trouble breathing. Patients are not to take Entresto again if they have had angioedema while taking Entresto. People who are black or who have had angioedema may have a higher risk of having angioedema if they take Entresto. Entresto may cause low blood pressure (hypotension). Patients are to call their doctor if they become dizzy or lightheaded, or they develop extreme fatigue. Entresto may cause kidney problems or an increased amount of potassium in the blood.

The most common side effects were low blood pressure, high potassium, cough, dizziness, and kidney problems.

Please see full Prescribing Information, including Boxed WARNING available at http://www.pharma.us.novartis.com/product/pi/pdf/entresto.pdf.

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "may," "can," "committed," or similar terms, or by express or implied discussions regarding potential new indications or labeling for Entresto, or regarding potential future revenues from Entresto. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that Entresto will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Entresto will be commercially successful in the future. In particular, management's expectations regarding Entresto could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety issues; unexpected manufacturing or quality issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets innovative medicines aimed at improving patients' lives. We offer a broad range of medicines for cancer, cardiovascular disease, endocrine disease, inflammatory disease, infectious disease, neurological disease, organ transplantation, psychiatric disease, respiratory disease and skin conditions. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58.0 billion, while R&D throughout the Group amounted to approximately USD 9.9 billion (USD 9.6 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 120,000 full-time-equivalent associates. Novartis products are available in more than 180 countries around the world. For more information, please visit http://www.novartis.com.

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