Getting to First-in-Human Clinical Trials: A Make-or-Break Milestone for Small Biopharmas

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“Faster and better” has become the mantra for biopharmaceutical companies as they face intense pressure to get therapies to market quicker than ever before.

The incentive of securing market share with first-to-market offerings is felt by all industry players. Pressure mounts from here for small companies, which often must meet certain milestones before receiving funding from investors. Quickly proving efficacy in first-in-human (FIH) trials is a make-or-break milestone for cash-strapped companies whose hopes for success hinge upon just one or two molecules.

Speed and revenue are also intertwined at Large Pharma. As Large Pharma struggles with R&D productivity, companies need to fill pipelines with promising options. Many large biopharma companies have numerous molecules with therapeutic potential but screening them at the same time and determining the best ones to pursue in FIH trials is a huge challenge.

Speed to market takes on even greater urgency when you consider that many biopharmaceuticals are intended for treating chronic, serious and/or life-threatening conditions. Many patients cannot wait years for therapies to enter the clinic and come to market.

Thus, whether biopharmaceutical companies have one candidate or 100, the directive is clear: moving quickly into FIH testing is essential. But, how?

Key Strategies for Speeding Time to Clinic

In response to this pressure, CDMOs are focusing on reducing timelines for producing high-quality clinical supply. For instance, our team recently launched the Quick to Clinic™ program for biologics, which uses three chief elements to move from cell line development to drug substance for clinical trials in as little as 14 months.

1

Cell line development flexibility.

When sponsor clients are restricted to using only the CDMO’s proprietary cell line and media for development product services, their flexibility to make strategic manufacturing decisions is greatly limited. We believe in the opposite approach. We offer clients options that are best suited to their molecule’s needs. With our Quick to Clinic™ approach, clients can use their own cell line or ours. In either scenario, we follow a pre-established set of parameters for process development that gives clients flexibility, can remove certain mandatory fees and make more efficient use of critical preclinical time. Alternatively, we can work with our client’s cell line and develop a slightly longer, more custom route.

2

Seamless transitions.

Companies can move to the clinic faster and less expensively if they use one qualified CDMO partner to seamlessly take a project from cell line development to a released drug substance and into drug product. In addition to better communication, clients can benefit from parallel development. While collecting stability data to file an IND, CDMOs with broad experience can start working on product filling/packaging/labeling, for instance. Likewise, CDMOs that can couple drug substance and drug product manufacturing save assay transfer costs and time since they can provide testing for both. Other benefits come from more efficient production scheduling.

3

Broad technology portfolio.

Now being part of Thermo Fisher Scientific, Patheon cuts the time it takes to move from drug substance to product by taking advantage of Thermo Fisher’s range of wide nutritional medias for CHO and other cells as well as Poros™ Cation Exchange Resins. No other CDMO offers this same breadth of services to clients.

Every day a drug is not on the market equates to lost revenue and delays in a patient from feeling better. Time matters, and so does the flexibility and expertise a CDMO can offer for getting to FIH testing as fast as possible.

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