

Novugen Secures First-to-File Status & Successful Resolution for Trametinib in the U.S.



We are pleased to announce that Novugen has reached another significant milestone by securing the exclusive first-to-file (FTF) status and achieving a successful resolution for Trametinib in the U.S. Securing the FTF status and favourable settlement puts us in a unique position to benefit from six months of exclusivity as a single-source supplier in the market. Should its ANDA be approved by the FDA, Novugen believes it will be eligible for 180 days of generic marketing exclusivity in the U.S.

Trametinib is a medication used to treat metastatic myeloma, non-small cell lung cancer (NSCLC), and thyroid cancer. In the years to come, our focus is on becoming the first and only generic to launch in the US, anticipating brand sales surpassing USD 500 million. This endeavour will mark a transformative journey for Novugen, solidifying our position as a key emerging player in the U.S. pharmaceutical market, delivering significant value to our customers and patients.