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Novartis' heart failure medicine LCZ696 granted FDA priority review

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- - Decision could speed access to LCZ696 for heart failure with reduced ejection fraction patients in the US, reducing total review time from 12 to 8 months(1)
- - Filing is based on results from the landmark PARADIGM-HF study(2)
- - Nearly six million people live with heart failure in the US, and despite current therapies, up to 50% of patients die within five years of diagnosis(3,4)

EAST HANOVER, N.J., Feb. 13, 2015 /PRNewswire/ -- Novartis announced today that the US Food and Drug Administration (FDA) has granted priority review for LCZ696, an investigational medicine for the treatment of heart failure with reduced ejection fraction (HFrEF). The designation is intended to accelerate the review of therapies that offer a significant improvement in the safety or effectiveness of the treatment, prevention or diagnosis of a serious condition.[5] For LCZ696, this reduces the total review time from 12 to 8 months, meaning the target FDA action date is in August 2015.[1]

"The FDA's decision to grant priority review brings us one step closer to making this promising treatment available to the millions of Americans who are struggling with this debilitating condition," said Christi Shaw, US Country Head, President of Novartis Corporation and President of Novartis Pharmaceuticals Corporation. "LCZ696 has the potential to change the way that many heart failure patients are treated in this country, giving them and their loved ones greater hope for their future."

The New Drug Application (NDA) is based on results from the landmark PARADIGM-HF study, the largest ever conducted in heart failure.[6] The study showed LCZ696 was superior to the accepted guideline therapy ACE-inhibitor enalapril on key endpoints, including the primary endpoint, which showed reduction of the risk of either cardiovascular death or heart failure hospitalization by 20%.[2,7]

In the European Union, the Committee for Medicinal Products for Human Use (CHMP) has granted accelerated assessment to LCZ696.[8]

About LCZ696 in heart failure

LCZ696, a twice-a-day medicine being investigated for heart failure, acts to enhance the protective neurohormonal systems of the heart (NP system) while simultaneously suppressing the harmful effects of the overactive renin-angiotensin-aldosterone system (RAAS). Currently available medicines for heart failure with reduced ejection fraction only block the harmful effects and mortality remains very high, with up to 50% of patients dying within 5 years of a diagnosis of heart failure.[4,7,9]

Heart failure is a debilitating and life-threatening disease in which the heart cannot pump enough blood around the body. Symptoms such as breathlessness, fatigue and fluid retention can appear slowly and worsen over time, significantly impacting quality of life.[10]

It represents a major and growing health-economic burden that currently exceeds $30 billion in the United States, accounting for both direct and indirect costs. Hospitalizations account for 80% of the $21 billion spent on the direct costs of heart failure.[11]

Disclaimer

The foregoing release contains forward-looking statements that can be identified by words such as "priority review," "could," "investigational," "intended," "target," "promising," "potential," "being investigated," "growing," or similar terms, or by express or implied discussions regarding potential marketing approvals for LCZ696, or regarding potential future revenues from LCZ696. 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 LCZ696 will be approved for sale in any market, or submitted for approval in any additional markets, or at any particular time. Neither can there be any guarantee that LCZ696 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 LCZ696 will be commercially successful in the future. In particular, management's expectations regarding LCZ696 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 manufacturing 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, cost-saving generic pharmaceuticals, preventive vaccines and over-the-counter products. Novartis is the only global company with leading positions in these areas. In 2014, the Group achieved net sales of USD 58 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 130,000 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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