SmartCella

Press release **Stockholm May 26, 2025**

Procella obtains regulatory approval to widen the scope of cell therapy manufacturing for clinical stages

ProCella, a unit within the SmartCella Regenerative Medicines business segment, has received updated approval by the Swedish Medicinal Product Agency for manufacturing and quality control testing of sterile biological medicinal products for cell therapy.

SmartCella is pleased to announce that Procella has successfully completed another routine authority inspection. The Swedish Medicinal Product Agency (MPA) has granted the updated manufacturing authorization as well as the GMP certification (Good Manufacturing Practice). The approval signifies the certification and quality control of pluripotent stem cell therapy products to clinical studies. The large-scale facility, located at SmartCella's headquarters in Tullinge near Karolinska University Hospital outside of Stockholm, is approved for the manufacturing and the quality control testing of internal therapeutic developments, for both pre-clinical and clinical phases.

Alden Kandic, Head of Quality and Qualified Person at ProCella, says: "We are immensely proud to have remained compliant in our existing world-class GMP manufacturing facility while successfully building a new Quality Control Laboratory intended for release testing of manufactured products. This important milestone will enable us to continue manufacturing now with new additional in-house capabilities for quality control testing in full compliance with GMP for clinical studies, both on the current SMART01 product but also on future products. The GMP cleanroom facility, built in 2022, covers approximately 300 square meters and includes two large grade B clean rooms, as well as one Grade C and one Grade D room. The newly established GMP Quality Control Laboratory, equipped with the latest technological equipment, has undergone comprehensive validation. It operates under a robust quality system to support the authorized manufacturing and testing of Advanced Therapy Medicinal Products (ATMPs) for clinical trials. This achievement is a true team effort across multiple functions within Technical Operations, with everyone fully committed to ensuring the effective completion of all validation activities."

Ricardo Baptista, CTO of SmartCella and Head of Procella, continues: "The authorization of our GMP manufacturing and Quality Control facilities by the MPA marks an essential milestone in the clinical development of our SMART01 cell therapy program for the treatment of cardiac failure. This certification not only enables the progression of SMART01 into Phase I/IIa clinical trials but also strengthens the development pathway for our broader pipeline of pluripotent stem cell therapies, including SMART02 for Parkinson's disease. Moreover, the approval from the MPA underscores the successful establishment of our integrated supply chain capabilities – from early-stage research to scalable, GMP-compliant manufacturing and quality testing – ensuring readiness to support future clinical needs for a diverse range of allogeneic cell-based therapies."

Contact

Nina Nornholm, Head of Communication +46 708 550 356

About SmartCella

SmartCella is a global biotech company pioneering the future of targeted therapies through delivery solutions and advanced therapy development. Founded in 2014, the company is built on globally renowned science and research from Karolinska Institutet in Sweden. SmartCella combines novel delivery platforms, such as the Extroducer® (an endovascular delivery device that enables direct injection to hard-to-reach organs and tumors), with cutting-edge development and manufacturing of cell therapies. The company operates in two business segments: Targeted Delivery and Regenerative Medicines. The Extroducer has been FDA-cleared for use in abdominal organs and is a clinical-stage investigational device for the heart.

The international team consists of scientists, visionary innovators, and experienced business leaders, all dedicated to shaping the future of targeted therapies and delivering life-changing treatments to patients.

Read more on www.smartcella.com
Follow SmartCella on LinkedIn