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### **Executive Summary**

Advanced Therapy Medicinal Products (ATMPs) — including gene therapies, somatic cell therapies, and tissue-engineered products — are reshaping the future of medicine. Sweden is emerging as a leader in this rapidly expanding sector, driven by world-class academic research, national infrastructure investments, and innovative local ecosystems like the one centred in Lund, Southern Sweden. This report highlights the status of Skåne's ATMP landscape, the challenges and opportunities ahead, and how Lund's unique model provides a scalable blueprint for national success.

# The Rise of ATMPs: A New Era of Medicine

ATMPs hold transformative potential for treating diseases that were previously considered incurable. Sweden's pharmaceutical exports now represent over 7% of total national exports, surpassing traditional industries. The national pharmaceutical market is expected to grow at 5-8% annually, while the cell and gene therapy sector is forecasted to surge by 25% annually.

#### **Lund: Sweden's Innovation Engine**

Lund is home to at least 27 active ATMP projects as of 2024, supported by <u>Lund University's Stem</u>
<u>Cell Center</u> and the newly launched LU-ATMP Center.
Research groups in Lund are leading efforts in Parkinson's disease, oncology, neurology, and rare genetic conditions.

#### Key developments include:

- STEM-PD: A groundbreaking clinical trial transplanting dopamineproducing cells in Parkinson's patients
- Gene therapy for Diamond-Blackfan Anemia (DBA): Patients with DBA have an inherited damage to the genes that reduces the bone marrow's production of red blood cells. Lund researchers are ready for clinical trials where they are using gene therapy to replace the damaged gene, so that the patient's own blood stem cells can produce healthy blood.
- Pre-GMP Facility: A cost-efficient, flexible space to de-risk and scale up manufacturing processes
- GMP Manufacturing Unit: A 1,100m<sup>2</sup> cleanroom facility at Skåne University Hospital
- Integration with Medicon Valley, Northern Europe's largest life science cluster made up of Skåne and Eastern Denmark.: Proximity to Copenhagen and strong industry ties





## A snapshot of the Lund ATMP pipeline

Neurology is the most common target of ATMPs being developed at Lund Stem Cell Center, followed by haematology and oncology. In addition to these major three indications, there are projects within infectious disease, respirology and bone regeneration.

### **Therapeutic targets**



#### Neurology

Restoring lost functions acquired through agering, disease and injury. Improving functions in psychiatric disorders.



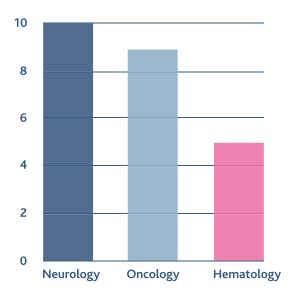
#### Oncology

Applying the tools of cell and gene therapy to fight cancer.



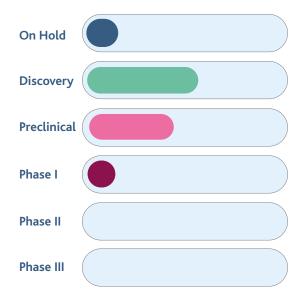
#### Hematology

Curing congenital conditions of the circulatory system or deriving transfusions in the future.



# ATMPs in pipeline according to the phases of development.

The 27 ATMPs under development are mostly found in the early discovery or pre-clinical stages of development. Thus, our investments in support and infrastructure to accelerate the progress of the projects for the benefit of patients.







# The National Landscape: Strengths & Gaps

Sweden's ATMP ecosystem is expanding with ATMP centres in Lund, Uppsala, Gothenburg and Stockholm.

### **Key strengths include:**

- High concentration of biotech SMEs (60 ATMPs in development by 19 companies).
- 45 clinical trials conducted to date; nine led by Skåne University Hospital.
- Strategic innovation infrastructures: Testa Center (Uppsala), CCRM Nordic (Mölndal), NorthXBiologics (Matfors) and the Novo Nordisk "Cellerator" (Copenhagen).

# However, Sweden does face a few challenges including:

- Limited reimbursement of ATMPs (only six out of 26 EMA-approved therapies reimbursed)
- Gaps in later-stage commercialisation and IP readiness
- At times, fragmented coordination between academia, hospitals & industry; to mitigate, Lund has developed an interdisciplinary collaboration called the ATMP model of Lund which focuses on value creation through strategic and integrated collaboration between academia, industry and the public sector.

# The ATMP Model of Lund: A Triple Helix for International Success

# Lund is demonstrating how inter-sectorial collaboration can accelerate ATMP development from lab to market:

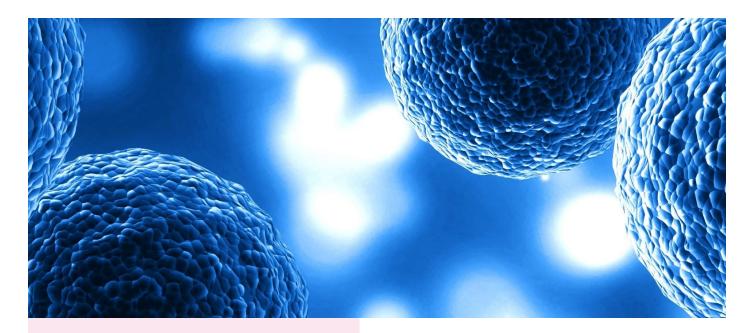
- Strong university-hospital-industry integration and collaboration
- Focused investment in process development, IP and regulatory support
- Support from the regional development and national programmes to connect developers with investors

### This model addresses known bottlenecks by:

- Creating seamless pre-GMP to GMP workflows
- Enabling local manufacture and clinical trial initiation
- Promoting early regulatory guidance and commercialisation planning



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### **Biotech developers in Lund**

## xintela

**Xintela**. Cell therapies based on mesenchymalstem cells, focusing on osteoarthritis and difficult-to-heal leg ulcers and, through its wholly owned subsidiary, <u>Targinta</u>, targeted antibody-based treatments for aggressive cancer, such as triple-negative breast cancer and the brain tumour glioblastoma. The focus is on diseases that cause great suffering and lack effective medical treatment options.



Asgard Therapeutics. Fighting tumours with gene therapy delivered in vivo cell programming. A spin-off from a research at Lund University, the company is pioneering a gene therapy approach based on its proprietary TrojanDC technology. The technology allows for the changing of cancer cells from the inside, by reprogramming them to induce an attack from the body's immune system against themselves. Asgard aims to build a pipeline of personalised cancer immunotherapies optimised for each unique patient.

## **Moving from vision to Impact**

The challenge ahead is aligning Sweden's growing infrastructure with real-time developer needs. By creating roadmaps, connecting ecosystems, and evaluating infrastructure return on investment (ROI), Sweden can lead Europe in delivering ATMPs to patients.

### **Conclusion**

Sweden stands at the frontier of a biomedical revolution. Applying Lund's collaborative ATMP ecosystem paving the way, the nation has a unique opportunity to translate its scientific excellence into accessible therapies, industrial growth, and global leadership.



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# **About Invest in Skåne**

We are the official investment promotion agency for southernmost Sweden. We help international companies looking to invest, establish and expand in southern Sweden, offering government-funded support to meet your unique needs. Contact us for more info.



Aleksandra Ellervik aleksandra.ellervik@skane.se



Christina Wenglén chritsina.wenglen@skane.se

# **invest** in skåne

Invest@skane.com • Investinskane.com • Linkedin: Invest in Skane