Novugen Launched Sacubitril and Valsartan Tablets in the U.S. Following Recent ANDA Approval

We are proud to announce that **Novugen has launched Sacubitril and Valsartan Tablets (24mg/26mg, 49mg/51mg, and 97mg/103mg) in the U.S.**, following the recent Abbreviated New Drug Application (ANDA) approval granted by the U.S. Food and Drug Administration (USFDA).

Our journey began with the ANDA submission on 7 July 2019, strategically filed one year ahead of the New Chemical Entity (NCE-1) exclusivity expiry. After six years of rigorous processes and unwavering commitment, we achieved the regulatory approval, securing first-to-file status in the U.S., alongside 17 other filers. This milestone positions Novugen among the first few companies to bring this product to market.

Sacubitril and Valsartan is indicated for the **treatment of heart failure** with reduced ejection fraction (HFrEF) and helps reduce the risk of cardiovascular death and hospitalization in patients with chronic heart failure. This launch marks a key milestone in our U.S. expansion strategy, reinforcing our presence in the cardiovascular space within a market projected to reach USD 6.5 billion by 2025.

This marks another proud moment in our journey to deliver life-changing medicines to patients around the world.