Novartis announces investment in FortiHFy clinical program of Entresto® and heart failure

- **Fortifying Heart Failure clinical evidence and patient quality of life (FortiHFy)** is an umbrella clinical program comprising over 40 active or planned trials

- The global clinical program will generate additional data on symptom reduction, efficacy, safety, quality of life benefits and real world evidence with Entresto

- Investigators and patients from over 50 countries to participate over 5 years

**Basel, May 19, 2016** – Novartis today announced the establishment of FortiHFy, the largest global clinical program in the heart failure disease area across the pharma industry to date, comprising over 40 active or planned clinical studies designed to generate an array of additional data on symptom reduction, efficacy, quality of life benefits and real world evidence with its novel heart failure medicine Entresto® (sacubitril/valsartan), and extend understanding of heart failure.

“The FortiHFy program reinforces our long term commitment to improving heart failure treatment for as many people as possible,” said Vas Narasimhan Global Head, Drug Development and Chief Medical Officer. “The outcomes of these trials will increase our understanding of heart failure, the patient population who may benefit from Entresto, and could potentially support applications to regulatory authorities”.

Major trials in the FortiHFy program include:

- **PARAGON-HF** examining the efficacy and safety of Entresto in heart failure patients with with preserved ejection fraction (compared to valsartan), expected study completion in 2019

- **PARADISE-MI** testing the hypothesis that Entresto can reduce cardiovascular death, heart failure hospitalizations and new onset heart failure in patients at high risk for heart failure after a myocardial infarction, expected study completion in 2020

- **TRANSITION** comparing in-hospital initiation of Entresto to initiation after hospital discharge in heart failure patients with reduced ejection fraction (HFrEF) who have recently been hospitalized for acute decompensation, expected study completion in 2018

- **PIONEER** investigating the effect of in-hospital initiation of Entresto on changes in NT-proBNP (compared to enalapril) in patients with HFrEF following an acute decompensation, expected study completion in 2018

FortiHFy trials that are already active are posted on clinicaltrials.gov and are currently enrolling patients in more than 50 countries worldwide. Entresto is approved in 57 countries to date for the treatment of heart failure with reduced ejection fraction (HFrEF), based on data from the PARADIGM-HF study which reported results in 2014.

**About Heart Failure**
Heart failure is a debilitating and life-threatening condition, which impacts over 60 million people worldwide. It is the leading cause of hospitalization in people over the age of...
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 and cost-saving generic pharmaceuticals. Novartis is the only global company with leading positions in these areas. In 2015, the Group achieved net sales of USD 49.4 billion, while R&D throughout the Group amounted to approximately USD 8.9 billion (USD 8.7 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 118,000 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.
Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.
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References

8. Entresto Prescribing Information.

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