

# First Annual Meeting

23<sup>rd</sup>-24<sup>th</sup> January 2020

Hotel AMANO Grand Central  
Heidestrasse 62, 10557 Berlin, Germany

**Thursday, 23<sup>rd</sup> January 2020 - Day I**

Meeting of the Executive Project Management Team (EPMT)

**09.00-11.00 Meeting restricted to EPMT members**

## Welcome & Introduction

**10.30-11.00 Registration & Welcome coffee**

### 11.00-12.30 Introduction

RESHAPE- Reshaping undesired Inflammation in challenged Tissue Homeostasis by Next-Generation regulatory T cell (Treg) Approaches - from Advanced Technology Developments to First-in-Human Trials

Petra Reinke - BeCAT, Charité - Universitätsmedizin Berlin, Germany

## WP1 - Next-generation Treg development platform

Chair: Ignacio Anegón- Université de Nantes, France

### 12.30-13.00 Task 1.1 Enhanced target antigen specificity by CAR Treg approach

(20 min + 10 min discussion)

- Subproject 1: Screening platform for antigen-specific CAR Treg

- Final MS: CAR constructs will be proven in primary Treg & compared to pre-existing CAR Treg

Dimitrios Laurin Wagner - Charité - Universitätsmedizin Berlin, Germany

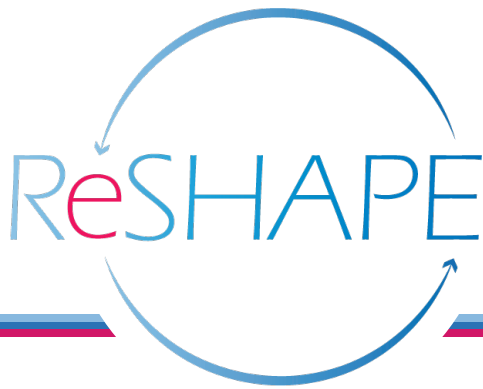
**13.00-14.00 Lunch**



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**14.00-14.30 Task 1.1 Enhanced target antigen specificity by CAR Treg approach**

(20 min + 10 min discussion)

- Subproject 2: Tissue(Autoantigen)-specific CAR-Treg
- Final MS: approved GMP manufacturing process

Elmar Jäckel - Medizinische Hochschule Hannover, Germany

**14.30-15.10 Task 1.2 Enhanced target antigen specificity by TCR Treg approach - Cas9 specific TCR-Treg as a role model (15 min + 5 min discussion)**

- Final MS: ready for transfer into GMP manufacturing process

Michael Schmück-Henneresse - Charité - Universitätsmedizin Berlin, Germany

**& Task 1.4 Enhanced stability of Treg products to inflammatory triggers by CRISPR/Cas9 mediated knock-down switch points (SPR-Treg) (15 min + 5 min discussion)**

- Final MS: selection of the most promising SPR-Treg product candidate for further development to GMP-grade product)

Dimitrios Laurin Wagner - Charité - Universitätsmedizin Berlin, Germany

**15.10-15.30 Task 1.7 Enhanced engraftment of Treg by inducing resistance to immune-suppressive drugs using CRISPR/Cas9 technology & by enabling to deliver locally IL-2 (15 min + 5 min discussion)**

- Subproject 1: Resistance to Immunosuppressive drugs by CRISPR/Cas9 technology
- Final MS: approved GMP manufacturing process

Leila Amini - Charité - Universitätsmedizin Berlin, Germany

**15.30-15.50 Task 1.7 Enhanced engraftment of Treg by inducing resistance to immune-suppressive drugs using CRISPR/Cas9 technology & by enabling to deliver locally IL-2 (15 min + 5 min discussion)**

- Subproject 2: Enabling Treg to secrete autocrine IL-2 in vivo
- Final MS: ready for transfer into GMP manufacturing process

Carole Guillonneau - Université de Nantes, France

**15.50-16.25 Task 1.3 Enhanced stability of Treg products by epigenetic modification**

(10 min + 5 min discussion)

- Final MS: ready for transfer into GMP manufacturing process

Julia Polansky-Biskup - Charité - Universitätsmedizin Berlin, Germany

**Task 2.3 Molecular Signature (RNA seq, TCR seq, Methylation) of Treg products**

(15 min + 5 min discussion)

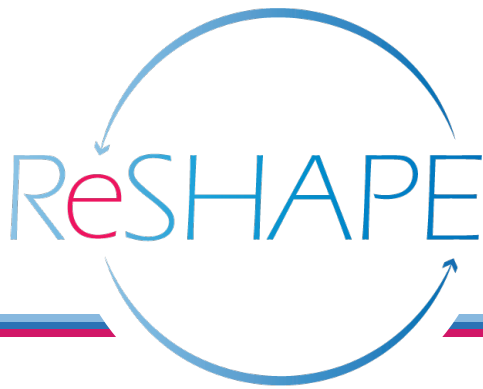
- Final MS: Molecular signature of preselected Treg candidates

Kristy Ou - Charité - Universitätsmedizin Berlin, Germany (10 min)

Nina Babel - Charité - Universitätsmedizin Berlin / Universitätsklinikum der Ruhr-Universität Bochum, Germany (5 min)

**16.25-16.40 Coffee break**





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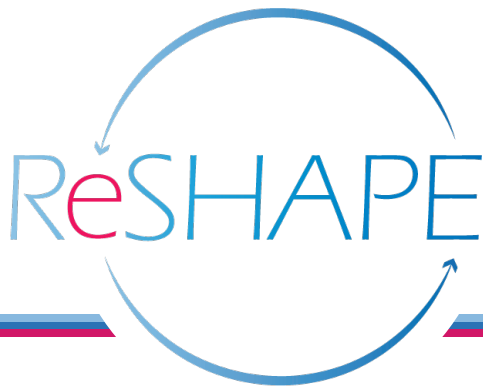
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- 16.40-17.00 Task 1.5 Generation of stable regulatory T cell by programming mitochondrial morphology & cellular metabolism** (15min + 5 min discussion)  
- Final MS: ready for transfer of the most promising candidate into GMP manufacturing process  
Birgit Sawitzki - Charité - Universitätsmedizin Berlin, Germany
- 17.00-17.30 Task 1.6 Exploring CD8+ Treg as an alternative and/or complementary to CD4+ Treg**  
(20 min + 10 min discussion)  
- Final MS: approved GMP manufacturing process  
Carole Guillonneau - Université de Nantes, France
- 17.30-18.00 Task 1.8 Development of virus-free gene transfer into Treg** (20 min + 10 min discussion)  
- Final MS: 1-2 fully validated non-viral gene transfer methods applicable for Treg  
Tristan Thwaites - Cell and Gene Therapy Catapult, United Kingdom  
Ilaria Santeramo - Cell and Gene Therapy Catapult, United Kingdom
- 18.00-18.30 Task 1.9 Exploration of the feasibility of using allogeneic off-the-shelf Treg products**  
(20 min + 10 min discussion)  
- Final MS: ready for transfer of the most promising candidate into GMP manufacturing process  
Ignacio Anegon - Université de Nantes, France
- 18.30-21.00 Group Discussion & Networking dinner**





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## Friday, 24<sup>th</sup> January 2020 - Day I

### WP2 - Next-generation Treg product characterisation platform

Chair: Markus Templin - Naturwissenschaftliches und Medizinisches Institut an der Universität Tübingen, Germany

**09.00-09.30 Task 2.1 Proteomics for characterisation of Treg products** (20 min + 10 min discussion)  
- Subproject 1: Targeted proteomics approaches: DigiWest and Luminex  
- Final MS: In-depth proteomics analysis of all preselected Treg candidates  
Markus Templin - Naturwissenschaftliches und Medizinisches Institut an der Universität Tübingen, Germany

**09.30-09.50 Task 2.1 Proteomics for characterisation of Treg products** (15 min + 5 min discussion)  
- Subproject 2: Unbiased proteomics approach  
- Final MS: In-depth proteomics analysis of all preselected Treg candidates  
Oliver Klein - Charité - Universitätsmedizin Berlin, Germany

**09.50-10.10 Task 2.2 Multiparameter Flow/Mass Cytometry for characterization of Treg products**  
(15 min + 5 min discussion)  
- Multiparameter Flow/Mass Cytometry for characterization of Treg products  
- Final MS: In-depth cytometric analysis of all Treg candidates  
Mathias Streitz - Charité - Universitätsmedizin Berlin, Germany

### WP3 - Next-generation test platform for new in vivo & in vitro preclinical models

Chair: Joanna Hester- University of Oxford, United Kingdom

**10.10-10.40 Task 3.1 In vivo (modified "humanized" rodents models) preclinical (disease) models**  
(20 min + 10 min discussion)  
- Final MS: Proof-of-Concept by in vivo analysis of all preselected Treg candidates  
Fadi Issa - University of Oxford, UK

**10.40-11.10 Task 3.2 In vitro (organ/human-on-the-chip technology) preclinical (disease) models**  
(20 min + 10 min discussion)  
- Final MS: Proof-of-Concept by in vitro analysis of all preselected Treg candidates  
Isabell Durieux - TissUse GmbH, Germany

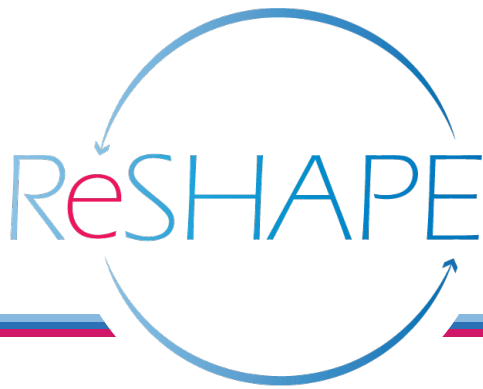
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## WP4 - Clinical Trial platform to prove the next generation Treg approaches

Chair: Elmar Jäckel - Medizinische Hochschule Hannover, Germany

- 11.30-11.50 Task 4.1 Improvement of in vivo engraftment of adoptively transferred Treg by specific conditioning of the Recipients** (15 min + 5 min discussion)
- Clinical study n° 2: "ProTreg Trial - A Phase I/IIa single dose study to investigate the safety and tolerability of tTregs as an adjunctive therapy in CD kidney recipients following anti-thymocyte (ATG) induction therapy"
  - Final MS: Clinical Proof-of-Concept
- Petra Reinke - BeCAT, Charité - Universitätsmedizin Berlin, Germany
- 11.50-12.10 Task 4.1 Improvement of in vivo engraftment of adoptively transferred Treg by specific conditioning of the Recipients** (15 min + 5 min discussion)
- Clinical study n° 3: "The TWO Study: Transplantation Without Over-immunosuppression"
  - Final MS: Clinical Proof-of-Concept
- Joanna Hester - University of Oxford, United Kingdom
- 12.10-12.30 Task 4.2 FIH clinical trials of the next-generation Treg products** (15 min + 5 min discussion)
- Clinical study n° 1: "The TacRes Trial- First-in-human (FIH) phase I trial for safety assessment of CRISPR/Cas9 permitted Calcineurin inhibitor (CNI) resistant (FKBP-KO) autologous tTreg application in CD renal transplant recipients"
  - Final Milestone: FIH clinical trial of next-generation Treg product
- Petra Reinke - BeCAT, Charité - Universitätsmedizin Berlin, Germany
- 12.30-12.50 Task 4.2 FIH clinical trials of the next-generation Treg products** (15 min + 5 min discussion)
- Clinical study n° 4: "The RESHAPE Study CD8+Treg Trial ("Eight-Treg")"
  - Final Milestone: FIH clinical trial of next-generation Treg product to prove safety and hints of efficacy
- Carole Guillonnet - Université de Nantes, France

## WP 5 Biomarker platform to monitor therapy response to next-generation Treg approaches

Chair: Hans-Dieter Volk - Charité - Universitätsmedizin Berlin, Germany

- 12.50-13.10 Task 5.1 Validation and performance of biomarker studies for safety, PK/PD, mode-of-action** (15 min + 5 min discussion)
- Final MS: Summary & conclusion regarding PK/PD, safety, putative surrogate markers, mode-of-action from biomarker analyses
- Hans-Dieter Volk - Charité - Universitätsmedizin Berlin, Germany

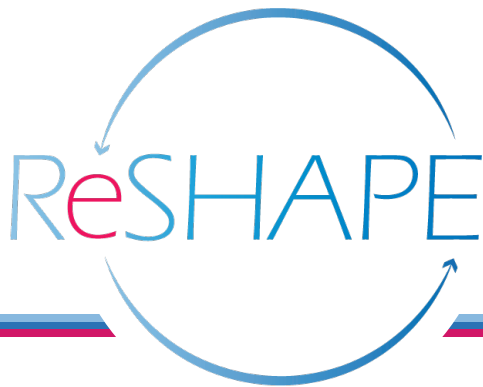
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## **WP6 - Clinical Development research and early HTA for supporting exploitation strategies & business models for next-generation Treg approaches**

Chair: Mohamed Abou El-Enein- Charité- Universitätsmedizin Berlin, Germany

**14.00-14.20 Task 6.1 Clinical Development Research** (15 min + 5 min discussion)  
Mohamed Abou El-Enein - Charité - Universitätsmedizin Berlin, Germany

**14.20-14.40 Task 6.2 Early Health Technology Assessment** (15 min + 5 min discussion)  
Panos Kefalas - Cell and Gene Therapy Catapult, United Kingdom

## **WP7 - Dissemination, exploitation, Communication**

### **WP8 - Project management and coordination**

Chair: Gabriella Dessolet - Innovation Acta Srl, Italy

**14.40-15.00 Management & Dissemination** (10 min + 10 min discussion)  
- Administrative and financial management  
- Updates on Communication and Dissemination activities  
Gabriella Dessolet - Innovation Acta Srl, Italy

**15.00-15.30 Coffee Break and Consultation round of the External Advisory Board**

**15.30-16.30 Statement of the External Advisory Board** (60 mins)(All)

## **Final Remarks, Farewell**

**16.30-17.00 Recapitulation & Discussion**

**17.00-17.10 Final Remarks, Farewell**  
Petra Reinke - Charité - Universitätsmedizin Berlin, Germany

