Media Statement: FortiHFy Global Clinical Program for Entresto®

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Novartis has established FortiHFy, the largest global clinical program in the heart failure disease area, comprising over 40 active or planned clinical studies designed to generate an array of additional data on symptom reduction, efficacy, safety, quality of life benefits and real world evidence with its novel heart failure medicine Entresto® (sacubitril/valsartan) tablets, and extend understanding of heart failure. FortiHFy (Fortifying Heart Failure clinical evidence and patient qualitY of life) will enroll patients from over 50 countries, including the US, to participate over 5 years.1 The FortiHFy program reinforces Novartis' long-term commitment to improving heart failure treatment for as many patients as possible. Major trials in FortiHFy include PARAGON-HF2, PARADISE-MI1, TRANSITION-HF3 and PIONEER-HF4.

Heart failure is a life-threatening disease that impacts nearly 6 million Americans and is the leading cause of hospitalization among people over the age of 65.5,6 About half of US patients with chronic heart failure have the reduced ejection fraction form of the condition (HFrEF), and the other half have preserved ejection fraction (HFpEF).5,7

We believe that Entresto represents a major medical advance and has the potential to significantly improve the way heart failure is treated in this country. Entresto is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic HFrEF (NYHA Class II-IV).8 It's the first and only medicine for HFrEF to demonstrate a significant reduction in the rate of cardiovascular death or heart failure hospitalization over a guideline-recommended therapy (ACE inhibitor enalapril).9 The outcomes of the trials in FortiHFy will increase our understanding of heart failure and additional patient populations who may benefit from Entresto, and could potentially support future regulatory applications for additional indications.

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