



ANALYST CONFERENCE CALL

Results for the first 6 months of 2016

Prof. Dolores J. Schendel, CEO/CSO

Dave Lemus, COO

Dr. Kai Pinkernell, SVP Medical Affairs and CMO

"Safe Harbor" Statement

This presentation contains forward-looking statements, which are based on our current expectations and assumptions.

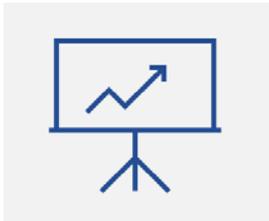
Due to various risks and uncertainties including changes in business, economic competitive conditions, regulatory reforms, foreign exchange rate fluctuations and the availability of financing, actual results, performance or achievements could differ materially from those included in the forward-looking statements. These and other risk factors are discussed in the Company's public reports. The company does not assume any obligations to update or revise any of these forward-looking statements, even if new information becomes available in the future.

Immunotherapy Programs Progress and Outlook

Highlights of the first 6 months 2016 at a glance



- Positive DSMB recommendation and start of Phase II of our DC vaccine clinical study in AML



- Updated clinical results on IIT studies of DC vaccines using our technologies presented at AACR and CIMT conferences by academic partners



- Granting of two new US patents expanding Medigene's DC and TCR platform technologies



- Medigene joins Max Delbrück Centre and Charité Hospital in Berlin for first clinical TCR study in Germany (BMBF funded) for patients with refractory/relapsed multiple myeloma

New IP relating to Medigene's platform technologies

DC Platform



- Patent US9,238,063: Use of semi-allogeneic anti-tumor vaccines with HLA haplo-identical antigen presenting cells
- Medigene holds an exclusive license to this patent from the German Research Center for Environmental Health

Announced in Q1

TCR Platform



- Patent US9,341,617B2: Method for identification of antigens and epitopes recognized by CD4⁺ T cells
- Medigene holds an exclusive license to this patent from the German Research Center for Environmental Health

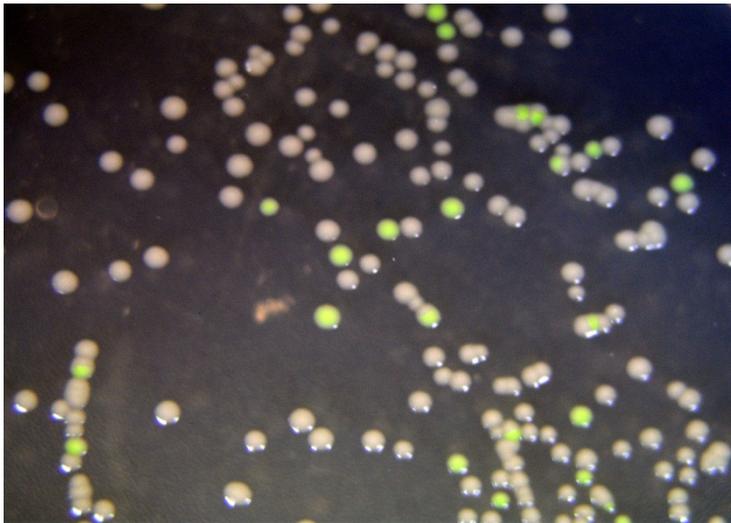
Announced in Q2

US patent granted for identification of CD4⁺ T cell antigens and epitopes



- Medigene expands TCR platform with patent US9,341,617B2: Method for identification of antigens and epitopes recognized by CD4⁺ T cells
- The patent, with an expected life-span until 2030, can be used to rapidly and efficiently identify unknown tumor antigens and MHC class II-restricted epitopes, including those recognized by tumor-infiltrating CD4⁺ T cells
- Provides a new source for potential TCR candidates derived from CD4⁺ T cells
- Expected to facilitate targeting of neoantigens in personalized T cell-based immunotherapies

A method for the identification of antigens recognized by CD4⁺ T cells



Milosevic S, et al., *J Virol*. 2006

Milosevic S, et al., *J Immunol Methods*. 2005

*For the visualization purpose, green bacterial colonies expressing the antigenic fragments in frame with GFP are presented. In the patented method these fragments are fused to chloramphenicol resistance marker allowing generation of selected bacterial pools expressing short antigenic fragments used for direct identification of DNA fragments carrying information about epitopes recognized by CD4⁺ T helper cells

- Simple and fast method to characterize antigens/epitopes presented on MHC class II molecules and recognized by CD4⁺ T helper cells
- cDNA fragments of chosen antigens or from total tumor-derived RNA are expressed as fusion proteins in bacteria
- Selection marker allows fusion protein expressing bacteria to be enriched
- Pooled bacteria are fed to MHC class II expressing antigen-presenting cells and incubated with CD4⁺ T cells
- By probing individual bacterial colonies of positive pools with CD4⁺ T cells appropriate cDNA fragments can be isolated, sequenced and antigen/epitope sequences can be deduced

Medigene's immunotherapy pipeline

PROJECT	INDICATION	PRECLINICAL RESEARCH	PHASE I	PHASE II	PHASE III
DC Vaccine	AML				
TCR	Undisclosed		Start 2017		
TCR	Undisclosed		Start 2018		
TABs	T-cell leukemias + new applications				
TCR-IIT*	Multiple Myeloma		Start 2017		

* Investigator-initiated study (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)

Medigene cooperates with MDC and Charité Hospital on the first TCR study in Germany

- First investigator initiated trial (IIT) with T cell receptors (TCRs) in Germany
- For patients with refractory or relapsed multiple myeloma (RR/MM)
- Patient's own T cells are equipped with tumor-specific TCRs



Grant-funded by BMBF (FKZ 01EK1515A/B)



Clinical partner, Sponsor of the study



GMP production and cellular analytics



Regulatory support, consultation on analytics and GMP production and required commercial partner

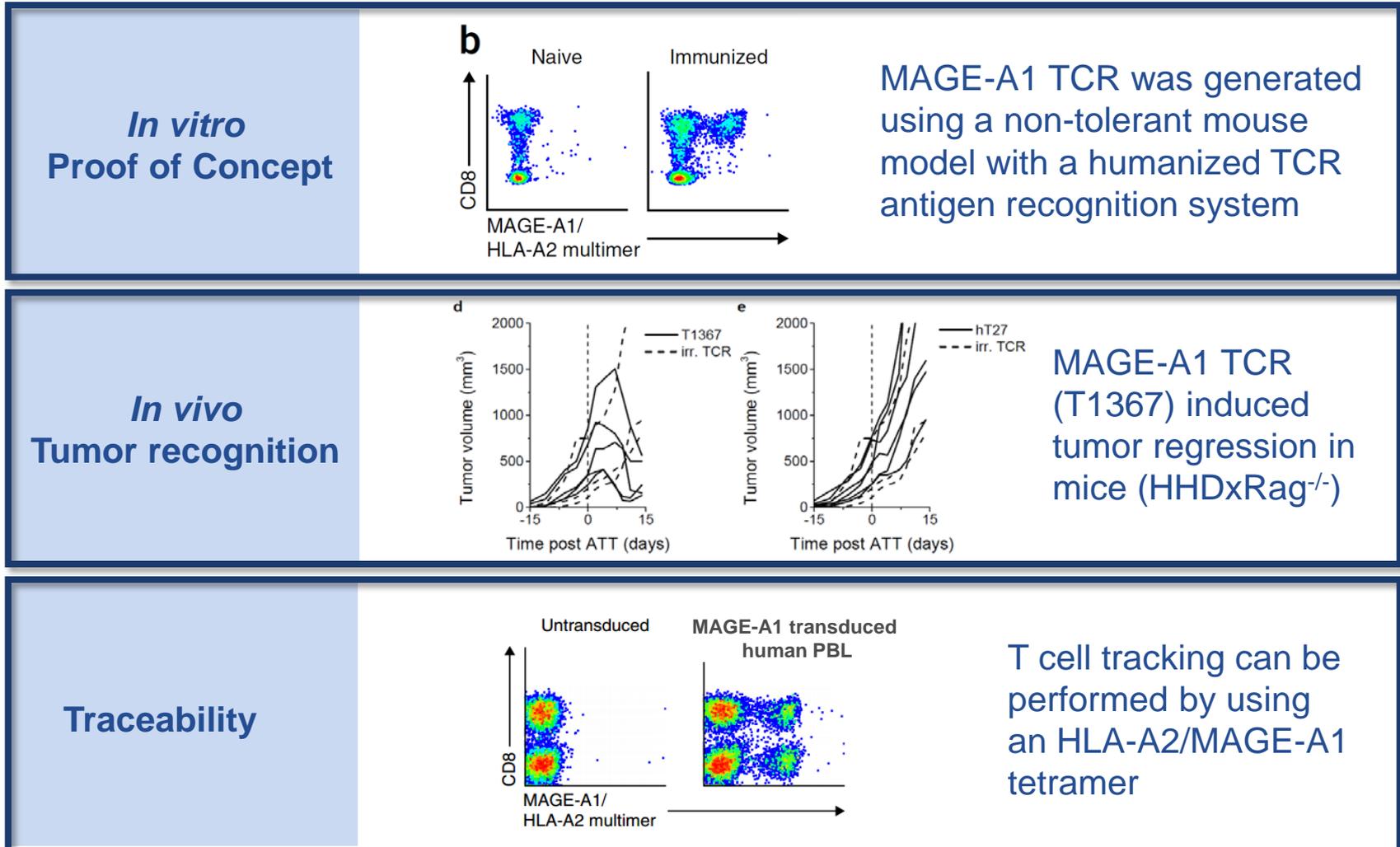
MAGE-A1 as the tumor-associated target antigen for TCR clinical study

- **Melanoma-Associated antiGEN 1**
- Member of the MAGE A gene family
- A cancer-testis antigen with unknown function
- Tumor-specificity: no known expression on vital organs except testis
- Dual purpose: antigen suited for a hematological indication and multiple solid tumors

MAGE-A1 expression seen in various tumor types*	
Multiple Myeloma	71%
Melanoma	47%
Gastric	33%
HCC	31%
Glioma	30%
NSCLC	25%
Breast	20%
Head and Neck	15%
Colorectal	12%

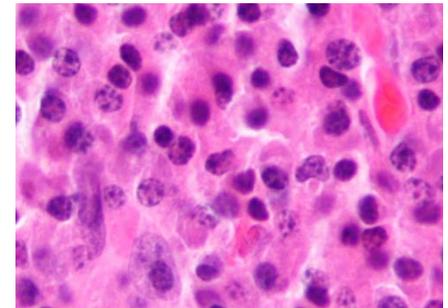
* % of cell lines positive, www.ebi.ac.uk

Characteristics of the MAGE-A1-specific TCR



About multiple myeloma (MM)

- **Multiple myeloma** is a cancer of plasma cells, a type of white blood cell normally responsible for producing antibodies to fight infections
- **Prevalence of multiple myeloma:**
 - 60,000 patients in the EU
 - 70,000 in the USA
- Multiple myeloma is the **second most common hematological malignancy** in the U.S. and constitutes 1% of all cancers
- Unfortunately, multiple myeloma cannot be cured and less than half of the patients survive 5 years after diagnosis (5yr. survival rate 45%)



The clinical trial: First TCR study in RR/MM in Germany

- Autologous, MAGE-A1-transduced cells in patients with relapsed and refractory multiple myeloma
- Single center trial and single site of production
- Trial design will follow typical Phase I approach to assess safety and feasibility of cellular immunotherapies
- Endpoints and other trial specific information will be announced by the collaboration partners

Status of Medigene's contribution to the Berlin TCR IIT collaboration

- ✓ Medigene contributed to TCR characterization: MAGE-A1 and TCR epitope expression in tumors / Expitope®
- ✓ Regulatory advice meetings held with competent authorities
- ✓ Investigational Medicinal Product Dossier (IMPD) in preparation for filing

Upcoming milestones in the collaboration

- Submission of Clinical Trial Application (CTA), which includes the IMPD
- Official approval of CTA
- Start of the trial: 2017

What will Medigene gain from this IIT study?

- Scientific benefit:
 - Validation of Medigene's *in silico* work on selected target antigens
 - Validation of several *in vitro* functional assays for TCR assessment
- Regulatory benefit:
 - Experience on critical regulatory activities and first hand feedback
 - Advanced templates for IMPD content for our own TCR studies
- Economic benefit:
 - First right of negotiation for license of MAGE A1 TCR for MM
 - Participation at fixed rate if Medigene will not exercise its option and another party acquires the rights

Selected therapies for MM in development or on the market

Proteasome inhibitor

- Velcade/Bortezomib (market)
- Kyprolis/Carfilzomib (market)
- Ninlaro/ Ixazomib (market)

Monoclonal antibodies

- Darzalex/Daratumumab (anti-CD38, market)
- Empliciti/Elotuzumab (SLAMF7 mab, market)

Immune modulators

- Revlimid/Lenalidomide (market)
- Pomalyst (US)/Imnovid (EU)/ Pomalidomide (market)

Adoptive T cell therapies

- CART-19 (Phase I)
- CART-BCMA
- NY-ESO TCR (Phase I/II)
- WT-1 CTL (Phase I)
- MAGE-A1 TCR

HDAC inhibitor

- Farydak/Panobinostat (market)

Adoptive T cell therapies for MM

	Target Expression	
	Multiple Myeloma	Normal B cells
CART-19 (University of Penn.)	Yes (2.5% ¹)	Yes (loss of Ig)
CART-BCMA (NIH-Kochenderfer)	Yes (100% ²)	Yes (loss of Ig)
NY-ESO TCR (Adaptimmune)	Yes (32% ³)	No (no loss of B cells reported)
WT-1 CTL (Atara Biotherapeutics)	Yes (11% ⁴)	Not detected ⁵
MAGE-A1 TCR (IIT, Consortium of MDC, Charité and Medigene)	Yes (70% ⁶)	Not detected

Percentages of positive patient samples or tumor cell lines

¹ 19 of 362 multiple myeloma patients (Bataille et al. 2006)

² all 44 multiple myeloma cell lines (<http://www.ebi.ac.uk/gxa/home>)

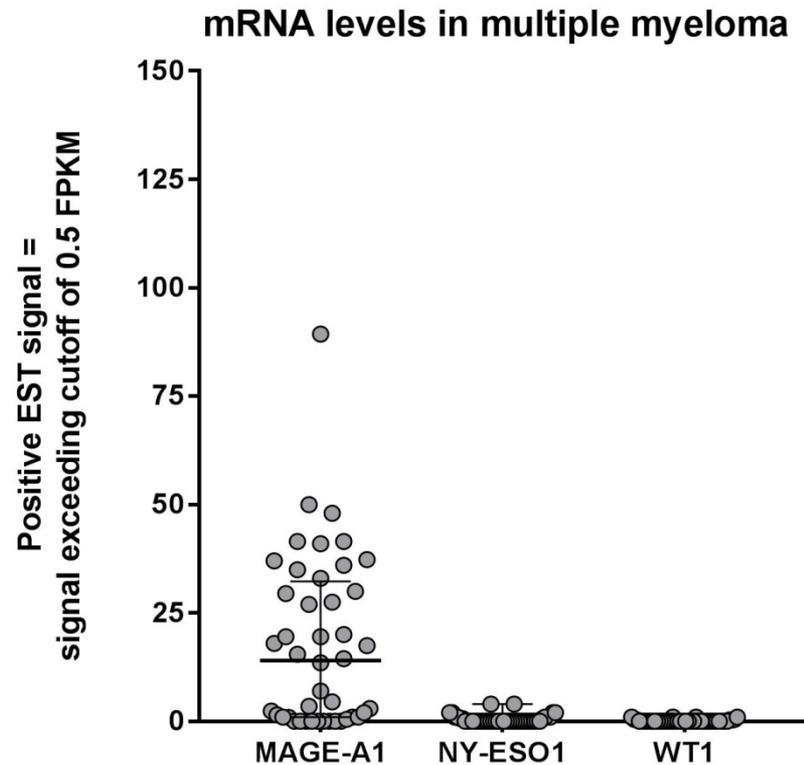
³ 14 of 44 multiple myeloma cell lines (<http://www.ebi.ac.uk/gxa/home>)

⁴ 5 of 44 multiple myeloma cell lines (<http://www.ebi.ac.uk/gxa/home>)

⁵ Spinsanti et al. 2000

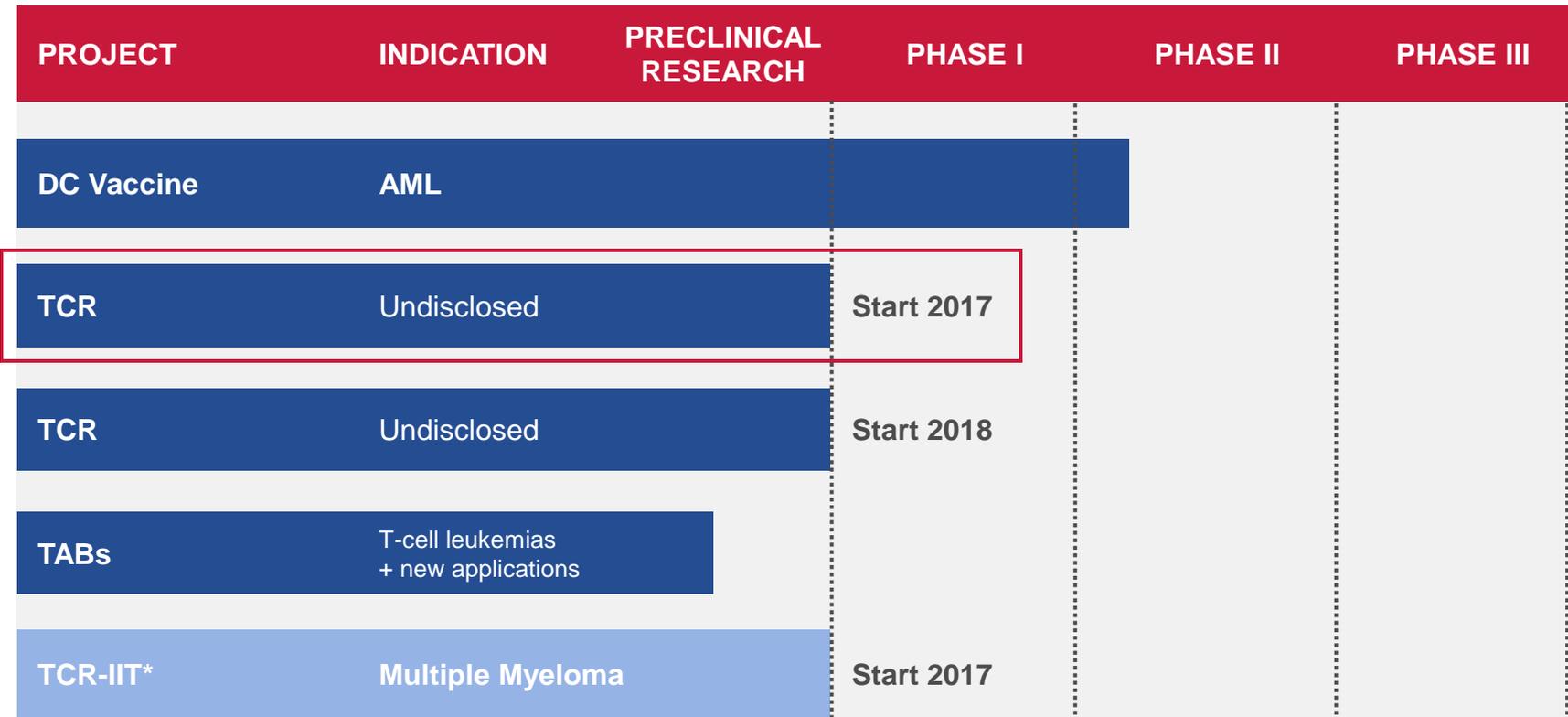
⁶ 31 of 44 multiple myeloma cell lines (<http://www.ebi.ac.uk/gxa/home>)

MAGE-A1 represents an optimal target antigen in MM for TCRs



Source: www.ebi.ac.uk

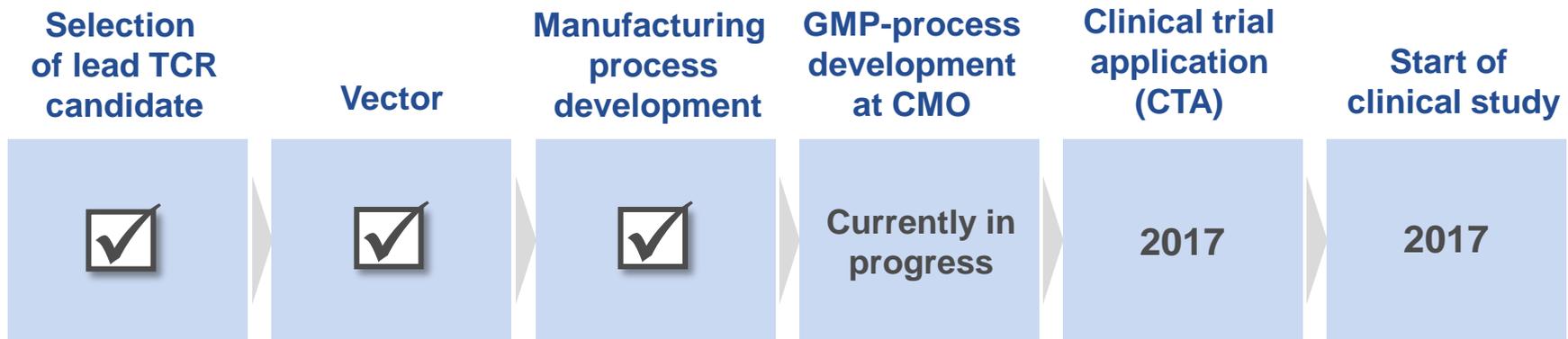
Medigene's immunotherapy pipeline



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Status Quo of preparations for first own TCR Study in 2017



Clinical outlook and milestones for 2016/17

- **MAGE-A1 TCR IIT, Berlin:**
 - IMPD submission as part of the clinical trial application and approval/start of IIT TCR-Study in Berlin
- **Medigene's first TCR trial:**
 - GMP process finalization and validation
 - Clinical trial application and approval
 - Study start
- **DC trial in AML, Oslo:**
 - Complete enrollment in 2017

Financial Report 6M-2016

Financial overview for the first 6 months of 2016

+ 62%

Total revenues increased by 62% due to EndoTAG[®] sale

+ 23%

R&D expenses

Increase in R&D expenses by 23%

6%

Improvement in EBITDA loss by 6%

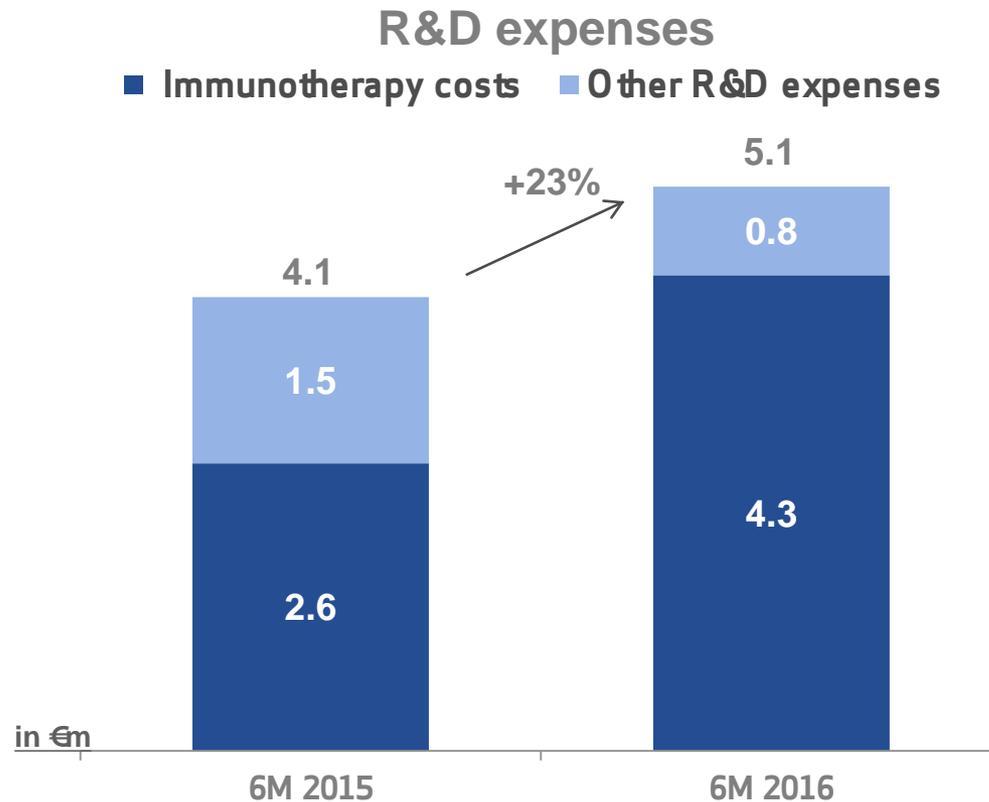
€ 48.7m

Cash & cash equivalents up by 4% to €48.7 m



Confirmation of financial guidance 2016

Increase in R&D expenses for immunotherapies by 68% due to progress in clinical programs

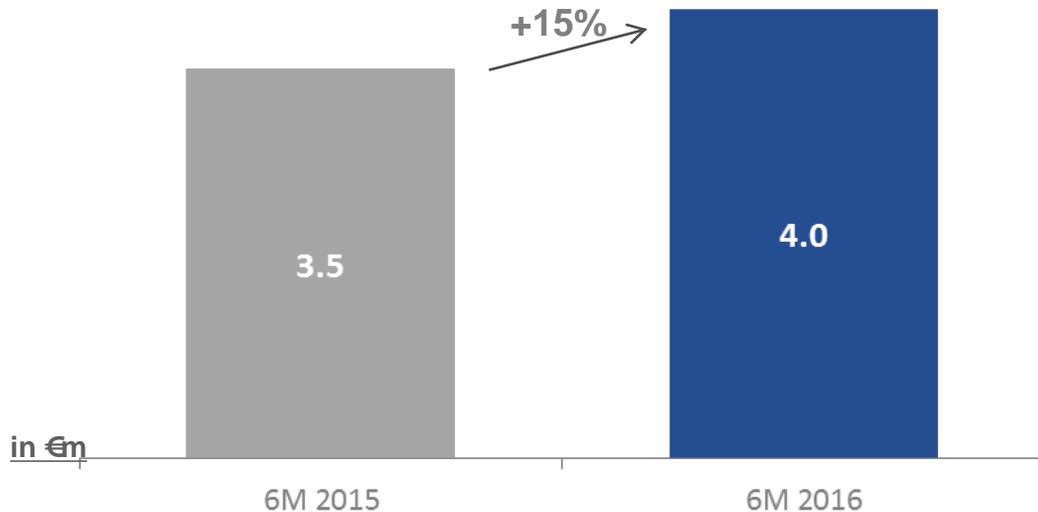


R&D expenses of €5.1 m for 6M-2016

- Increase in expenses for DC and TCR immunotherapies (6M-2016: €4.3 m; 6M-2015: €2.6 m)
- Decrease in expenses for non-core product candidates

Higher General & Administrative Expenses relate to management changes

SG&A costs

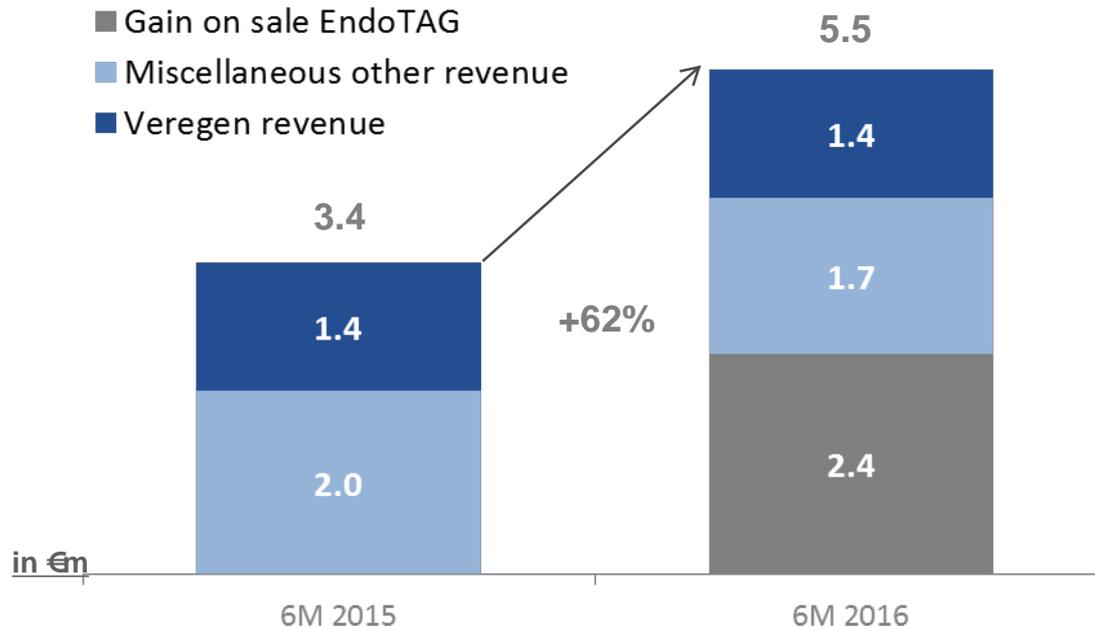


Planned increase in SG&A costs

- Hirings and expanded management team
- Stable selling and administration costs in Q2 2016 compared to Q2 2015

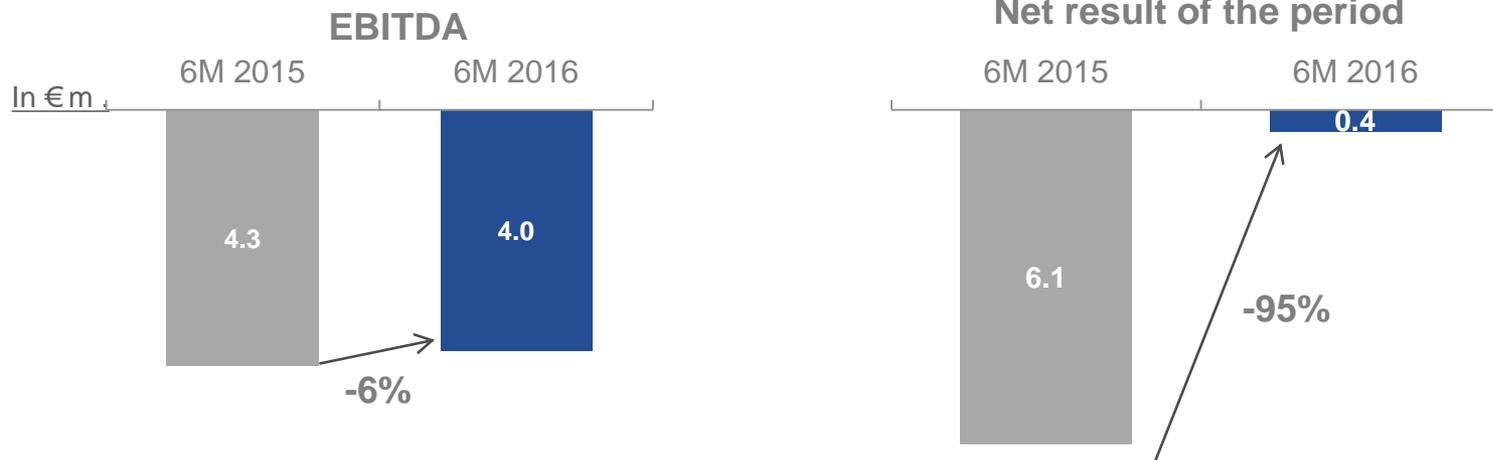
Increase in total revenue by 62% influenced by sale of EndoTAG®

Total revenue



- Increase in other operating income due to one-off effect:
 - EndoTAG sale (2016: 2.4 m, 2015: 0.0 m)

EBITDA loss reduced by 6%



- Decrease in EBITDA and net loss in spite of higher expenditures for immunotherapies mainly due to EndoTAG[®] sale
- EBITDA loss for 6M-2016 without one-time effect: € 6.4 m
- Net result of the period influenced by EndoTAG[®] sale and sale of Immunocore shares
- Difference between EBITDA and net result due to:
 - financial result
 - translational currency differences

Milestone payment to former contributing shareholders of Medigene Immunotherapies

- Treatment start of first phase II-patient in Medigene's ongoing phase I/II trial with DC vaccine in AML in April 2016 triggered 2nd milestone
- Payment of approx. €3.2 m made by Medigene to former contributing shareholders of Medigene Immunotherapies
- Settlement through issuance of 392,875 new shares from authorized capital in May 2016
- Increase in subscribed capital from €19.7 m to €20.1 m as of 30 June 2016

Medigene realized €6m by partial sale of stake in Immunocore in April 2016

- Sale of 50% in private biotech company Immunocore, UK, for GBP4.9 m (approx. €6 m) on 4th April 2016
- Significant increase in value: Medigene held 64,815 ordinary shares in Immunocore which were valued at GBP 2.8 m (approx. €3.6 m) in 2014
- Gain of sale was realized as financial result in Q2

Financial guidance 2016 - Outlook

	2015	Guidance 2016
Total revenues	€6.8 m	Stable/increasing
Veregen® total revenue*	€3.1 m	€3 – 4 m
R&D expenses Immunotherapies	€5.5 m	€9 – 11 m
EBITDA loss	€9.5 m	€10 - 12 m

* assuming constant exchange rates

No changes in guidance

Questions & Answers



Medigene AG

Lochhamer Straße 11

82152 Planegg/Martinsried

Germany

T +49 - 89 - 20 00 33 - 0

F +49 - 89 - 20 00 33 - 2920

investor@medigene.com

www.medigene.com

Listed on Frankfurt Stock Exchange (MDG1, Prime Standard)