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Aragen launches new cell line development and early manufacturing platform

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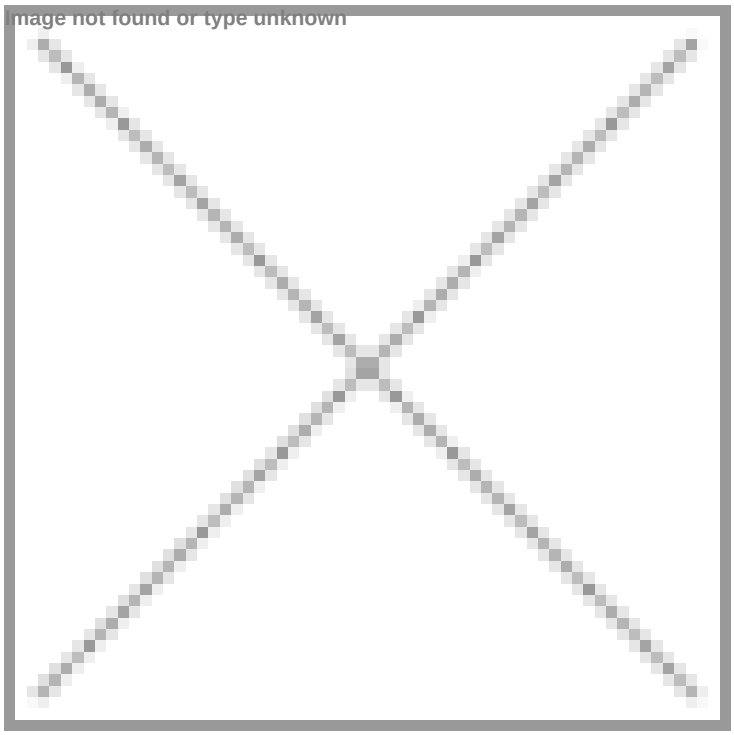
Accelerated platform for DNA to IND-enabling clinical supply in ~10 months



Aragen has announced the launch of CHOMax™, a new cell line development and early manufacturing platform that supports an integrated path from DNA to IND-enabling clinical supply in ~10 months for suitable standard IgG monoclonal antibodies.

This accelerated, royalty-free approach provides biotech and pharma partners with a clearly structured development pathway, including both drug substance and drug product support.

CHOMax^{TM} – which has been refined across 200+ CHO programmes – integrates cell line development, process development, analytics, and GMP manufacturing under quality processes designed to meet global regulatory expectations including FDA, EMA and PMDA. Crucially, key CMC activities can run in parallel where appropriate, reducing avoidable rework risk and timeline uncertainty.

Client programmes using CHOMax^{TM} follow platform-defined workflows and phase-appropriate practices across the development lifecycle. Speed is driven by early process development starting from pools, in-house Master Cell Bank (MCB) creation, early developability assessment, and parallel GMP readiness planning.

Typical integrated CHOMax™ programmes include generation of a clonal research cell bank (RCB) in ~16 weeks, with stage gates for vector design, transfection, pool screening, single-cell cloning and clone characterization. Once lead clones are identified, phase-appropriate process development, analytical method development and GMP campaign planning run in

parallel, guided by pre-agreed decision points. Analytical development, method qualification and Master Cell Bank (MCB) creation are executed within Aragen’s biologics network. GMP drug substance manufacturing is performed under quality processes designed to meet global regulatory expectations, with drug product support for first-in-human dosing provided through qualified partners.