**MEDIA STATEMENT • MEDIA STATEMENT • MEDIA STATEMENT**

**Investigational heart failure medicine LCZ696 (sacubitril/valsartan) receives Promising Innovative Medicine designation in the UK**

* *PIM designation is the first step to inclusion in the Early Access to Medicines Scheme (EAMS), providing patients with faster access to innovative medicines*
* *LCZ696 is the first non-oncology medicine to receive this designation since the scheme’s inception in April 2014*

**Frimley, UK, 23 April 2015 -** Novartis is delighted to announce that the Medicines and Healthcare products Regulatory Agency (MHRA) has granted a Promising Innovative Medicine (PIM) designation for its investigational medicine for patients with heart failure (HF) with reduced ejection fraction, LCZ696 (sacubitril/valsartan).

The PIM designation is the first step towards inclusion in the EAMS, a UK scheme run by the MHRA, that aims to give patients with life-threatening conditions access to specified pre-licence medicines when there is a clear medical need. LCZ696 has been awarded the PIM designation based on the results of the PARADIGM-HF trial, which showed that LCZ696 significantly improved patient outcomes compared to the current gold standard treatment, including a reduction in cardiovascular deaths. Today, around 900,000 people in the UK live with HF and HF hospital admissions are projected to rise by 50% over the next 25 years[[1]](#endnote-1).

Hugh O’Dowd, General Manager at Novartis UK & Ireland, commented on the announcement: “Despite widespread use of available treatments and implementation of NICE heart failure guidelines, outcomes remain poor for those diagnosed, with around 60% dying from heart failure within five years.[[2]](#endnote-2) It is therefore very encouraging that LCZ696 has been recognised as a scientific innovation that can improve the lives of people living with this debilitating condition.”

The EAMS, part of the Government’s Strategy for UK Life Sciences, aims to ensure the UK is a world leader in life sciences and improve the wider environment for health life sciences companies. The Government believes that a successful and competitive UK life sciences sector can improve the lives of UK patients, increase efficiency in the NHS and benefit the UK economy.

-ENDS-

**About heart failure**

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.[[3]](#endnote-3)

It presents a growing health-economic burden globally and consumes almost 2% of the National Health Service (NHS) budget in the UK, which equates to approximately £1.9 billion. Hospitalisations comprise 60-70% of treatment costs.[[4]](#endnote-4)-[[5]](#endnote-5)[[6]](#endnote-6)[[7]](#endnote-7)

**About LCZ696 in heart failure**

LCZ696 is an ARNI (Angiotensin Receptor Neprilysin Inhibitor) and has a unique mode of action which is thought to reduce the strain on the failing heart.[[8]](#endnote-8),[[9]](#endnote-9) It harnesses the body's natural defences against heart failure, simultaneously acting to enhance the levels of natriuretic and other endogenous vasoactive peptides, while also inhibiting the Renin-Angiotensin-Aldosterone System (RAAS).

**About the PARADIGM-HF study**

PARADIGM-HF is a randomised, double-blind, Phase III study that evaluated the efficacy and safety profile of LCZ696 versus enalapril (a widely studied ACE inhibitor) in 8,442 patients with HFrEF.[[10]](#endnote-10) The baseline characteristics showed the patients enrolled were typical HFrEF patients with NYHA Class II-IV heart failure.[[11]](#endnote-11) PARADIGM-HF was specifically designed to see if LCZ696 could decrease CV mortality by at least 15% vs. enalapril.8 Patients received LCZ696 or enalapril in addition to current best treatment regimen. The primary endpoint was a composite of time to first occurrence of either CV death or heart failure hospitalisation and it is the largest heart failure study ever done.8,11

Secondary endpoints were a change in the clinical summary score for heart failure symptoms and physical limitations (as assessed by Kansas City Cardiomyopathy Questionnaire) at eight months; time to all-cause mortality; time to new onset atrial fibrillation; and time to occurrence of renal dysfunction.8 PARADIGM-HF was initiated in December 2009 and in March 2014, the Data Monitoring Committee (DMC) confirmed that patients given LCZ696 were significantly less likely to die from CV causes, leading to the trial being stopped early. The DMC also confirmed the primary endpoint had been met.

**About Novartis**

Novartis 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 2013, the Group achieved net sales of USD 57.9 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 and sell products in more than 150 countries around the world. For more information, please visit <http://www.novartis.com>.

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