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Aragen to manufacture Renaissance Pharma's FDA Fast Track mAb in Bengaluru facility

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Daretabart, a humanised monoclonal antibody targeting GD2 for high-risk neuroblastoma



Aragen, a leading global Contract Research, Development, and Manufacturing Organisation (CRDMO), has successfully tech-transferred and manufactured the first commercial-scale GMP batches of Renaissance Pharma's lead candidate, Daretabart – a humanised monoclonal antibody (mAb) targeting GD2 for high-risk neuroblastoma – in just 9 months.

The anti-GD2 monoclonal antibody received Fast Track Designation from the FDA in April 2026 for the treatment of high-risk neuroblastoma (HRNB), a rare pediatric cancer. This milestone builds on a broader strategic partnership between the two companies, with Aragen having developed the cell line and initial process at its Morgan Hill site in California. GMP manufacturing for the programme has now transitioned to Aragen's commercial biologics facility in Bengaluru, India at the commercial scale.

The Aragen Bengaluru site plans to have multiple 2KL bioreactors enabling both scale-up and scale-out. This manufacturing strategy will allow the same molecule to be run across bioreactors, supporting faster readiness towards clinical and commercial supplies.

The manufacturing suite is capable of producing 60-70 batches annually at 2 KL scale with a turnaround of one batch every 4–5 days at full capacity. Additionally, the suite can be operated in a scale-out mode with two 2 KL bioreactors running in parallel to provide a batch size of 4KL. This facility supports both fed-batch and intensified fed-batch production.

The successful transfer to Aragen's newly built \$40 million commercial facility in Bengaluru marks an acceleration in clinical production. During the technology transfer to the new site, which features up to 2KL single-use bioreactor, the titer was increased several folds, with right-first-time execution from bench to 2KL GMP scale.

This latest tech transfer marks the sixth programme to progress from early-phase development in Morgan Hill to clinical supply in Bengaluru, demonstrating a discovery-manufacturing model designed to accelerate biotech programmes toward BLA submission.