

# 6-Months Report 2020 Conference Call

7 August 2020

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# Key investment highlights



- Innovative T cell-based immunotherapies with broad cancer applicability
- Novel DC vaccine focused on inducing T cell responses to cancer
- Existing partnerships & global business development opportunities
- Continuous technology innovation and growing IP portfolio
- Management team with complementary experience and skills

**Prof. Dolores J. Schendel**  
CEO & CSO

# Key information

## Company

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- Martinsried, near Munich, Germany
- ~140 employees
- ~€39.9 m cash\*

## COVID-19 Situation Update

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- **Personnel**  
Work from home and on-site staffing, no infection to date
- **Partner Programs**  
Uninterrupted R&D activities
- **Clinical Trials**  
No delays in patient recruitment, manufacturing, regulatory

## Listing

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- Frankfurt Stock Exchange (MDG1)
- ~24.6 m shares outstanding
- ~€130 m market cap\*\*

## Outlook

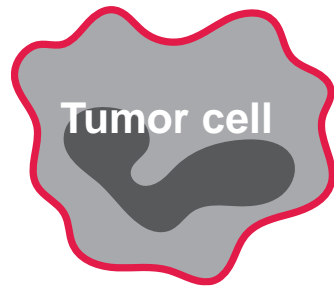
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- MDG1011 Phase I/II trial dose escalation readout by end Q1 2021
- Ongoing MDG1021 Phase I trial in patients post allo-HSCT with relapsed hematological cancers
- MAGE-A4 TCR-T to enter Phase I (bluebird bio)
- DC vaccine detailed data Phase I/II results in H2 2020
- Publication of preclinical data at conferences

# TCR-T vs. CAR-T cells

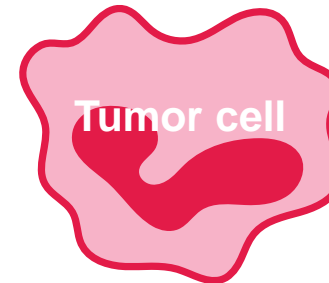
TCR-Ts offer more target options, power, sensitivity and control

## Chimeric antigen receptor (CAR)



- **Surface** proteins only
- ~**30%** of human proteome as targets
- **High target density per cell required** for effective CAR-T triggering
- Often **toxicity** against healthy cells (e.g. B cells)

## T cell receptor (TCR)



- Both **surface & intracellular** proteins
- **100%** of human proteome as targets
- **Very low target density per cell sufficient** for effective TCR-T triggering
- Many targets available with great **tumor cell – healthy cell discrimination**
- HLA-dependent recognition adds **specificity**

# Innovation & technology differentiation

## Safety & activity

- Natural TCRs without mutations for higher safety
- PD1-41BB switch receptor to enhance TCR-T function
- Controllable TCR through on-off switch (iM-TCR)
- Suicide switch studied for drug product elimination

## Diversity & specificity




- Multiple epitopes for one HLA
- Multiple HLAs for one antigen
- HLA class I and class II epitopes
- Epitope safety via *in silico* and *in vitro* tools

## Drug product process development

- Monoclonal transgenic TCR-Ts
- Steppingstones to full automation and fully closed process
- Proprietary and evolving GMP production process
- Proprietary SIN-RV vector system

Optimization towards next-generation TCR-Ts

# Growing immunotherapy pipeline

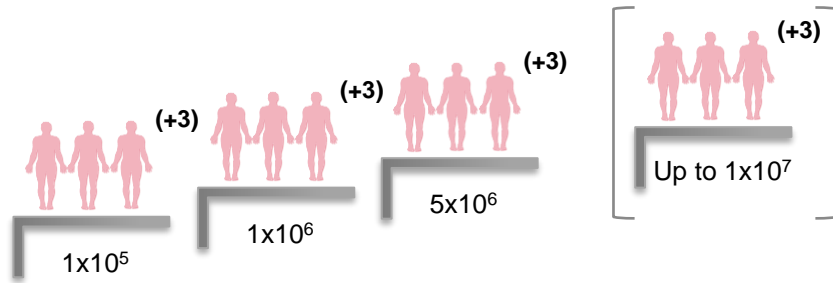
	Project	Target	Preclinical	Phase I	Phase II	Partner
TCR-T	MDG1011	AML, MDS (PRAME)	Completed	Ongoing	In preparation	
	MDG1021	Post-HSCT relapse (HA-1)	Completed	Ongoing		
	MDG10XX	Solid tumors (undisclosed)	Ongoing			
	bluebird bio	Undisclosed (MAGE-A4)	Completed	In preparation		
	Cytovant (CVT-TCR-01)	Synovial sarcoma, MM, solid tumors (NY-ESO-1)	Ongoing			
DC	DC vaccine	AML (WT-1 / PRAME)	Completed	Completed	Completed	
	Cytovant (CVT-DC-01)	AML (WT-1 / PRAME)	Ongoing			

PRAME, HA-1, MAGE-A4, NY-ESO-1, WT1: Tumor antigens;

Completed; Ongoing; In preparation

# MDG1011 – Phase I/II trial design

## Phase I



Single defined dose of TCR-transduced T cells/kg

- Open-label, multi-center study, 3+3 dose escalation design, up to 4 cohorts
- Primary endpoints: Safety at 3 months and MTD
- Dose ranges from 100,000 to 10,000,000 TCR-transduced T cells per kg body weight
- Single administration via i.v. infusion
- DSMB review after each dose cohort

## Phase II



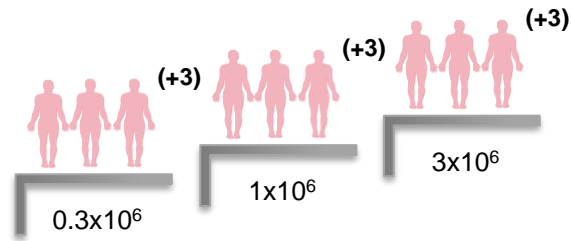
40 treated + 40 control patients

- Approx. 2 indications to be carried into Phase II
- 40 HLA-A\*02:01 and PRAME positive patients to be treated with MDG1011 (20 per indication)
- 40 HLA-A\*02:01 negative and PRAME positive patients serve as control groups (20 per indication)



# MDG1021 – Phase I trial design

## Dose-escalation portion



Patients with relapsed or persistent hematological malignancies after allo-HSCT w/wo DLI

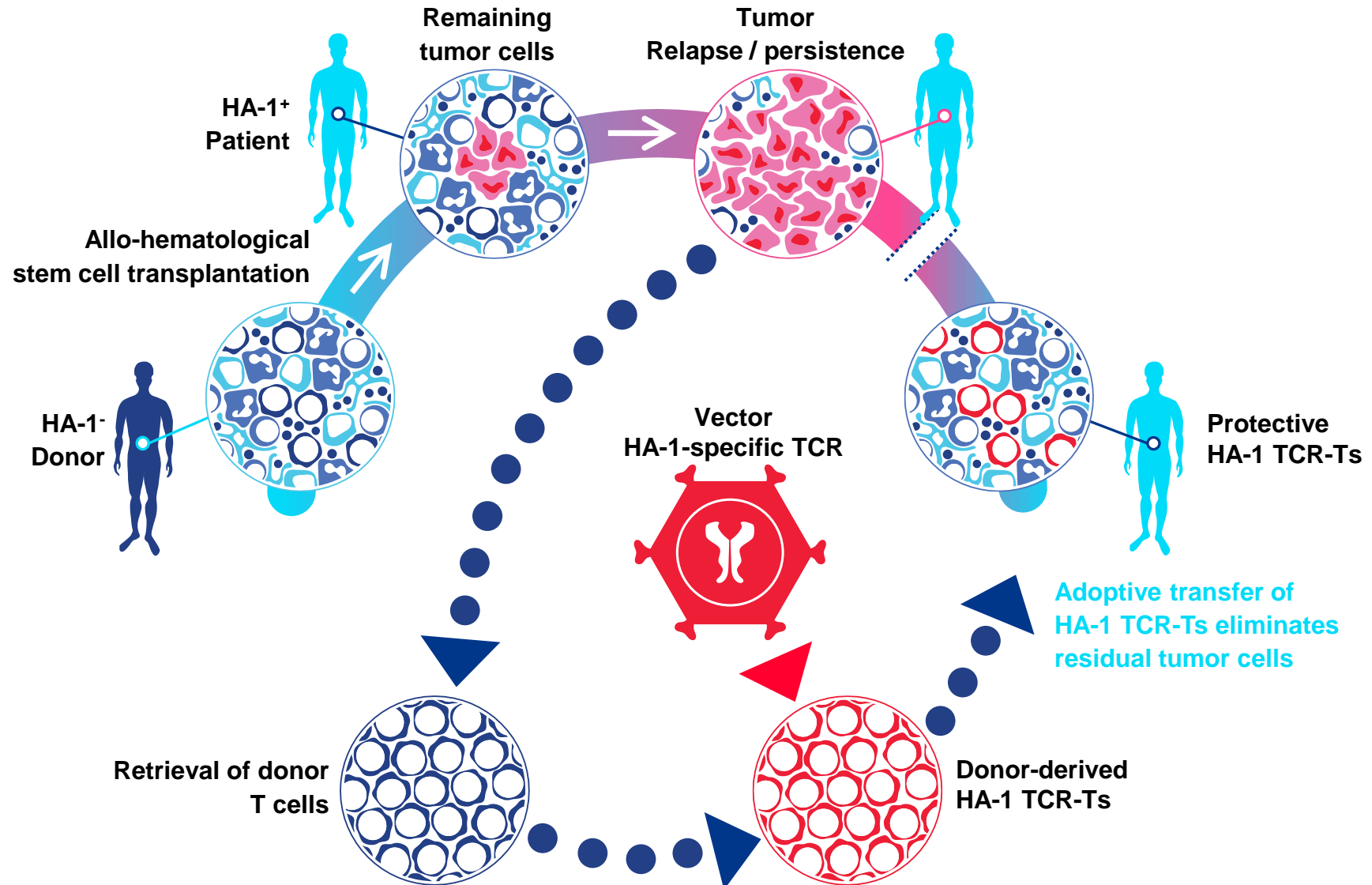
- 3+3 design with at least 9 patients
- Dose 1:  $0.3 \times 10^6$  HA-1 TCR-transduced T cells per kg body weight
- Dose 2:  $1 \times 10^6$  HA-1 TCR-T cells/kg
- Dose 3:  $3 \times 10^6$  HA-1 TCR-T cells/kg
- Assessment of safety, feasibility and preliminary efficacy

## Dose-expansion portion



- 20 patients in an expansion group at the selected dose of MDG1021

# MDG1021 – Treating relapse or persistence after HSCT



# Partnerships validate Medigene's technologies

## bluebird bio

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- 6 TCR discovery projects for defined antigen/HLA combinations
- **Worldwide** development and commercial rights and exclusive license for IP
- **Clinical development of first TCR lead for MAGE-A4/HLA-A2 expected to start in 2020**
- MDG eligible for R&D funding, development, regulatory and sales milestones and tiered, up to double digit % royalties

6 TCRs

## Roivant / Cytovant

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- Research-stage TCR specific for the target NY-ESO-1; clinical indications chosen
- **DC vaccine program for AML**
- Discovery projects for 2 further TCRs tailored for Asian population
- **Regional** license rights for **Greater China, South Korea and Japan**
- MDG eligible for R&D funding, development, regulatory and sales milestones and tiered, up to double digit % royalties

DCs and 3 TCRs

# Financial review and outlook

	H1 2019	H1 2020	Guidance 2020
Total revenues	€5.6 m	€3.7 m	€7-9 m
R&D expenses	€10.9 m	€11.7 m	€24-29 m
EBITDA loss	€8.5 m	€11.3 m	€19-27 m

- Liquid assets and time deposits as of 30 June 2020 amounted to ~€39.9 m
- Medigene has sufficient financial resources to fund business operations until the end of 2021
- No milestone payments or cash inflows are included from existing or future partnerships or transactions

# Key development milestones in 2020

## ■ Clinical trials

- ✓ Topline data on Phase I/II DC vaccine trial (2-years-treatment)
- ✓ H1 2020 entered Phase I clinical development of MDG1021 in post-HSCT relapsed patients
- Q4 2020 complete dosing of three dose cohorts in MDG1011 Phase I dose escalation trial in AML and MDS
- bluebird bio to start Phase I clinical trial of MAGE-A4 TCR

## ■ Pre-clinical

- ✓ Characterization of new TCR candidates
- Optimization of future TCR therapies for solid tumors

## ■ Business development

- Continue pre-clinical development with bluebird bio and Roivant / Cytovant

**Thank you – Q&A**

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