ANDA Approval for Trametinib

Back in April, we shared the exciting news that Novugen had secured the exclusive first-to-file (FTF) status and achieved a successful resolution for Trametinib in the U.S., positioning us for six months of market exclusivity as a single-source supplier.



Today, we are delighted to confirm that the **Trametinib Dimethyl Sulfoxide 0.5mg & 2mg Tablets ANDA has been officially APPROVED by the USFDA as of 6th of August 2024**, achieving this within our 10-month goal date. This makes us the exclusive first filer to obtain ANDA approval in the U.S. market.


This achievement marks one of Novugen's fastest executed projects, a testament to Novugen's competencies and capabilities from the initial stages to filing and litigation. On the 8th of August 2024, we gathered at the Novugen HQ office in Glenmarie to celebrate this momentous achievement together.

We extend our deepest gratitude to every member of Novugen's team for the hard work and ingenuity. This achievement not only reflects our collective commitment but also sets the stage for future successes and growth.