

Physician Views: New data for Novartis' LCZ696 set the Street abuzz, but how do cardiologists see it fitting into highly genericised heart failure market?

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Abstracts

The potential blockbuster status of Novartis' LCZ696 has seemingly been cemented in the eyes of the Street thanks to solid results from the Phase III PARADIGM-HF study that were presented over the weekend.

Indeed, the chronic heart failure agent is believed to represent both a significant growth driver for Novartis as well as, alongside the PCSK9 class of dyslipidaemia products, among the first in a new wave of medicines in late-stage development at Big Pharma for cardiovascular indications.

Data from the PARADIGM-HF trial had been highly anticipated ever since Novartis announced in March that the study was being stopped after LCZ696 significantly reduced the primary composite endpoint of time-to-first occurrence of either cardiovascular death or heart failure hospitalisation compared to the standard ACE inhibitor enalapril.

Based on the reaction from analysts, the full data package did not disappoint. According to Bank of America Merrill Lynch analyst Graham Parry, 'in our opinion, the data are impressive with a 20-percent reduction in CV death and 16 percent reduction in overall mortality and reassuring safety profile that support FDA approval and widespread use.'

'We believe our \$3 billion un-risk adjusted peak sales forecast, which assumes 30 percent penetration in the 6 million US CHF patients and 20 percent in the 6.5 million EU patients, looks increasingly conservative in the light of presented data,' Parry added.

Novartis itself is doing little to lower expectations about the programme. 'It will be



possibly the most exciting launch the company has ever had,' Novartis division head David Epstein told an investor meeting.

However, despite LCZ696's clear efficaciousness and relatively clean safety profile, Novartis will be entering a cardiovascular marketplace where price-sensitivity has become increasingly important, a consideration that will undoubtedly play a role in the company's price-setting calculus.

Based on the new data, JP Morgan analyst Richard Vosser believes LCZ696 has 'multi-blockbuster potential' and said he is upping his 2020 sales forecast to \$6 billion from \$5 billion.

Thus, FirstWord polled cardiologists in the US and EU5 about their thoughts on the PARADIGM-HF data and how LCZ696 is likely to be used in the real world. Specifically we are asking them.

LCZ696 reduced CV death by 20 percent and overall mortality by 16 percent versus the ACE inhibitor enalapril in patients with heart failure and reduced ejection fraction in the PARADIGM-HF study. Do the data mean LCZ696 - once approved - will quickly become the standard of care in this setting?

A month's supply of enalapril costs roughly \$4, whereas analysts predict LCZ696 will be priced between \$7 and \$8 per day (in the US). Assuming this level of price disparity, to what percentage of patients with heart failure and reduced ejection fraction would you expect to prescribe LCZ696?

How important will the incorporation of LCZ696 into treatment guidelines be for increasing use of the medicine?

How confident are you that LCZ696's benefit will translate into heart failure patients with preserved ejection fraction?

Amgen recently filed a marketing application with the FDA for ivabradine, a drug already marketed outside the US for heart failure. Given the emergence of LCZ696 (predicted launched in late 2015) and lingering questions about ivabradine's safety, roughly what percentage of patients would you expect to use ivabradine in 18 months from now?



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