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Specific Immunomodulation versus unspecific Immunosuppression

Tolerogenix GmbH

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TOLEROGENIXxX

Tailored specific immunomodulation

Standard immunosuppression

Broad unspecific weakening of the immune system

Side effects
- Infection
- Cancer
- Diabetes
- Heart problems

2x daily intake lifelong

single infusion

With a single treatment, patient’s become fully tolerant to certain tissue or transplanted organ while being fully responsive against other antigen such as bacteria, viruses and malignancy.
Clinical evaluation of MICs
Prototype phase-I TOL-1 study at Heidelberg University Hospital: 10 tolerant patients after living donor kidney transplantation

The feasibility and safety of a MIC cell administration for the induction of a donor-specific tolerance was clearly confirmed by the Phase I study.

GMP: Good Manufacturing Practice, MIC: Mitomycin C-induced cells, PBMCs: mononuclear blood cells, SOC: Standard of care
**Business model of TolerogenixX**

1) **Patient treatment in the Hub**
Donor and recipient visit the Hub, the recipient is treated with the modified cells of the donor. The organ transplantation takes place in the home center.

2) **PBMC treatment in the Hub**
Donor PBMCs are collected in local hospital and sent to TolerogenixX for modification. TolerogenixX sends the modified cells back to the hospital. Cells are infused in the local center, where the transplantation takes place later.

MICs should be infused within 24 hours. To ensure worldwide delivery during this short time frame, approximately 4 further hubs are necessary.

PBMCs = mononuclear blood cells
Summary
The smart way to immune tolerance

• Specific and effective therapy without side effects
• The simplest possible approach to individualized cell therapy (ATMP, Advanced Therapy Medicinal Product)
• Platform technology, widely applicable in transplantation and autoimmune diseases
• Novel mode of action, the key tolerogenic cells (tolerogenic DCs, Bregs) of the immune system can be directly induced in the patients
• Unwanted reactions of the immune system (rejection, autoimmune reactions, etc.) can be specifically switched off while the desired reactions (defence against pathogens, tumour cells, etc.) are not interrupted.
• Significantly reduced treatment costs for the health system (approx. 200.000€/patient)
• Already successfully tested in the clinical phase I TOL-1 study
• First approved product will be available in 2021
The TolerogenixX Team

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Chief Executive Officer
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