FURTHER ACCELERATING CELL LINE DEVELOPMENT AND CMC TIMELINE: THE JOURNEY FROM COVID TO NON-COVID PROGRAMS

Sam Zhang, WuXi Biologics
sam.zhang@wuxibiologics.com
Kee Wee Tan, WuXi Biologics
Junghao Wang, WuXi Biologics
Weichang Zhou, WuXi Biologics

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Since the COVID-19 outbreak, unconventional cell line development (CLD) strategies have been taken to enable development of SARS-CoV-2-neutralizing antibodies at expedited speed. We previously reported a novel chemistry, manufacturing, and control (CMC) workflow and demonstrated a much-shortened timeline of 3-6 months from DNA to investigational new drug (IND) application. Hereafter, we have incorporated the proven CMC strategies for all SARS-CoV-2-neutralizing antibody programs at WuXi Biologics. A total of seven COVID programs are summarized here, some of which have received EUA approval in less than two years. We demonstrate that stable pools generated under GMP conditions exhibited similar productivity and product quality at different scales and batches, enabling rapid initiation of phase I clinical trials; clones with comparable product quality as parental pools were subsequently screened and selected for late-stage development and manufacturing. Stability study on the critical path with a shorter duration has been proved to greatly reduced the time required for final clone determination and NGS-based viral testing has been routinely used for rapid conditional release of MCB for GMP production. Furthermore, we are able to implement strategies abovementioned in non-COVID programs with challenging timeline requirement and deliver expedited timeline from DNA to IND in less than 10 months for typical biologics programs.