

#RESEARCHNEVERSTOPS

# **Cell Therapy at Evotec**

Integrated approach to deliver new therapies to patients

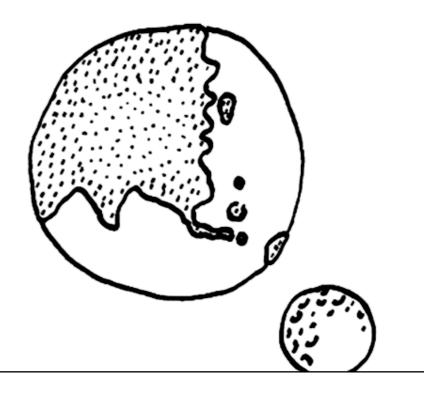


#### Agenda

#### Cell therapy at Evotec

iPSC cell therapy platform

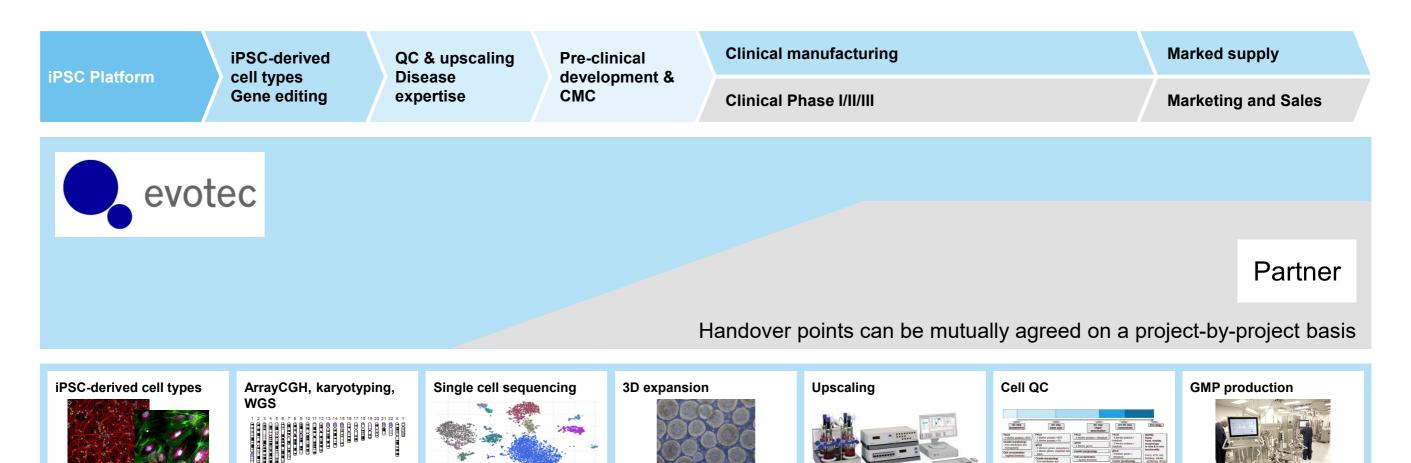
Manufacturing capabilities





# Delivering cell therapies to patients through a world class integrated platform

EVO*cells*: End-to-end solution for iPSC-based cell therapeutics



Evotec

Partner



#### Innovative iPSC-based cell therapy assets available for partnering

Internal pipeline spans a range of different cell types & disease areas

Field	Program/Project	Disease area	Exploratory	Pre-clinical research	Pre-clinical development	IND / Phase I	iPSC-derived cell types
Oncology	iNK	IO <sup>1)</sup>			2)		iNK Natural killer cells
	iM	IO					• iT $\alpha\beta$ - and $\gamma\delta$ - T cells
	γδ iT	IO					• iM Macrophages
	αβ ίΤ	IO					iBeta Pancreatic islets
Regenerative Medicine	E.iBeta (gen 1)	Diabetes					<ul> <li>iCM Cardiomyocytes</li> </ul>
	QRbeta (gen 2)	Diabetes					<ul> <li>iMSC Mesenchymal stromal c</li> </ul>
	iCM	Heart failure					
Immune- modulation	iMSC exosomes	Various					
	iNK, iTreg	Anti-fibrotic, auto-immune					

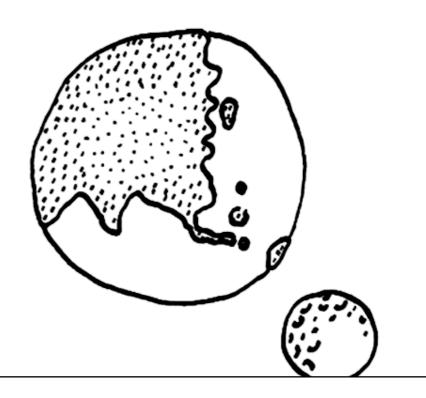


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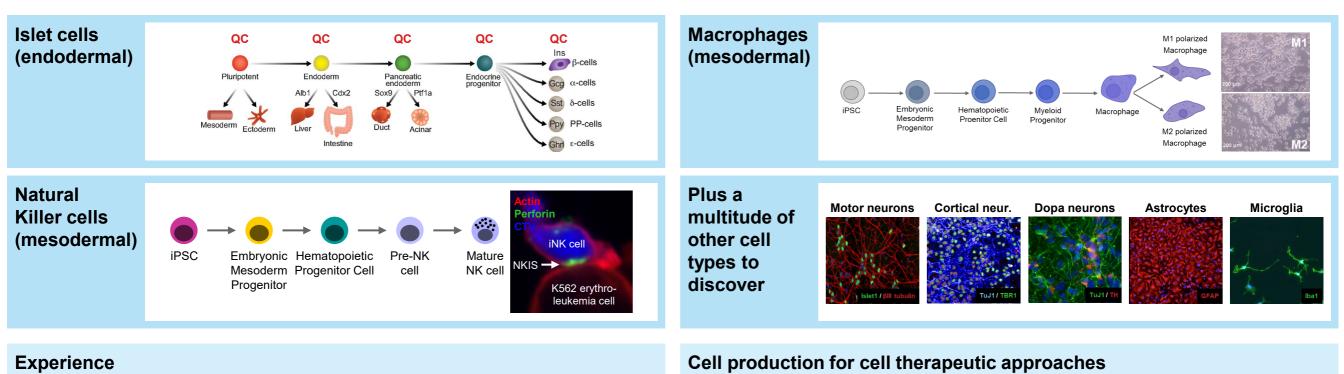
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# A decade of expertise with iPSC differentiation

Ability to produce a multitude different iPSC-derived cell types

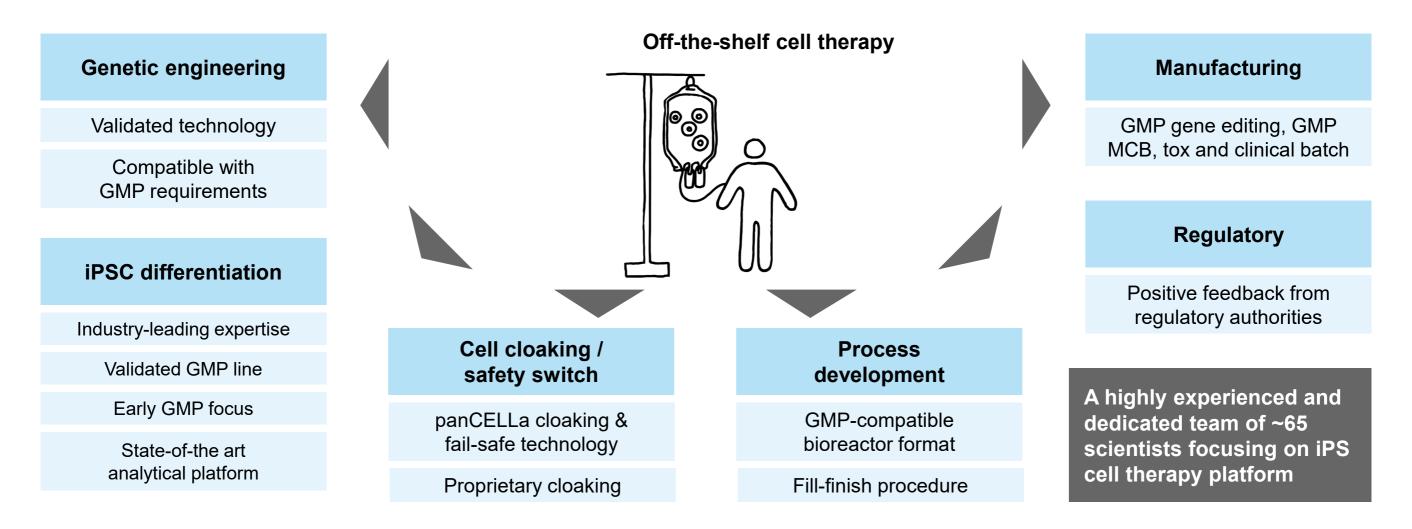


- > 10 years of iPSC biology experience
- Intricate know-how of developmental biology
- One of the largest iPSC platform groups in the industry with >100 people dedicated to developing iPSC-derived cells for drug discovery and cell therapy
- Focus on industrialization, robustness, scalability and GMP compatibility from day one
- Translation from R&D to full GMP
- Comprehensive QC at key intermediate stages & end stage as core element



### **Outstanding iPSC platform & expertise**

Leading iPS cell therapy platform



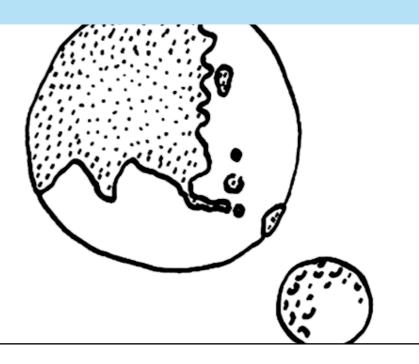


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# Centre of excellence for cell therapeutics manufacturing

#### Evotec Modena





- Founded in 2009 as spin-off of the University of Modena and Reggio Emilia
- Scientific founder Prof. Massimo Dominici is one of the pioneers in clinical cell therapy
- State-of-the art GMP manufacturing facility (5 clean rooms, 350 m<sup>2</sup>) with room for significant expansion
- cGMP facility accredited by Italian Authority for the manufacturing of clinical stage cell and gene therapies
- Experienced to manufacture complex cell and gene therapies including pre-GMP optimization steps
- Experience with MSCs, TILs, CAR-T, dendritic cells and exosomes
- Tech transfer for manufacturing of iPSC-based therapeutics on-going

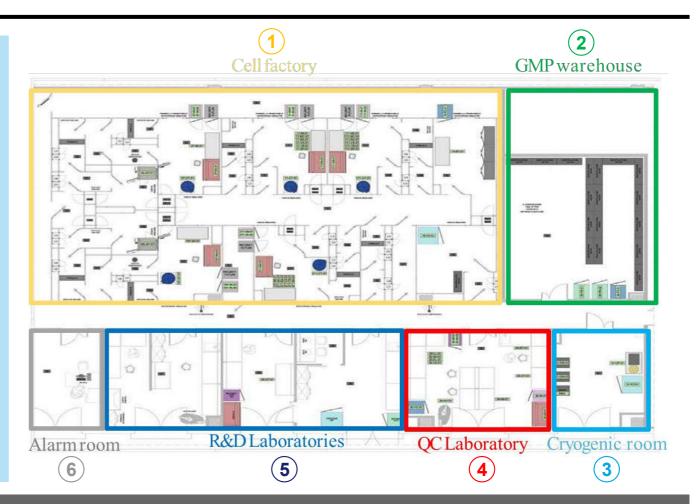


### The EVOTEC Modena cell factory

Facility overview

#### **EVOTEC MO Cell Factory**

- The GMP manufacturing facility is composed of:
  - A cell factory: equipped with 5 sterile cleanroom / manufacturing suites, suitable for aseptic manipulation of sterile medicinal products (Grade A/B cleanroom) according to EU and US cGMP rules
  - 2) A class C GMP warehouse with ambient storage: with a dedicated airlocks and a Grade D transfer material zone
  - **3) A cryogenic room:** for qualified controlled storage at -80°C to 196°C with vapor phase liquid nitrogen under 24-h remote control
  - 4) A QC laboratory: equipped to perform microbiologic tests to monitor the classified rooms and to execute quality and safety controls on intermediate and final products
  - 5) A R&D laboratory: for ATMP research purposes
  - 6) An alarm room: enabling monitoring of the cryogenic room via SCADA
- Areas n°1 and n°2 i.e. cell factory and GMP warehouse are in a cleanroom space of 450m<sup>2</sup>



EVT MO can perform all production steps of ATMP manufacturing, from development to production, cold temperature storage and quality control in compliance with GMP requirements



# Manufacturing suites

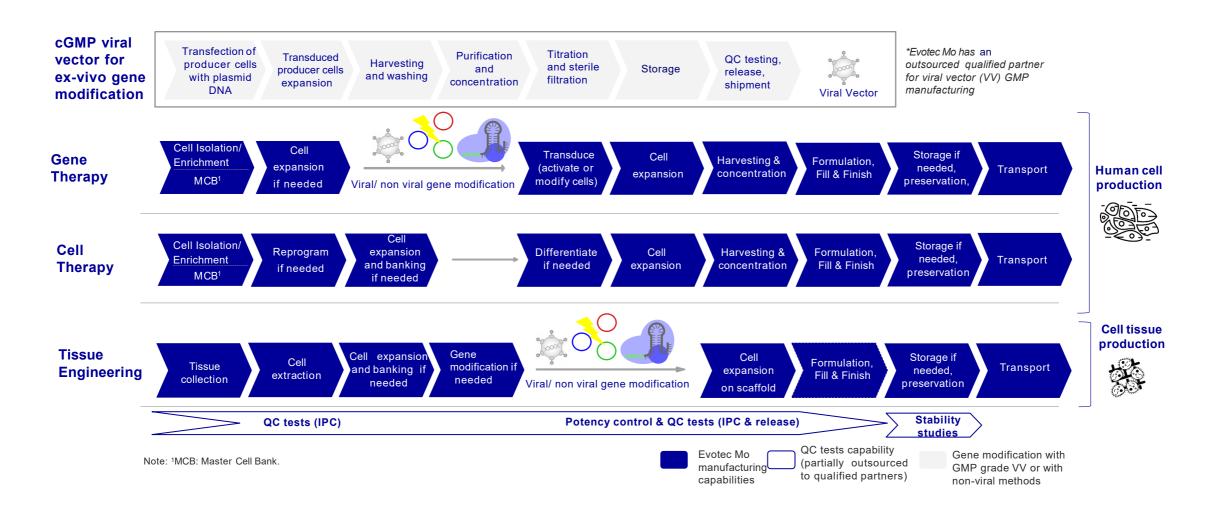
#### EVT MO has 5 class B manufacturing suites with 24/7 monitoring





# **EVOTEC MODENA** manufacturing capacity

EVOTEC MO produces cell & gene therapies from procurement to patients





# Elevating ideas to cell therapy products

Evotec Modena expertise for cell/gene therapy acceleration

