

My Biotech Success could be yours

A Small Biotech Recognizes the Importance in How You Think of Manufacturing in Selecting a CDMO

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

Manufacturing is crucial to the success of any drug development project but is too often overlooked. Dr. Andrea Cubitt, VP of External Scientific Alliances and Intellectual Property at aTyr Pharma, explains how her company has benefitted from the extensive experience that CDMO partner Lonza has developed in mAb manufacturing, including its rapid and cost-competitive DNA-to-IND Ibex[®] Design program, and manifestation of its strong reputation and track record in manufacturing expertise.

tRNA Synthetase & NRP2 Receptor Biology

For small biotech innovators, working with a reputable contract manufacturer is essential to the success of individual programs and sometimes the company itself. aTyr has experience working with several medium and large-size CDMOs, so we have know-how in the selection of outsourcing partners and advancing programs with them. We have an experienced team, including people like me, with over 25 years of outsourcing to contract manufacturers.

aTyr is a clinical stage biotech, and we are focused on translating findings from our proprietary tRNA synthetase platform to develop first-in-class tRNA synthetase-derived therapeutics to treat fibrosis and inflammation. Our pipeline also includes monoclonal antibodies (mAbs) that target solid tumors and autoimmune diseases.

Our discovery platform is seeking to unlock hidden therapeutic intervention points by uncovering signaling pathways driven by our library of domains derived from all 20

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.

“ Lonza’s Ibex® Design program is an attractive prospect for manufacturing antibodies, with its transparent costs and set timelines and product quantity. ”

tRNA synthetases. ATYR2810 is the first IND candidate from our monoclonal antibody research program to selectively target the Neuropilin-2 (NRP2) receptor and its associated signaling pathways.

Choosing the Best CDMO for mAbs

When you are looking for a partner for a monoclonal antibody, and there is nothing particularly unusual about the candidate, it gives you a reasonably broad spectrum of mammalian cell culture-based manufacturers to choose from, though nobody wants to take on any unnecessary risk. In many cases, selection teams go back to providers they have worked with before. We were conscious of supply chain and geopolitical risks that we didn’t want, but other than this, we were focused on the standard parameters of reliable delivery and short timelines.

aTyr had not worked with Lonza before but representatives from the Switzerland-headquartered CDMO had been in touch with us prior to this program starting to show interest in our pipeline and potential programs we might be looking to advance. There was a preconceived idea among our colleagues that Lonza was not very approachable, but this clearly wasn’t the case. We also felt Lonza might be expensive and possibly difficult to work with, but they discussed the Ibex® Design program and its specific conceptualization for biotechs who want a mAb program with transparent costs and defined product quantity.

For our lead mAb candidate, ATYR2810, this was quite attractive as we wanted to move quickly and efficiently, so the idea of working with a CDMO that has a strong reputation but can run a competitive program like a machine was one we found interesting.

Giving Manufacturing the Necessary Attention

Manufacturing expertise is often not prioritized in small biotech companies, but in truth the ultimate production of a therapeutic compound is as important as the clinical therapeutic efficacy of the product. You need to be able to make the drug, to be able to show that it works, but you’ve got to continue to manufacture it reproducibly at the same quality standards.

Working with Lonza accelerated the path to achieving that reproducible process on ATYR2810 for aTyr. The depth of Lonza’s experience – from working on hundreds and hundreds of different IgG antibodies – is invaluable, because this garners knowledge of what does and doesn’t work for such programs, which saves a lot of time.

With Lonza’s extensive scientific knowledge, its team was quickly able to identify the top three approaches with respect to production strains, purified resins, and buffers that had the greatest likelihood of working well with our molecule. This made the program highly efficient by eliminating the need for extensive scientific discussion, numerous change orders, adjustments to the scope of work, and so on.

Validation of our CDMO Selection

Our decision to work with Lonza has been validated. A year after we began, we have a kilogram of product ready to enter the clinic. Our expectations that Lonza would be a reliable partner and de-risk the manufacturing supply chain have also proven true. And its Ibex® Design program enabled the production to be completed on time and with transparent, accurate costs. A further benefit of working with Lonza is its ability to support our program all the way from where we began to commercialization if all goes well.

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.