Enabling a Healthier World

Lonza Biologics

Executive Summary

How Lonza's Ibex® Design 2.0 Program Accelerates Time to IND

From DNA to TOX drug substance in 5 months and IND in 11 months

Nathalie Knabe
Senior Director, Strategic Marketing, Mammalian
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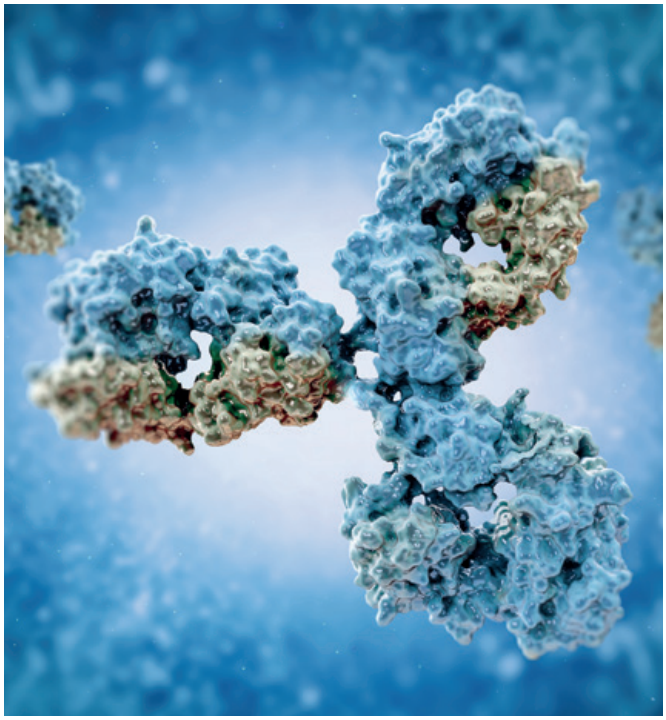
Speed to clinic and to market is increasingly gaining importance among biopharmaceutical drug developers. Companies ranging from small Biotech to large Pharma are constantly driving to shorten development time and gain faster approval for their therapies that may address unmet medical needs.

A partner that guarantees* 11 months from DNA to IND

As a biopharma company you are under increasing pressure to advance your molecules for first-in-human trials faster than ever. But drug development is a risky, time-consuming business where only around one in a thousand lead candidates making it past Phase 1 studies. So, if you want to stack the odds in your favor, what can you do? For starters, you could look to work with an experienced development and manufacturing partner that can help you balance risk with speed while maintaining project costs.

By offering next generation Ibex® Design 2.0, a fully integrated fixed price program which guarantees delivery of a standard monoclonal antibody (mAb) from DNA to Investigational New Drug Application (IND) or Investigational Medicinal Product Dossier (IMPD) in just eleven months*, Lonza is that partner. We do not cut timelines by compromising on quantity either as we will provide you with a minimum 1.5 kg GMP drug substance, ensuring you have plenty for your first-in-human trials. If you want it, you can even have TOX drug substance for toxicological testing in just five months to help you find any undesirable safety issues before you make potentially expensive mistakes when moving into GMP manufacturing.

*For antibodies. From transfection. Subject to terms and conditions.



How can we deliver in such record time?

Using state of the art cloning and expression technologies such as the Beacon® Optifluidic Technology and running workstream activities in parallel through an integrated services approach enables us to reduce timelines without increasing development risks.

In our Ibex® Design 2.0 program, we use the GS Xceed® expression system in combination with GS piggyBac® as well as optimized media/feeds which means we can find the right combination to efficiently express your molecule. The combination of host cell line, vector and stringency of selection enables us to provide our customers with high producing cell lines suited to fit a commercially relevant process.

Furthermore, our GS Xceed® expression system is well-known to world-wide regulatory authorities both at the clinical and commercial dossier level.

When we have optimized cell lines, to shave time off process development, our Ibex® Design 2.0 utilizes tried and trusted platform approaches including using stable pool material, ahead of lead clone selection. Our extensive data shows that early pool mAbs are representative of mAb material from a clonal cell line indicating that we can safely use this approach to deliver faster process and formulation development without increasing risk.

Holistically combining our proprietary Ibex® Design 2.0 platform processes including stability studies, storage, and supply chain management and running many of these development activities in parallel, balances risks with speed, ensuring we can deliver GMP quality drug product in just 11 months.

In addition, with Ibex® Design 2.0, we offer integrated drug substance and drug product capabilities under one quality system and can guarantee you a manufacturing slot for clinical resupply if your lead candidate successfully progresses into later phase trials.

Guaranteeing control over timeline, quantity and costs allows you to deliver submission-ready chemistry, manufacturing and controls (CMC) data for an IND, helping you progress to your technical and funding milestones on time and on budget.

The convergence of technological innovations, platform approach and over 35 years of track record can make Lonza the perfect partner to accelerate your project without compromise.

To discover more about Ibex® Design 2.0 visit:
https://pharma.lonza.com/ibexdesign

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