Lonza
Biologics

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Lonza Shows Flexibility with Ibex® Design Platform to Accommodate tRNA Synthetase-Derived mAbs

–Andrea Cubitt, Ph.D., Vice President External Scientific Alliances and Intellectual Property, aTyr Pharma

aTyr Pharma is a clinical stage biotech focused on translating findings from a proprietary tRNA synthetase platform to develop first-in-class therapeutics to treat fibrosis and inflammation, and monoclonal antibodies targeting solid tumor cancers and autoimmune disease. With a robust pipeline, aTyr has experience working with several large, global contract manufacturers. Dr. Andrea Cubitt, VP of External Scientific Alliances and IP, explains aTyr's selection of Lonza as CDMO for its lead mAb candidate, and subsequent experience with its Ibex® Design program, which dispelled preconceived views about Lonza's suitability for smaller biotechs.

Finding the Right CDMO

aTyr Pharma has manufactured several biologic drug candidates with contract manufacturers located around the world, so we have experience in this process. We begin with a request for proposal, which is sent out to a shortlist of CDMOs that we consider a good fit for the program. For our preclinical monoclonal antibody (mAb) candidate, ATYR2810, which selectively targets the neuropilin-2 (NRP2) receptor and its interaction with VEGF as a potential disease-modifying therapy for patients with aggressive solid tumors, we were naturally looking for CDMOs with solid experience and the requisite expertise in mammalian production.

We knew Lonza, of course, but perceptions among our team were that, given its size and prominent position in the market, it might be overly bureaucratic and

aTyr

Andrea Cubitt, Ph.D.
VP External Scientific Alliances and Intellectual Property

Dr. Andrea Cubitt has served as aTyr's Vice President, External Scientific Alliances and Intellectual Property since February 2018, and was formerly VP, Product Protection from 2011 to 2018. She also previously worked as a senior patent agent for Global Patent Group LLC, and co-founded Anaptys Biosciences, a therapeutic antibody company. Dr. Cubitt did her postdoctoral training at Weill Cornell Medical College in New York, and the University of California San Diego. Dr. Cubitt holds a Ph.D. in biochemistry from the University of Sheffield and a B.Sc in medical biochemistry from the University of Birmingham in the UK. She is co-inventor or co-author of 18 issued US patents and 20 publications.

> **“ The Ibex® Design program is cost competitive and also offers set timelines and product quantity. That combination is very attractive for a biotech. ”**

difficult for an organization like ours to work with, as well as less competitive. However, Lonza had reached out to us and been in dialogue about its commitment to biotechs and its Ibex® Design program, which offered short timelines and very clear, transparent costs. These discussions and Lonza's approach made a strong impression.

De-Risking the Process

There is always the potential to take a project like this to a CDMO in Asia for cost benefits, but at this time, we had to factor in some short and long-term geopolitical concerns with this approach. The program was unlikely to be complicated, so we wanted a reliable partner that would de-risk our outsourcing and deliver on time and in full.

One of the things we found with Lonza was that the proposal it provided in response to our RFP was very thorough – more so than most. There is a perception that the biggest CDMOs are more expensive, but although the cost at face value can be higher, when you have a very thorough proposal, it is far less likely to miss things that result in changes and increases. This means that the cost ends up being competitive overall in the end.

Lonza's Ibex® Design program is attractive because it provides one of the fastest timelines for mAbs, and you also know what the costs and other parameters are going to be, so everything is very clear and easy to manage.

Flexibility in the Process

We initially thought that the characteristics of ATYR2810 would definitely fit Lonza's Ibex® Design parameters. However, we discovered that some of them fell slightly outside of the generally accepted range for the program. Lonza worked closely with us to overcome this issue and accommodate our candidate, which showed very helpful flexibility on their part. More importantly, they started the additional de-risking work early and did it in parallel, so our overall timelines weren't compromised.

We also faced some minor technical challenges, as is often the case with any project. Lonza overcame these hurdles with no apparent difficulty. This is evidence of Lonza's renowned technical strength, which is a key reason why Board members and investors never question biotechs selecting Lonza as a CDMO.

We experienced one area of concern when Lonza wanted to change the fill-finish site, which would have meant we had a smaller batch size. Our Account Manager helped us resolve this and ultimately deliver a win–win situation in which we could get the drug filled in the right batch size without any undue delays or changes.

Delivered as Promised

For us, the Ibex® Design program delivered exactly as prescribed, and everything went very smoothly. We had our kilogram of product within 12 months*, ready to progress with our clinical study. Lonza delivered on everything that was promised, so aTyr has certainly benefitted from the relationship. It is rare these days for a project to go so reliably to plan with a CDMO. We had fewer issues working with Lonza than any other relationship in my 25 years of outsourcing experience.

As a result, we have a very positive view of Lonza in general and what its Ibex® Design program can deliver for the right molecule.

aTyr Pharma

aTyr is a clinical stage biotechnology company translating proprietary R&D in tRNA synthetase biology into new therapies for fibrosis and inflammation and developing monoclonal antibodies (mAbs) to target solid tumors and autoimmune diseases. ATYR2810 is aTyr's first IND candidate from an in-house program designing mAbs to selectively target the Neuropilin-2 (NRP2) receptor and its associated signaling pathways.