



ACTITREXX



Activated Treg
for tolerance

Andrea Tüttenberg
CEO

Pharma Forum 16.03.2023



Mainz, Rheinland-Pfalz (Spin-off of the University Medical Center Mainz)



Biotech start-up in CTA-enabling stage, **11 employees**



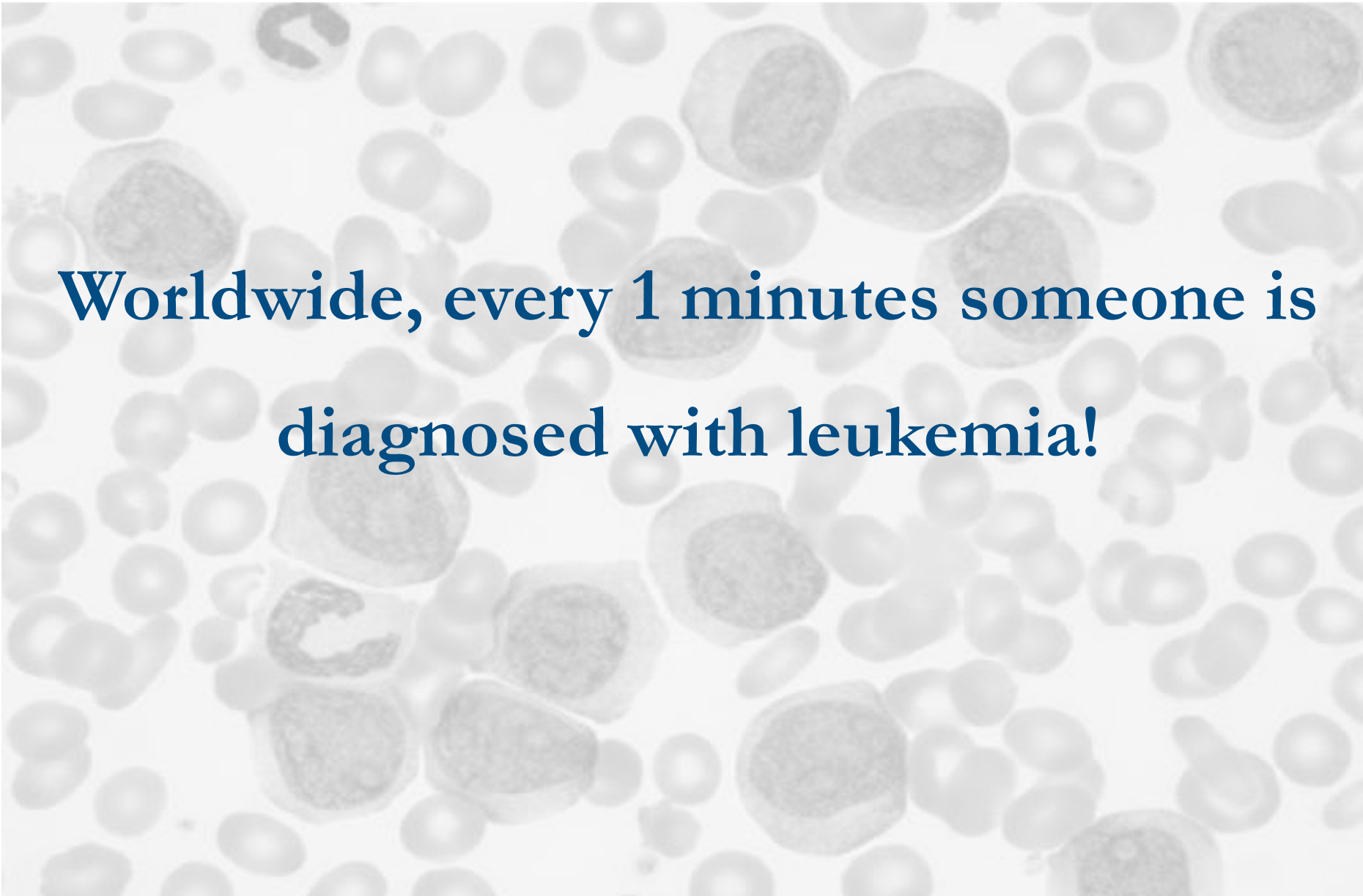
Founded 2020 (A. Tüttenberg, H. Jonuleit, F.-J. Schneider, M. Kring)



GmbH



- **GO-Bio I** (€ 4 Mio) **GO-Bio II** (€ 5.5 Mio), **BMBF**
- **Series A** (€ 3.5 Mio): **LBBW Venture Capital GmbH, MediVentures, HTGF, WFT Rheinland-Pfalz**

A microscopic view of blood cells, showing various types of white blood cells (leukocytes) with prominent nuclei and some red blood cells (erythrocytes) in the background. The cells are stained and appear in shades of gray and blue.

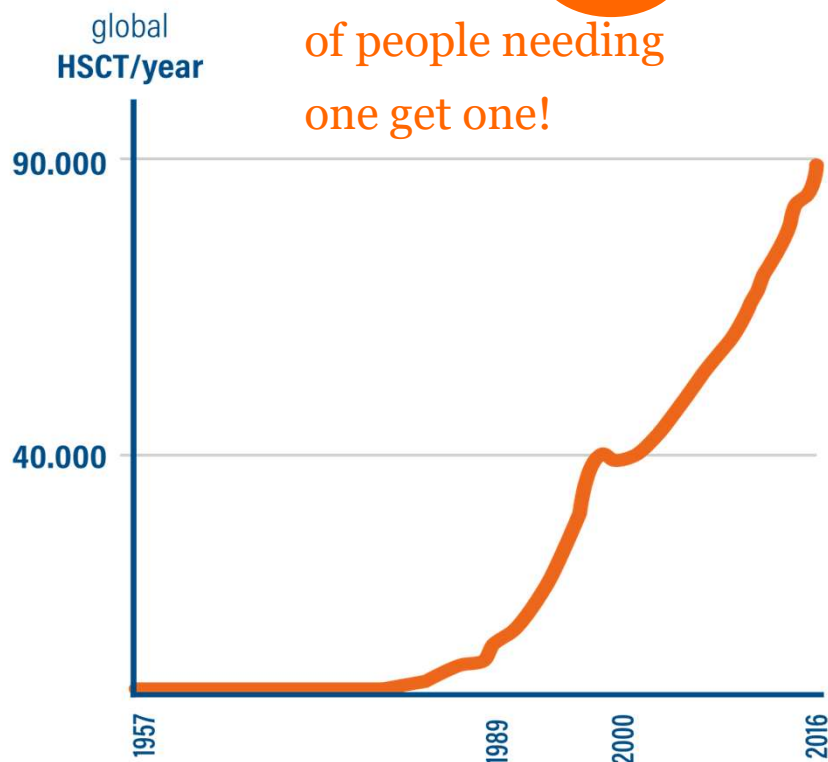
**Worldwide, every 1 minutes someone is
diagnosed with leukemia!**

The Problem: Transplant rejection (GvHD)

ACTITREXX
^

Stem Cell Transplantation (HSCT) ➡ only potential cure for leukemia

But: only **10%** of people needing one get one! → Two challenges:



Source: The American Society of Hematology 2019

1 Need of a compatible donor

2 Lethal Complication:

transplant rejection in **50%** of transplanted patients

Massive inflammation of organs,
loss of quality of life,

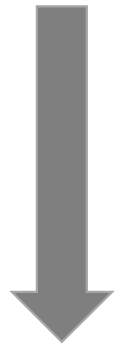
20% mortality

Urgent and high unmet medical need addressed by ACTITREXX
^

Solution: Waking up Treg – Tolerance induction via Treg

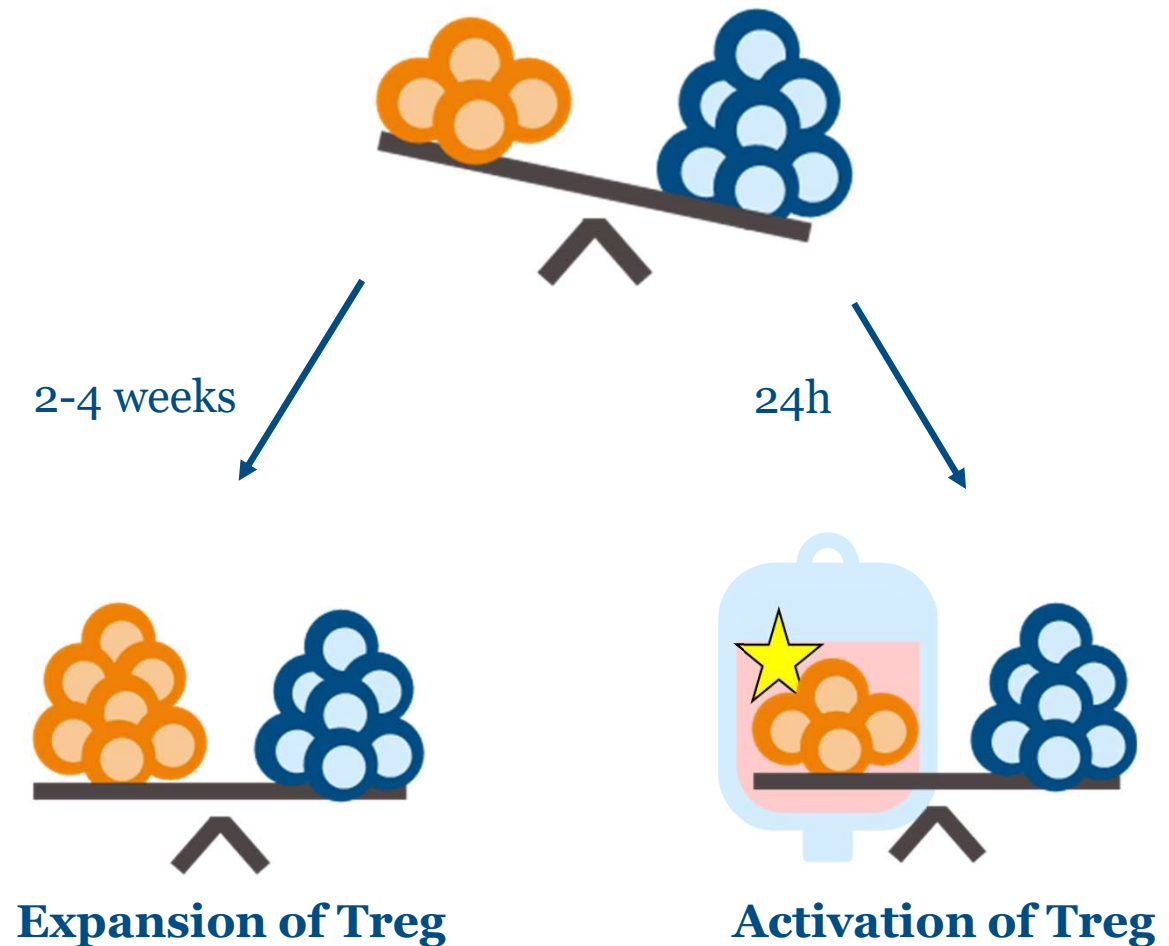
ACTITREXX
^

**Uncontrolled immune
Response / Imbalance**



**Reconstitution of
immunological
balance:**

Treg-Therapy



Solution: ATreg to prevent GvHD

ACTITREXX
^



Activated regulatory T cells (ATreg) -> Actileucel

Achievements so far

R&D & Pre-clinical

Upcoming Milestones

First-in-Human Study (Phase I)

Demonstrated Proof of Mechanism

- Safe, easy to administer
- Off-the shelf
- 24h ready-to-use
- Price below current treatment costs



➤ Start in Q2/2023

US: 7 years EU: 10 years
Treatment in HSCT
market exclusivity upon
first market approval.



GO-Bio I

€ 4 Mio

GO-Bio II

€ 5.5 Mio
BMBF

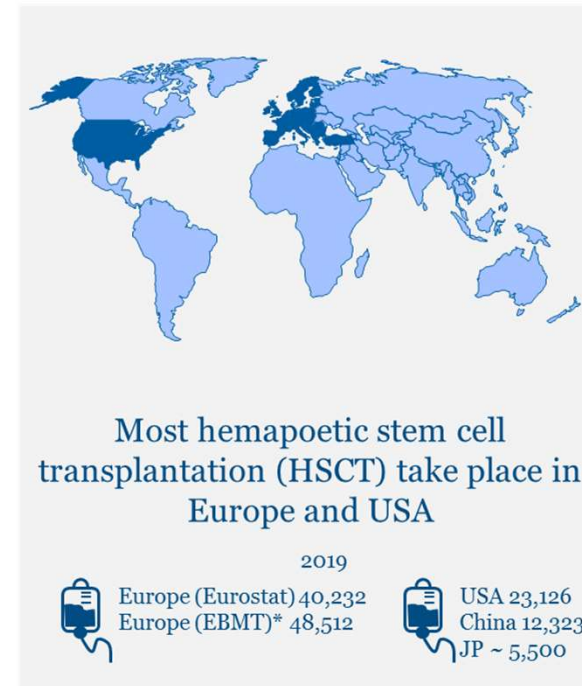
Series A:

€ 3.5 Mio

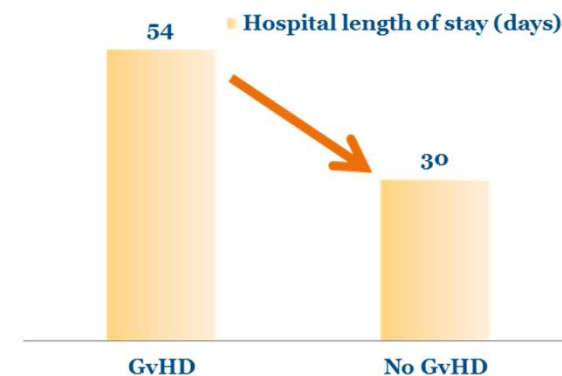
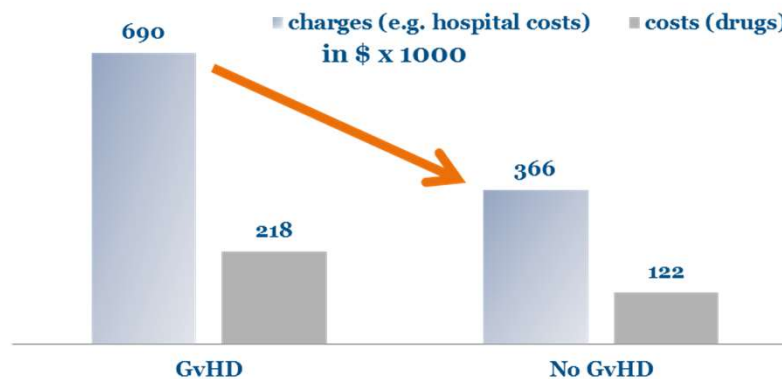
LBBW Venture Capital GmbH,
MediVentures, HTGF, WFT
Rheinland-Pfalz

Market Potential

- **Largest markets Europe and USA:**
~65,000 HSCT/yr.
- **Market growth:** 6.2 – 15% p.a.



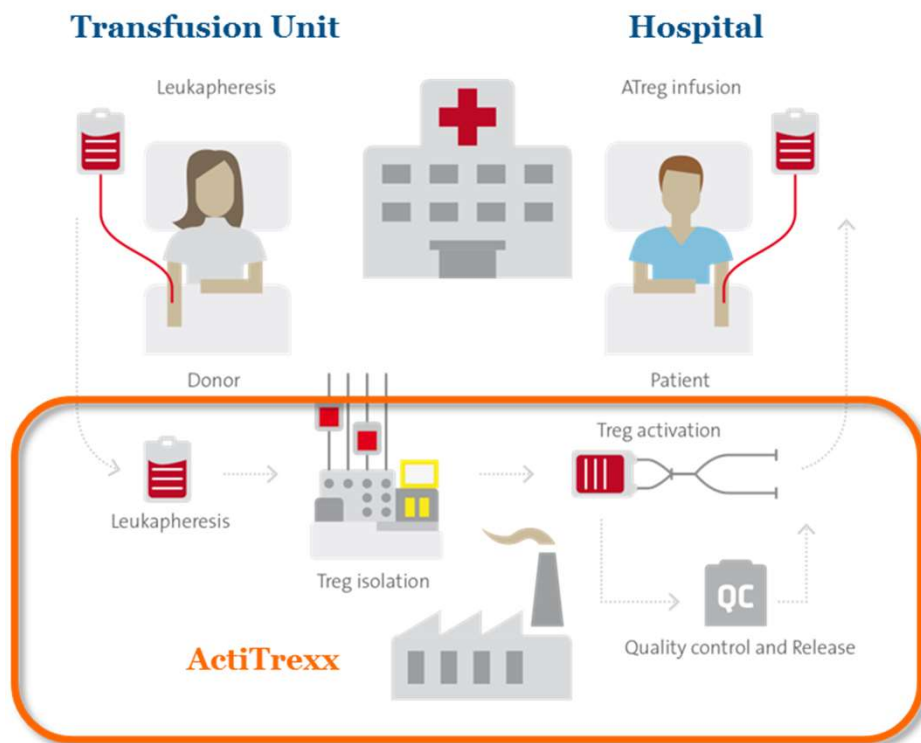
- Significant **reduction of costs** in transplanted patients without development of GvHD



ASCO presentation (Oct 2017, Yu et.al.) *p < 0.001

Business Model

- ActiTrex produces & releases Actileucel for Phase I



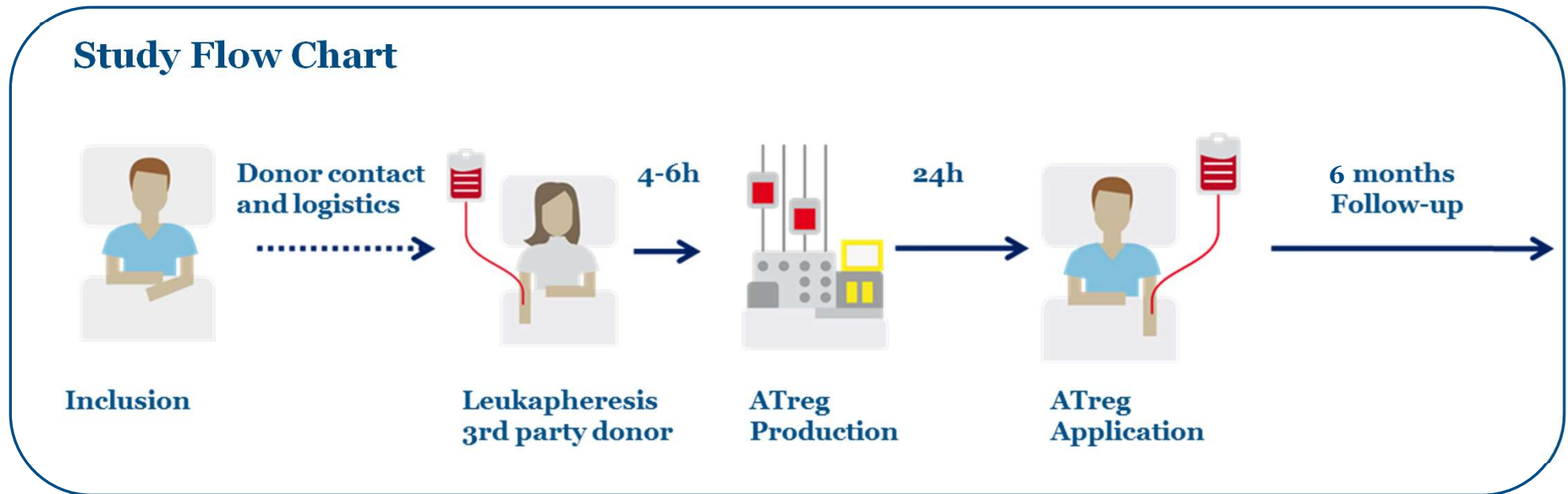
- Phase III ActiTrex / CDMO

- Covering the European market with 1 single production site



- M&S**
 - DACH: ActiTrex
 - EU: License partner
 - US: License partner

Phase I Study -> Start in Q2/23 in Mainz (UM Mainz, Dresden)



Main clinical objective: Assessment of feasibility, safety and tolerability of Actileucel

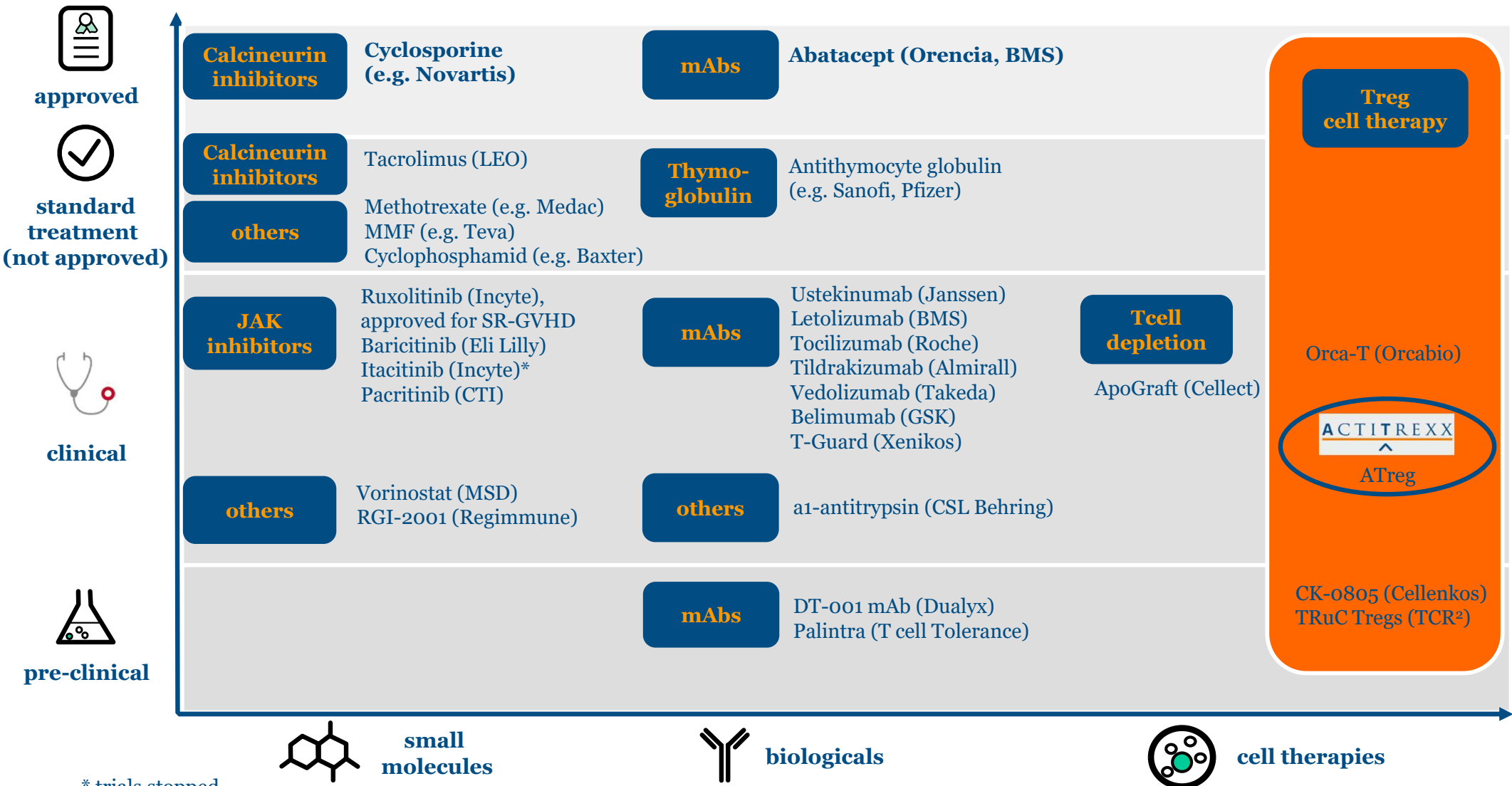
Intended purpose:

- Reduction of patients' risk to develop GvHD
- Reduction of severity of GvHD
- Reduction of immunosuppressive burden

Competitive Landscape GvHD Prevention



Current standard treatment and novel approaches



* trials stopped

Meet the Team

- Highly experienced, strong and **diverse** team
- **>100 years experience** in medicine, academia, biotechnology, business and pharma
- Experienced advisory board, scientific advisors and consultants



Andrea Tüttenberg
CEO/CMO

- Medical Background
- Translational Research
- > 20 years



Helmut Jonuleit
CSO

- Manufacturing
- Basic Research
- Inventor of Atreg
- > 25 years R&D



Franz-Joseph Schneider
CKO

- IP
- Industry
- > 25 years R&D



Michael Kring
CFO (external)

- Finance
- > 15 years CFO e.g.



Sylvia Bold
Head BD

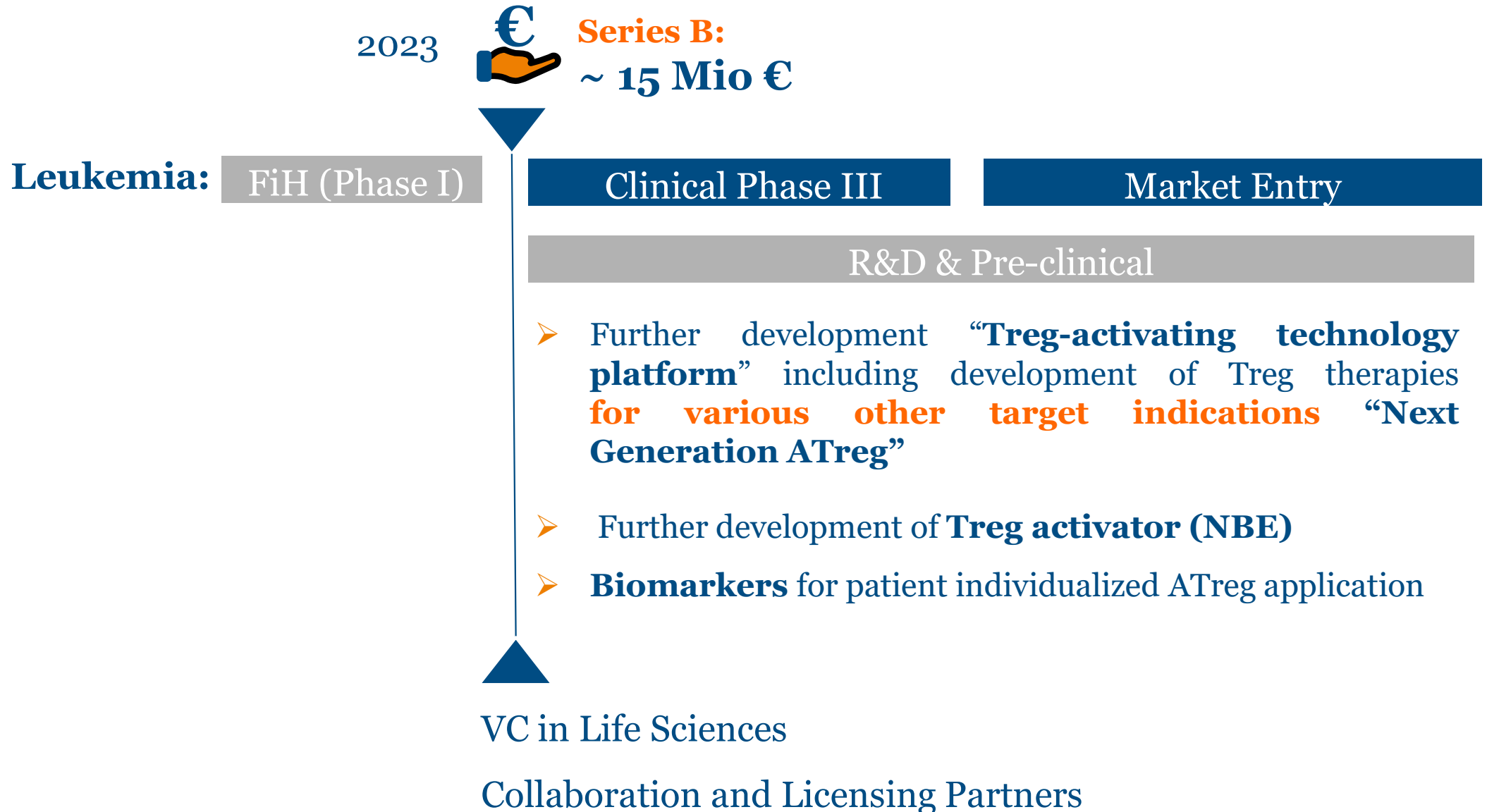
- Business Development
- > 20 years Consulting and BD, eg.



Meet the Team – Production / R&D

- R&D lab and office space at University of Mainz
- GMP clean room facilities
- Team with long-lasting experience in cellular immunology, GMP processes and quality management

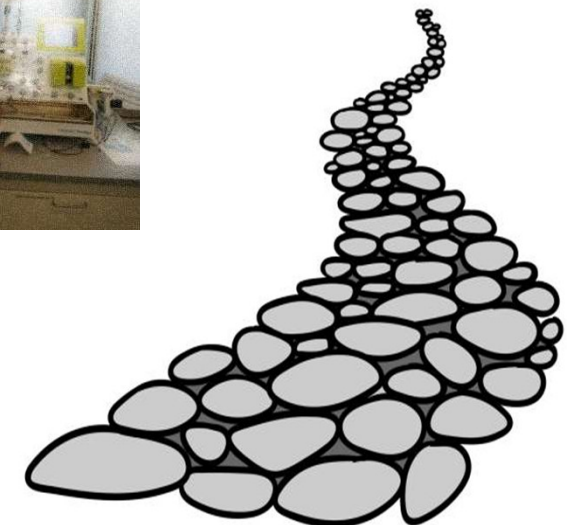




From Bench to Bedside to Market

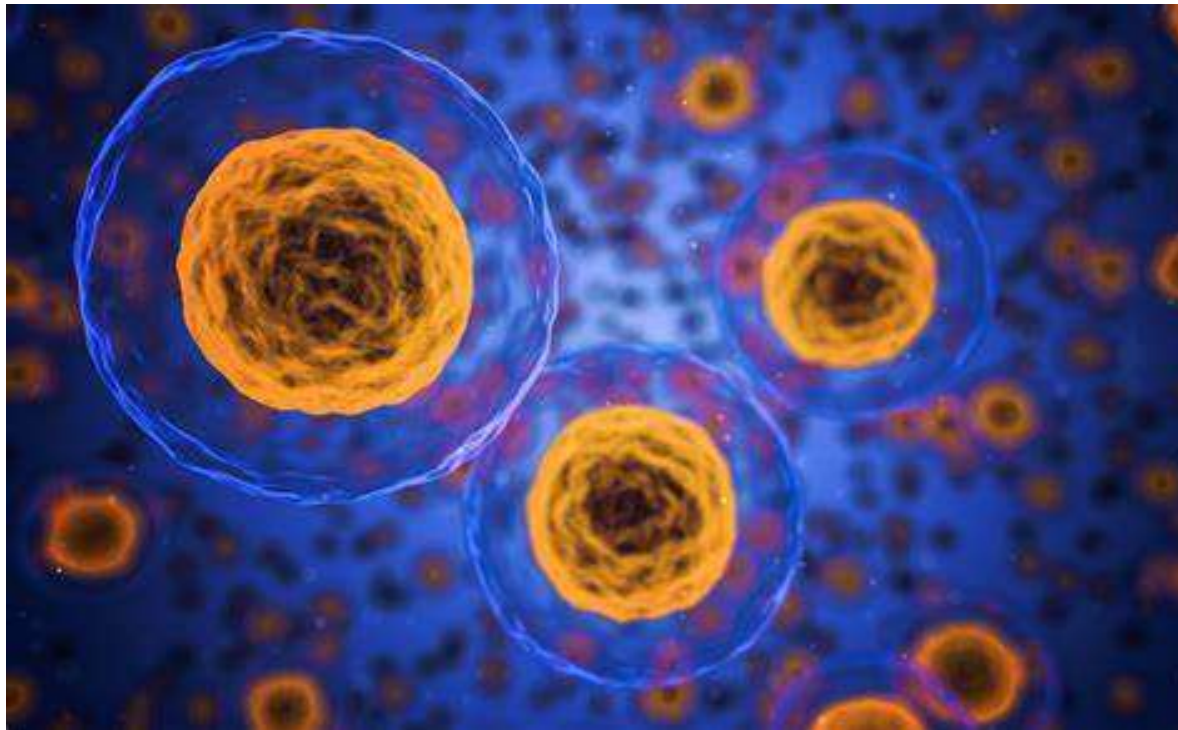
- a long way!

ACTITREXX
^



Imagine, Leukemia becomes Curable.....

Stem cell transplantation for everyone who needs it



»Leukemia must become curable. Always and in all cases.«
— José Carreras

Thank you!

Prof. Dr. Andrea Tüttenberg, CEO

ActiTrex GmbH
c/o Langenbeckstr. 1
55131 Mainz
Germany
Tel.: +49-173-655 2473
andrea.tuettenberg@actitrex.de
www.actitrex.de

