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Immunotherapy – the future of cancer treatment

Classical Mainstays
- Surgery
- Radiation
- Chemotherapy

Targeted Treatments
- Hormone therapies
- Small molecule targeted therapies
- Antibody therapies
- Stem cell transplantation
- Immune response modifiers
- DC vaccines
- Latest developments:
  - Adoptive cell therapies
  - CARs and TCRs

Before 1990

1990-2010

From 2010
Fighting cancer with cutting-edge technologies

TCRs
Generating large numbers of cancer-specific T cells to recognize and kill cancer cells.

DCs
An entirely new generation of DC vaccines being developed.

TABs
Developing monoclonal antibodies to recognize T cells.
### Progress of Immunotherapy Pipeline

<table>
<thead>
<tr>
<th>Project</th>
<th>Indication (Target)</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
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</thead>
<tbody>
<tr>
<td>DC vaccine</td>
<td>Acute myeloid leukemia (WT-1 / PRAME)</td>
<td></td>
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<tr>
<td>TCR clinical trial 1</td>
<td>AML, MDS*, MM** (PRAME)</td>
<td></td>
<td></td>
<td>CTA submitted</td>
</tr>
<tr>
<td>TCR clinical trial 2</td>
<td>Undisclosed</td>
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<td></td>
<td>CTA submitted</td>
</tr>
<tr>
<td>TCR-IIT ***</td>
<td>Multiple myeloma (MAGE-A1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TABs</td>
<td>T cell leukemias + new applications</td>
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</tr>
</tbody>
</table>

* Myelodysplastic syndromes
** Multiple myeloma
*** Investigator-initiated trial (IIT) of a publicly funded collaboration between MDC, Charité and Medigene.

Additional IITs utilizing Medigene’s DC vaccine technology are ongoing at LMU Munich (Phase I/II in AML) and Oslo University Hospital (Phase II in prostate cancer).
Personalized cancer treatment with TCRs

1. Leukapheresis & T cell isolation
2. GMP: activation of T cells and transfer of TCR from TCR pipeline
3. GMP: expansion, freezing and quality tests
4. TCR T-cell product

Thawing and re-infusion into patient

TCR T-cell product
DCs are major players in the immune system and initiating T cell responses

Dendritic Cell (DC)

DC presents antigens via MHC complex

Antigens

T cells

Activation of T cells → immune response

Tumor antigens presented by MHC complex, e.g. HLA-A2

T cell with T cell receptor (TCR)
Interconnected technology platforms

Step 1
Loading with tumor-associated antigens (iVT-RNA)

Step 2
Priming process: priming T cells of healthy donors

Vaccination of patient
→ T cells recognize DC vaccines and tumor cells

Adoptive T-cell therapy
Adoptive T cell therapy
T cells target tumor cells
Different types of antigen for TCRs and DC vaccines

**Virus-derived antigens:**
- **Example:** EBV, HPV
- **Indication:** lymphomas, specific cancers

**Minor histocompatibility antigens:**
- **Example:** H-Y, HA-1,-2,-3,…
- **Indication:** stem cell transplantation, donor lymphocyte infusion

**Differentiation antigens:**
- **Example:** gp100, tyrosinase, PSA
- **Indication:** melanoma, prostate cancer

**Overexpressed antigens:**
- **Example:** survivin, hTERT
- **Indication:** most tumors

**Cancer-testis antigens:**
- **Example:** MAGE-A1, PRAME, NY-ESO-1
- **Indication:** hematological malignancies, diverse solid tumors

**Neoantigens (mutations):**
- **Example for shared antigens:** K-ras, bcr-abl
- **Indication:** selected tumors
- **Example for individual antigens:** patient-defined
- **Indication:** most tumors
TCRs target a broader spectrum of tumor targets compared to CARs

**TCRs target intracellular proteins:**
- App. 70% of human proteome
- Recognize intracellular targets, with many thousands of options (more addressable targets)
- Recognition is MHC-restricted (adds specificity)
- Lower risk for side effects if TCRs are natural, non-mutated structures

**CARs target surface proteins:**
- App. 30% of human proteome
- Limited to cell surface antigens, only tens of options
- Recognition is MHC*-independent
- Higher risks of side effects

* MHC: Major Histocompatibility Complex

Examples of targets:
- HER2
- CD19
- Mesothelin
- CD38
- Cancer-germline antigens
- Viral antigens
- Universal antigens
Robotics enable choice of best lead TCRs

Selection of T cells

Screening of TCR candidates

High-throughput TCR analysis

TCR pipeline

- High standardization and reproducibility
- Several thousands of T cell clones per run
- Over 300 T cell clones ready for NGS after 1 week
Rapid, efficient and lean process selects lead TCR candidates

Medigene’s profound knowledge of:
Antigens, T cell clones, allo- and auto-priming,
characterization, specificity and safety tests, functional tests, immune monitoring

TCR pipeline

Antigen selection
Preparation
Priming
Expansion
Selection

0 weeks  Antigen selection
3 weeks  Set up *in vitro* cultures
6 weeks  Sort and expand T cells
8 weeks  Test clones + NGS
1 week  TCR sequences available
6-8 weeks  Functional testing

Selected lead TCR
Immune Monitoring Facility supports the entire value chain

Target validation ✓     Safety analyses ✓     Potency evaluation ✓

Lead

R&D
- Assay development
- Assay validation
- Assay training
- Inter-laboratory controls

Preclinic
- Multi-color ELISPOT
- Cytokine assays
- Cytotoxicity assays
- Self-peptide analysis
- Alanine scan
- Expitope (in silico)
- Nanostring methods
- Statistical data evaluation

Clinic
- GCP/GCLP-compliant immune monitoring
- FACS sorting
- Multi-color flow cytometry
- Cytokine secretion assay

Market
- Data evaluation
- Documentation

R&D

Preclinic

Clinic

Market

Therapy
Value creation along the TCR development chain

**TCR R&D collaborations**
- Additional TCRs potentially available for partnerships

**TCR generation module**
- TCR leads

**TCR development collaboration**
- Target antigen: MAGE-A1
  - First TCR study in Germany!
- cGMP process potentially of interest to other parties

**Clinical development program**
- Medigene’s own TCR product development program
- Start of first Medigene TCR study in 2017
- Possible clinical stage partnerships

**TCR-based therapies**
Bluebird deal validates TCR technology

- **Deal structure:**
  - Upfront payment of US$ 15 million
  - Fully funded R&D activities
  - Potential preclinical, clinical, regulatory and commercial milestone payments up to US$ 1 billion
  - Royalties on net sales

- T cell receptor (TCR) therapeutic candidates against four targets
- Medigene generates and delivers TCRs to bluebird bio
- Joint preclinical development of all product candidates
- bluebird bio gains worldwide development and commercial rights and exclusive license for IP covering the TCRs
- Medigene **retains all rights** for its proprietary TCR development programs
Medigene’s TCR studies in preparation

- Medigene’s first company sponsored trial (2017): MDG1011
  - Additional viral vector production capacities secured at EUFETS
  - Commercial manufacturing partner selected and cell GMP process nearing completion
  - Centers selected for clinical study
  - CTA submitted to Paul-Ehrlich-Institute (July 2017)

- Grant-funded IIT with Charité Hospital and MDC in Berlin (2017):
  - Clinical indication Multiple Myeloma
  - T-cell receptor selected
  - Viral vector produced by EUFETS GmbH
  - GMP process established
  - CTA submitted

- Developments needed to drive Medigene’s clinical TCR studies:
  - Identification of TCRs and preclinical work
  - Process development for GMP-compliant patient-individualized cell products
MDG1011 Phase I/II study: CTA submitted

Target:
- PRAME (Preferentially Expressed Antigen in Melanoma)
- PRAME is a well characterized tumor antigen overexpressed in multiple hematological and solid tumor indications

MDG1011:
- T cells expressing a HLA-A2:01 restricted T cell receptor (TCR) specific for PRAME
- Has demonstrated favorable preclinical safety and efficacy

Clinical trial outline, pending regulatory discussion and approval:
- Planned is a combined Phase I/II safety and feasibility
- Disease indications are acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), multiple myeloma (MM); all in advanced stages
- Phase I part: dose escalation, testing up to 4 dose cohorts in a 3+3 design
- Phase II part: will expand the dose cohort from Phase I and include a prospective control group
The CTA is submitted for the first company-sponsored TCR-based clinical study – MDG1011
Interconnected technology platforms

Step 1: Loading with tumor-associated antigens (ivt-RNA)

Step 2: Priming process: priming T cells of healthy donors

Vaccination of patient → T cells recognize DC vaccines and tumor cells

Adoptive T-cell therapy

Adoptive T cell therapy
T cells target tumor cells
Personalized cancer treatment with DC vaccines

1. Isolation of DC precursor cells from patient’s blood
2. GMP: generation of DCs and loading with tumor-target antigens
3. GMP: freezing of vaccine cells in multiple aliquots and quality testing
4. Thawing and vaccination

DC vaccine product
Medigene’s “new generation” DCs mature fast and show optimal immunotherapeutic potential

Best biological properties for improved clinical efficacy

- Defined antigen loading with ivt-RNA replaces unknowns of loading with peptides or lysates
- Use of full length antigen requires no need for patient HLA selection
- Positive co-stimulatory profile is optimal with young 3-day mature dendritic cells
- Optimal cytokine polarization supports both innate and adaptive immune responses
- High quantity yields of DCs allow for 20+ vaccinations (>85% mature polarized DCs)

Best product characteristics for commercialization

- 3-day production is cost effective and amenable to automation
- RNA as source of antigens is versatile, inexpensive and has no need for tumour material
- Single-batch production reduces time, costs and is patient friendly (only one apheresis)
- Frozen vaccine formulation gives 2+ years of shelf-life and simplified logistics
Lead indication acute myeloid leukemia (AML)

Disease characteristics:
- Most common type of leukemia in adults
- About 20,830 cases in USA*
- Median age at diagnosis: 63 years
- 5-year survival rate decreases with age

*Source: NIH, SEER Stat Fact Sheets: Acute Myeloid Leukemia (AML)
DC trial in AML: Phase II part ongoing

Trial Design:
- **Phase I/II**: open-label, prospective, non-randomized trial
- **20 AML patients**: 6 phase I + 14 phase II, complete remission after chemotherapy, not eligible for allo-transplantation
- Patients selected with AML expressing the vaccine antigens: WT-1 with or without PRAME
- **Continuous vaccination for 2 years** or until progression/ death

Study objectives:
- Primary: feasibility and safety
- Secondary: overall survival (OS), progression free survival (PFS), control of minimal residual disease (MRD), time to progression (TTP), induction of immune responses

ClinicalTrials.gov Identifier: NCT02405338
Results from IIT* and Compassionate Use**
DC vaccine treatment in AML patients

- High success rate for GMP generation of DC vaccines
- Efficient logistics for DC vaccine delivery
- Vaccine antigens demonstrate immunogenicity
- T cell responses as potential biomarkers of DC activity
- Excellent safety profile of DC vaccines

Production efficiency & safety profile allow extensive vaccination

(*IIT at Ludwig-Maximilians-University Munich; **CU Patients at Oslo University Hospital)
T-cell-specific antibodies (TABs)

- Full-scope platform for antibody isolation
- Unique animal models to assess mode of action and clinical efficacy
- Proof-of-principle is established
- Removal of unwanted T cells:
  - T-cell leukemia therapy
- TCR-modified T cells:
  - Tool for ex vivo tracking of T cells
  - In vivo removal of T cells
- Status quo:
  - Ongoing studies establish proof-of-concept in preclinical models
Summary
Outlook for 2017

TCR IIT, Berlin (MAGE-A1 in MM)
- IMPD submission as part of the clinical trial application
- Approval and start of IIT TCR study

MDG1011, Medigene’s first TCR trial
- GMP process finalization and validation
- Clinical trial application
- Approval and study start

DC trial in AML, Oslo
- Completion of enrollment
- Final read-out in 2019

Progress in bluebird collaboration
Shareholder structure

Key share information

- Listed on Frankfurt Stock Exchange (Prime Standard)
  Symbol: MDG1;
  ISIN: DE000A1X3W00;
  TecDax

- Number of outstanding shares: 22.1 m

- Current market cap of approx. € 222m

- > 28% of shares owned by US investors

Shareholder structure by countries

As at 30.6.2017, rounded
Based on Medigene AG information and estimates

August 2017

Numbers based on last voting right notifications
**shareholding below 3%
Financial guidance for 2017 confirmed

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>GUIDANCE 2017</th>
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</thead>
<tbody>
<tr>
<td>Total revenue</td>
<td>€ 9.7m</td>
<td>€ 8-10m</td>
</tr>
<tr>
<td>R&amp;D expenses</td>
<td>€ 11.5m</td>
<td>€ 16-18m</td>
</tr>
<tr>
<td>EBITDA loss</td>
<td>€ 12.3m</td>
<td>€ 16-18m</td>
</tr>
<tr>
<td>Cash usage</td>
<td></td>
<td>€ 23-27m</td>
</tr>
</tbody>
</table>

- Cash & cash equivalents as of June 30, 2017: €59.9 m
- Sufficient financial resources beyond the forecast horizon of two years and to the time points that data from DC trial and TCR trials become available