POLAND



Polpharma Biologics is a biopharmaceutical company with state-of-the-art facilities across Europe. Polpharma Biologics has multiple international centers of excellence specializing in cell line development, product and process development, clinical manufacturing, commercial scale production, and regulatory affairs. They work with their partners to advance their biological pipeline (biosimilars and novel biologics) by providing top-quality contract development and manufacturing services to the industry.

Trzy Lipy 3 Building A 80-172 Gdańsk, Poland +48 58 770 95 59 www.polpharmabiologics.com olpharma Biologics is a fastgrowing company that develops and manufactures new molecular entities and biosimilars with R&D centers in Poland and the Netherlands.

In 2016, Polpharma Biologics acquired Dutch-based Bioceros and their proprietary cell line development platform CHO^{BC®}, as well as their comprehensive discovery, process development, and analytical capabilities. Polpharma Biologics is now taking a further step and integrating Bioceros' Utrecht site and their advanced cell line development capabilities fully into an already extensive biologics development and manufacturing offering and retiring the Bioceros name. This change makes Polpharma Biologics a truly integrated CDMO, offering the complete spectrum of services from discovery to commercial supply.

Polpharma Biologics is excited by the change, because the cell line development platform is truly market leading, offering comprehensive services for both the development of novel biologics and biosimilars using their proprietary CHO-K1-derived cell line CHO^{BC®}, which was developed by the team with over 25 years of experience in generating high-yield production cell lines for innovative and biosimilar proteins.

For the development of novel biologics, the proprietary CHO^{BC®} expression platform allows rapid generation of high-quality cell lines, and high-throughput

technologies are deployed to increase productivity and achieve the highest titers possible.

For the development of biosimilars, Polpharma Biologics has industry-leading expertise in modifying glycosylation patterns during upstream development, which have a significant effect on ADCC, half-life, stability, and immunogenicity. In addition, they are able to use process modulation tools to steer the charge profiles to meet originator profiles. They then use a detailed understanding of interplay between intracellular enzymes to modify the building of these units to match the patterns of the originator without affecting productivity.

Once a cell line has been established, it can be transferred to Polpharma Biologics' facility in Gdansk, Poland for process development utilizing a number of advanced techniques to quickly establish processes that will yield the optimal outcome at the highest level of efficiency for both upstream and downstream processes. This is achieved through running multiparametric experiments in parallel using high-throughput systems to optimize media and culture conditions for scalability.

With an effective process established, Polpharma Biologics' manufacturing facilities provide maximum flexibility, scalability, and efficiency to produce drug substance and drug product for preclinical, clinical, and commercial supply in both microbial and mammalian systems at up to 1000-L scale.

Polpharma Biologics is also establishing a state-of-the-art large-scale manufacturing plant in Warsaw, which will initially add 4×2000 L to their existing drug substance manufacturing capacity and will be ready for clinical and commercial supply in 2021. The site has been designed for rapid expansion of capacity when needed, with space for a further 6×2000 L.

The full integration of Bioceros' capabilities into Polpharma Biologics and the additional drug substance capacity complements the already significant support provided to client projects from concept through development and to clinical and commercial scales.

Polpharma Biologics is now joining the ranks of leading CDMOs with a world-class offering to help partners take their product from concept to commercial supply.

