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Medigene at a glance

1. A global leader in T cell immunology
2. Growing clinical pipeline in multiple indications
3. High-throughput assays for antigen and TCR discovery
4. DC vaccines as first validation of cellular therapies
5. High-profile partnerships to drive near and long term value
6. Strong and experienced management team
Key highlights

TCR-Platform

T cell receptor-modified T cell therapeutics (TCR-Ts)

- MDG1011, **first clinical TCR trial in Germany** started for AML, MDS and MM
- First patient treated Feb 2019 with PRAME specific TCR-T cells
- **De-risked** HA-1 TCR candidate in-licensed, evaluation ongoing for potential development
- Chimeric co-receptor for second generation TCR-Ts for **solid tumors**
- Selected development projects partnered with **bluebird bio (worldwide)** and **Roivant/Cytovant (Asia)**

DC-Vaccines

Dendritic cell cancer vaccines

- Ongoing **Phase I/II** trial in AML patients
- 20 patients receive PRAME/WT-1 vaccines for two years
- Interim overall positive 12 m **topline data** presented Dec 2018, final readout Dec 2019
- Regional partnership with Roivant/Cytovant in Asia

Cash of €65.6 m as of March 31, 2019; Cash runway through 2020
# Medigene’s immunotherapy pipeline

<table>
<thead>
<tr>
<th>PROJECT</th>
<th>INDICATION (TARGET)</th>
<th>PRECLINICAL</th>
<th>PHASE I</th>
<th>PHASE II</th>
<th>Partners</th>
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<td>DC vaccine</td>
<td>Acute myeloid leukemia (WT-1 / PRAME)</td>
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<td>TCR 1 (MDG1011)</td>
<td>AML, MDS, MM (PRAME)</td>
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<td>TCR 2</td>
<td>Post-HSCT** relapse (HA-1)</td>
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<td>TCR Cytovant</td>
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<td>TABs</td>
<td>T cell leukemias + new applications</td>
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* Investigator-initiated trial (IIT) under the responsibility of Max Delbrück Center and Charité, Berlin

** Hematopoietic stem cell transplantation

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)
Medigene’s TCR-T immunotherapies replace CARs with natural TCRs to target tumor cells

TCRs are receptors that recognize HLA-restricted target peptides on tumor cells

Introduce recombinant TCRs into T cells of HLA-matched patient and return TCR-modified T cell product (TCR-Ts) to the patient
High potential and de-risking through growing TCR research pipeline

<table>
<thead>
<tr>
<th>Project</th>
<th>Indications</th>
<th>Target selected</th>
<th>Priming and TCR seq determination</th>
<th>Initial TCR characterization (“Assay tree”)</th>
<th>Clinical TCR lead selected</th>
<th>Non-clinical development</th>
<th>Submission of CTA</th>
<th>Phase 1</th>
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<td>PRAME</td>
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<td>Partnered projects</td>
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<td>TCRs for liquid and solid tumors</td>
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<td>TCRs for diverse HLA restrictions</td>
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* MDC & Charité
* MDC & Charité
** bluebird bio project
*** Cytovant project
MDG1011
First TCR therapy clinical trial
PRAME is the target of Medigene’s MDG1011

- PRAME ( Preferentially Expressed Antigen of Melanoma) is a well described cancer-testis (CT) antigen

- Literature reports (in addition to in-house data) that PRAME expression is high in tumors but very scarce or absent in normal tissues

- Medigene’s clinical trials indicate that using a PRAME DC vaccine is safe and well tolerated, confirming other vaccine trials targeting PRAME

- PRAME mRNA is expressed in 9 out of 10 common non-hematological cancers (NCI):
  - bladder, breast, colorectal, kidney, liver, lung (NSCLC & SCLC), prostate, thyroid and uterus
PRAME RNA expression is prevalent in a broad spectrum of tumors

- Tumor expression patterns with each circle representing an individual patient:

Scale is given as RSEM. RSEM quantifies gene and isoform abundances from single-end or paired-end RNA-Seq data.
First patient treated in Phase I in February 2019

Multi-center study at currently three sites (University of Regensburg, Würzburg, Erlangen and Dresden & more to be added) with approx. 12 patients

- ≥1 AML/MDS, ≥1 MM
- (1x10^5 cells/kg) (+3)
- 1x10^6 cells/kg
- 5x10^6 cells/kg
- up to 1x10^7 cells/kg
- (1x10^7 cells/kg) (+3)

Additional 3 patients to be treated if dose limiting toxicity occurs

Spacing between patient treatment

= independent Data and Safety Monitoring Board (DSMB) decides on progression between dose cohorts.

https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-000440-18/DE
MDG1011 clinical trial design for Phase II includes control group

Estimate that 2 of 3 indications will be carried into Phase II (after a DSMB and PEI/ethics committee vote)

- PRAME positive
- HLA-A*02:01 positive
- PRAME positive
- HLA-A*02:01 negative

(genetically not suitable for MDG1011)

<table>
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<tr>
<th>Indication 1</th>
<th>Indication 2</th>
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<tr>
<td>MDG1011 treatment</td>
<td>Investigator’s choice treatment</td>
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<tr>
<td>Treatment group</td>
<td>Control group</td>
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</tbody>
</table>
Clinical trial protocol amendment 2 (May 2019): Broadening of indication, earlier leukapheresis

- The indication AML has been broadened to
  - Patients with non-response after intensive induction chemotherapy
  - Patients after allogeneic hematopoietic stem cell transplantation ('bone marrow transplantation') with recurrence of AML

- Apheresis may be performed on HLA-A*02:01 and PRAME-positive patients who may be eligible for the study later
  - AML/MDS, but also MM, are fast progressive diseases
  - The production can be performed for patients with PRAME and HLA positivity, and MDG1011 is given as soon as the patient fulfills all study criteria (and signs informed consent)
  - Changed procedure can save up to 2 months in time for inclusion / PRAME-HLA testing/production
Expanded number of clinical centers

- The study has so far been carried out at three university hospitals in Germany
  - University Clinic Regensburg
  - University Clinic Erlangen
  - University Clinic Würzburg
- Dresden University Hospital was added as the fourth center in May 2019
- Up to four additional centers will be launched in Q2 through early Q3 this year
Involvement of referring centers (Hospitals; Focus doctors practices)
DC vaccine trial in AML
Treatment scheme of Medigene’s DC trial embodies extensive vaccination over a 2-year time period

- **Open-label, prospective, non-randomized trial with 20 AML patients**
- **Primary objectives:** feasibility and safety
- **Secondary objectives:** overall survival (OS), progression free survival (PFS), control of minimal residual disease (MRD), time to progression (TTP), induction of immune responses
Abstract on previously published topline data accepted at EHA conference

- Medigene will present data on the 12 months interim analysis at the European Hematology Association (EHA) conference in June.

- First topline data published on 19 Dec 2018:
  - Very good feasibility for manufacture of vaccines from patient-derived monocytes
  - Excellent safety and tolerability profile

- The final 24 months read out of data will happen at the end of 2019.
Medigene’s TCR discovery platform
Medigene’s TCRs target a broader spectrum of tumor antigens compared to CARs

**CARs target only surface proteins:**
- App. 30% of human proteome
- Limited to cell surface antigens, only tens of options
- Recognition is Major Histocompatibility Complex (MHC)-independent
- Potentially higher risks of side effects

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

**TCRs offer more options, more power, more sensitivity and more control**
Medigene has the ability to generate TCRs against multiple HLAs

- TCRs with different HLA restrictions are necessary to cover patients in a certain geography
- Approximately 2-5 HLA types are required to cover >90% of a population in a given geography

HLA allele frequency data from www.allelefrequencies.net; Population sizes: Germany (69K), USD (2.9M) China (7K) Japan (20K).
Unique TCR discovery process uses healthy donors

- **Antigen selection**
- **Cancer antigen (ivt-RNA)**
- **Proprietary maturation cocktail**
- **GM-CSF + IL-4**
- **Monocytes**
- **Lymphocytes**
- **Healthy donors**
- **Mature DCs**
- **Priming of T cells with mature DCs**
- **Enriched T cell repertoire**
- **Isolation of antigen specific T cell clones**
- **Sequencing and full characterization of TCRs**
- **Vector encoding selected TCR sequence (SIN-virus)**

**Proprietary maturation cocktail**
Rapid and efficient TCR lead candidate identification uses high-throughput automation

- **Antigen selection**
- **Priming of multiple healthy donors using DC and T cell co-cultures**
- **Expansion of single T cell clones**
- **Functional selection of specific T cell clones**

**TCR leads from priming**

- Highest level of standardization and reproducibility
- Exemplified by output over 12 month timeframe:
  - 145,000 wells automatically screened
  - 50,000 screened clones
  - 3,500 characterized specific T cell clones
Collaborations and next TCR-T generations
Strategic R&D partnership with Roivant/Cytovant for cellular therapies in Asia

- It’s Medigene’s strategy to generate tailored TCRs and license them out to certain territories and markets.
- Cytovant licenses rights for Greater China, South Korea and Japan for a research-stage TCR against the tumor antigen NY-ESO-1 and for Medigene’s dendritic cell (DC) vaccine.
- Medigene to discover two further TCRs tailored for the Asian population against targets to be chosen by Cytovant.
- Medigene receives an upfront payment of USD 10 m, complete R&D funding from Cytovant, potential development, regulatory, and commercial milestone payments which in aggregate could total over USD 1 billion for the four products across multiple indications and royalties of a low double-digit percentage in the relevant countries.
- Cytovant is part of the Roivant Sciences Group.
bluebird bio talks about the Medigene projects
bluebird bio presented data and clinical plans on the first TCR

- Selected TCR candidate targets the MAGE-A4 tumor antigen which is expressed on a variety of solid tumor types.
- Preclinical data confirm high antigen sensitivity and strong recognition of tumor cell lines.
- MAGE-A4 TCR showed functional response in both CD8+ and CD4+ T cells (turns also CD4+ T cells into effective killer cells).
- TCR candidate displays activity against solid tumors without need of a co-receptor.
- Bluebird bio plans to bring the MAGE-A4 TCR candidate into clinical development in 2020.
MAGE-A4 TCR T Cells Respond Vigorously to Tumor Cell Lines

High-magnitude, specific responses to 6-of-6 MAGE-A4⁺ cell lines

Source: http://investor.bluebirdbio.com/static-files/5dda1939-2a1c-417b-aec9-7cdf58fe093
Potent MAGE-A4 TCR T Cell Activity *in vivo* Against Tumor Xenografts

**Durable tumor elimination in a subcutaneous melanoma model**

Source: [http://investor.bluebirdbio.com/static-files/5dda1939-2a1c-417b-aec9-7cddf58fe093](http://investor.bluebirdbio.com/static-files/5dda1939-2a1c-417b-aec9-7cddf58fe093)
Expansion of TCR pipeline through licensing agreement with Leiden University

- Medigene licensed a Histocompatibility Antigen 1 (HA-1)-specific TCR from Leiden University
- HA-1 belongs to the group of minor Histocompatibility Antigens (mHA)
- The Leiden University HA-1-specific TCR was already tested in a small IIT Phase I trial with five patients, showing safety and tolerability, making it a partially de-risked preclinical/clinical asset
- The TCR will be assessed internally at Medigene for its potential for clinical development in numerous liquid and solid tumors
Antigen
• HA-1 extensively studied in-house
• Very well defined, easily assessed by PCR
• Well characterized tissue expression pattern

Clinically validated T cell target in SCT

Patients
• High medical need
• Broad HA-1 expression in liquid & solid tumors
• Especially interesting in the stem cell transplantation setting; mismatched in 10-20% of cases

Clinically de-risked TCR

TCR
• First safety & tolerability data from IIT in Leiden with five patients

Well defined indications for clinical use

HA-1: Unique opportunity to complement and advance TCR-T clinical development program
PD-1/4-1BB: In-licensed co-stimulator to enhance TCR therapies for solid tumors

- Medigene entered an exclusive license agreement with Helmholtz Zentrum Munich (HMGU) for a chimeric co-stimulatory receptor (fusion protein of PD-1 and 4-1BB)

- The PD-1/4-1BB molecule is designed to reverse the “stop” signal to a “go” command to help T cells overcome the checkpoint blockade in the tumor microenvironment

- To be explored in combination with Medigene’s TCR-Ts for the treatment of solid tumors

- Worldwide, exclusive license for the therapeutic and diagnostic use

- HMGU receives an upfront fee, an annual maintenance fee, milestone payments and royalties on marketed therapeutic and diagnostic products containing the chimeric co-stimulatory receptor.
Chimeric co-stimulatory receptor to „boost“ TCR power in solid tumors

Co-stimulation and co-inhibition in balance

Co-inhibition

Turning co-inhibition into co-stimulation
Corporate & financial highlights
Sale of remaining rights and stocks of legacy product Veregen® to Aresus Pharma

- The sale of the non-core product Veregen® completes Medigene’s transformation into a pure play immunotherapy company
- Aresus takes over all existing relevant contracts with distribution partners and external service providers for the Veregen® business including API stock
- Aresus Pharma will focus on the further global commercialization and clinical development of Veregen® in further indications and markets
- Aresus Pharma is led by an experienced team with a sound background in dermatology and clinical research
- Medigene will receive up to approx. EUR 7.75 m, thereof EUR 300 k upfront and from 2021 onwards, the rest of the balance within the next ten years as annual revenue-based earn-out payment
Financial overview for the first 3 months of 2019

- **Stable total revenues**: €2.1m
- **Increase in R&D expenses**: +28% due to progress in clinical programs & manufacturing
- **Stable revenues from immunotherapies**: €1.4m
- **Increase in EBITDA loss**: €-5.0m by 31% as planned
- **Cash & cash equivalents**: €65.6m
- **Financial guidance 2019 revised**: Revenue guidance changed due to Roivant deal
Revised financial guidance 2019 due to recent transactions

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<th>2018</th>
<th>GUIDANCE 2019</th>
<th>REVISED GUIDANCE 2019</th>
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<td>R&amp;D expenses</td>
<td>€ 17.1 m</td>
<td>€ 24-29 m</td>
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<tr>
<td>EBITDA loss</td>
<td>€ 16.3 m</td>
<td>€ 23-28 m</td>
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- Liquid assets and time deposits as of March 31, 2019 amounted to € 65.6 m
- Medigene has sufficient financial resources for beyond the forecasting horizon of two years
- No milestone payments or cash inflows are included from existing or future partnerships or transactions
Outlook 2019

MDG1011, Medigene’s first TCR trial:
- Treatment of first dose cohorts

Medigene’s DC trial in AML:
- Analysis of 1-year-treatment (half of treatment period) to be presented at EHA in June 2019
- Final read-out (2-years-treatment) expected end of 2019/early 2020

HA-1 TCR:
- Further preclinical evaluation
- Decision on clinical development

TCR IIT by MDC & Charité:
- Study start

Progress in partnerships with bluebird bio and Roivant/Cytovant
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IR Calendar 2019

Annual General Meeting 22/05/2019
Half-year Report 07/08/2019
Q3 Report 13/11/2019

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