

## SmartCella obtains approval for GMP manufacturing and quality control testing of cell therapies

*SmartCella, through its business unit ProCella, has been approved 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 been granted manufacturing authorization as well as Good Manufacturing Practice (GMP) certification from the Swedish Medicinal Product Agency. The approvals signify the ability to start clinical production of cell-based therapies for clinical studies. The facility, located at SmartCella's headquarters in Tullinge near Karolinska University Hospital outside of Stockholm, will be available both for the manufacturing of internal therapeutic developments and for third-party manufacturing, for pre-clinical and clinical development phases.

Alden Kandic, Head of Quality and Qualified Person at ProCella, says: "We are immensely proud of this important milestone. This world-class GMP facility will enable us to manufacture according to cGMP for clinical studies. The 300 square meter facility, built in 2022, consists of two large grade B cleanrooms, and one grade C and D room, respectively. Over the last year, the team conducted comprehensive validation activities of both the facility and equipment. Furthermore, we have implemented a solid quality system underpinning the manufacture of Advanced Therapy Medicinal Products (ATMP) for clinical trials. This has been a true team effort, and everyone has been fully dedicated ensuring a successful completion. The grand finale was the authority inspection, and we couldn't be happier with the positive outcome."

Niklas Prager, CEO of SmartCella, continues: "The approval of our GMP facility is a key milestone for SmartCella. We now have capabilities across the entire life cycle of product development, from early Research and Development within SmartCella Solutions to proof of concept in ProCella, with all relevant process development and subsequent technology transfer to production. This, in combination with a stellar quality control system, makes us unique and we have a competitive advantage for future cell therapy product development. Lastly, we have also launched one of the most advanced endovascular delivery devices, the Extroducer, that enables the delivery of a wide range of therapeutic agents directly into organs and tumors, thus making SmartCella a truly comprehensive provider for targeted therapies."

### Contact

Niklas Prager, CEO, +46 768 117744; [niklas.prager@smartcella.com](mailto:niklas.prager@smartcella.com)

### **About SmartCella Holding AB**

*SmartCella, founded in 2014, is an innovative biotechnology company based in Stockholm, Sweden. SmartCella's vision is to combine first-in-class delivery platforms with cutting-edge cell and gene therapies to unleash the full potential of targeted therapies. The company has three main business units, Smartwise, SmartCella Solutions and ProCella.*

### **Smartwise**

*Smartwise is developing and manufacturing a first-in-class endovascular delivery device, the Extroducer, that enables direct tissue/organ infusions through the vessel wall directly into hard-to-reach organs and tumors. There is a significant unmet need in the field of targeted delivery of different types of therapies for regeneration of tissue and for treatment of cancer tumors. Smartwise received regulatory approval from the US FDA for the Extroducer*

*in June 2022 and is now actively licensing out the technology to global companies with therapies that benefit from direct delivery.*

**SmartCella Solutions**

*SmartCella Solutions create novel mRNA therapies and platforms that enable cell-mediated delivery of protein and mRNA to specific regions, even within organs or microenvironments. A pipeline of projects within regeneration and tolerization, focusing on oncology, is in pre-clinical development.*

**ProCella**

*ProCella has advanced capabilities within stem cell therapy development and inhouse cGMP manufacturing of cell-based therapies, with a proven platform to take stem cell projects from discovery phase to clinical development. A globally licensed cardiac stem cell therapy is entering clinical stages (in collaboration with AstraZeneca) and there is a growing pipeline of projects in different stages of development, with dopamine producing cells for Parkinson's Disease and our own iMSCs most advanced.*

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