

3-months 2018 Earnings Call

May 9, 2018

Prof. Dolores J. Schendel, CEO/CSO

Dr. Thomas Taapken, CFO

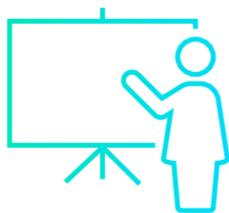
Dr. Kai Pinkernell, CMO/CDO

"Safe Harbor" Statement

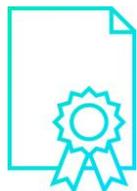
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Major events since the beginning of 2018



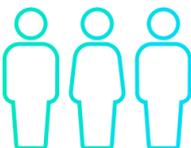
- Medigene starts first clinical trial with TCR-T cell therapy MDG1011



- Medigene appoints Dr. Kai Pinkernell to the Executive Management Board as CMO/CDO



- Medigene presented data on the successful production of AML DC vaccines and Oslo University presented clinical data for DC vaccine in prostate cancer IIT study at AACR conference

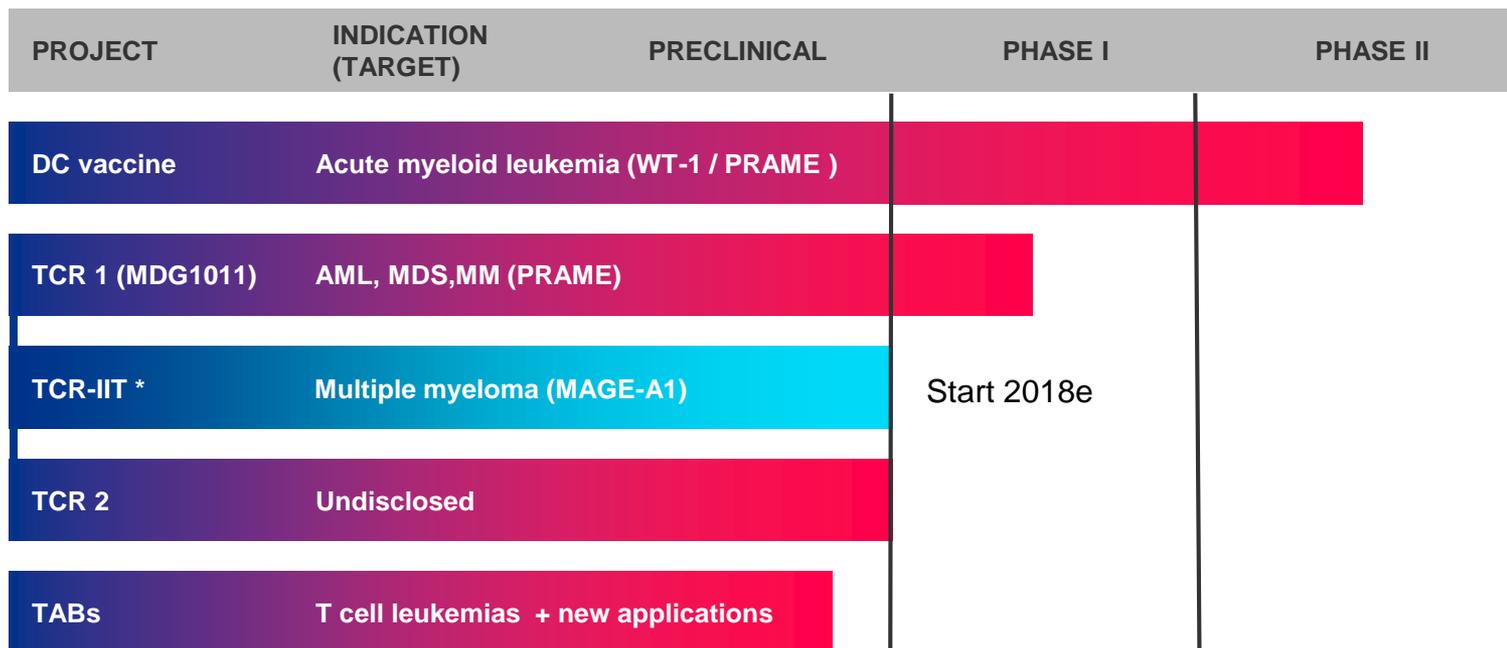


- Medigene strengthens its patent portfolio with a US patent on a tagged TCR and a European patent covering T cell identification method



- Publication of scientific paper on Expitope 2.0, helping Medigene to identify safer antigens for immunotherapy of cancer

Progress of immunotherapy pipeline



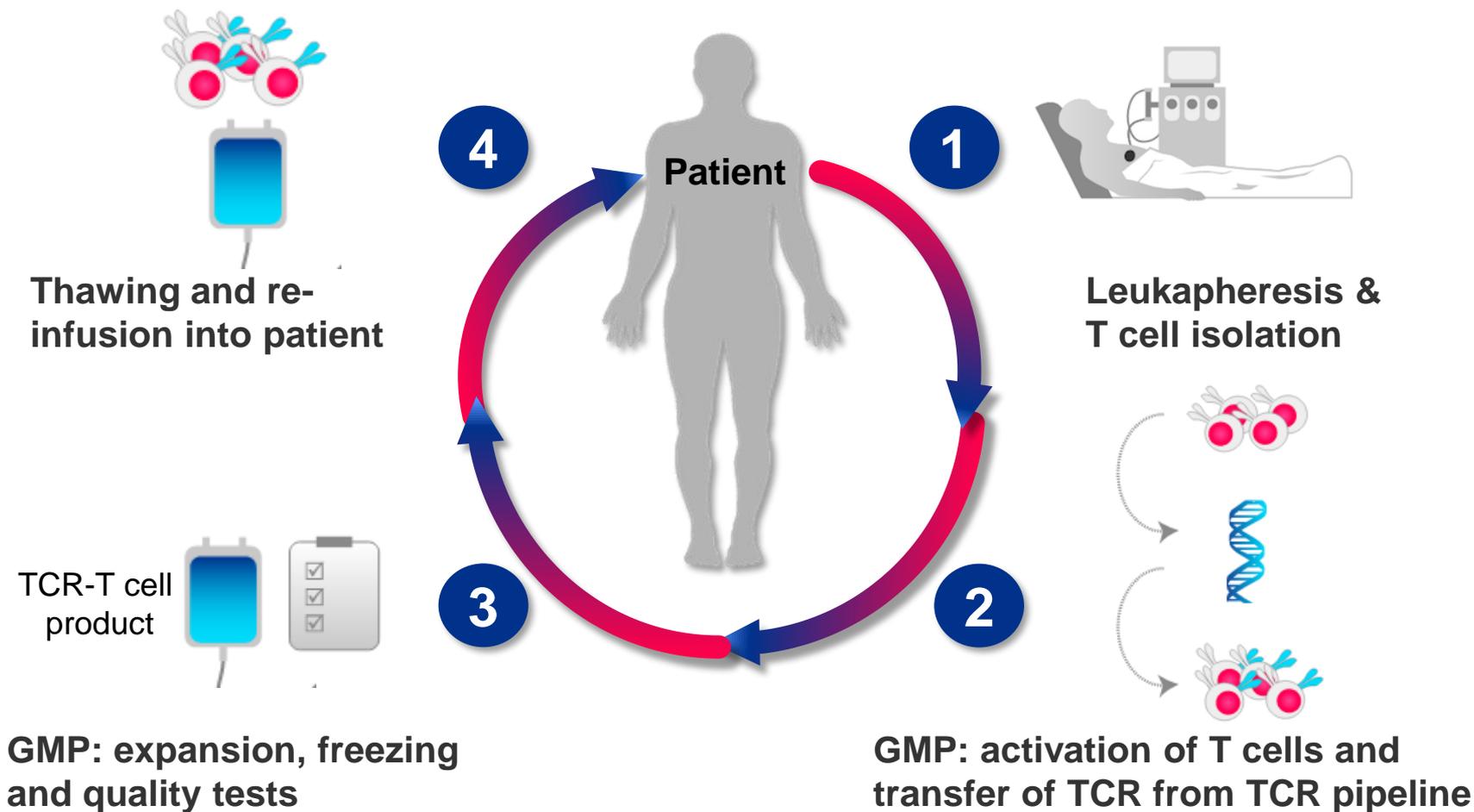
* Investigator-initiated trial (IIT) of a publicly funded collaboration between MDC, Charité and Medigene.

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)

MDG1011

First TCR-T cell therapy clinical trial

Personalized cancer treatment with TCRs



Phase I/II clinical trial of MDG1011 in myeloid and lymphoid malignancies

Target:

- PRAME (**P**referentially Expressed **A**ntigen in **M**elanoma)
- PRAME is a well characterized tumor antigen overexpressed in multiple hematological and solid tumor indications

The drug, MDG1011:

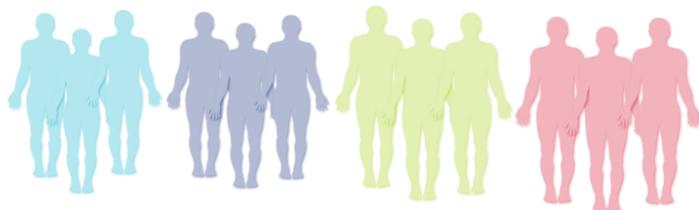
- T cells expressing a HLA-A*02:01-restricted T cell receptor (TCR) specific for PRAME

Trial outline:

- Combined Phase I/II safety, feasibility and early efficacy clinical trial
- Disease indications for Phase I, all in advanced stages:
 - acute myeloid leukemia (AML)
 - myelodysplastic syndrome (MDS)
 - multiple myeloma (MM)
- 2 of the 3 indications will be carried over into Phase II

MDG1011 clinical trial design

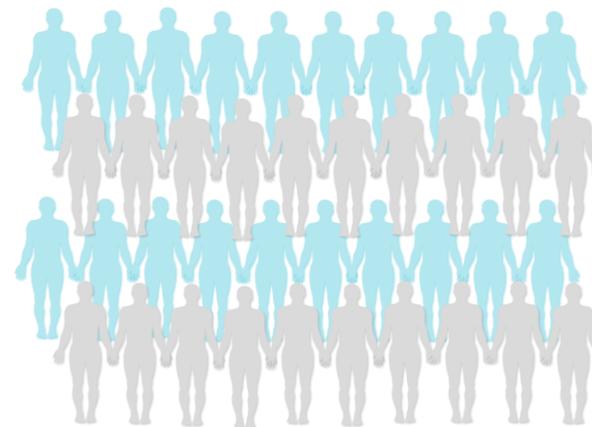
Phase I



**Approx. 12 patients
in up to 4 dose cohorts**

- 3+3 dose escalation design, up to 4 cohorts
- Each indication needs to be represented in a cohort
- Dose ranges from 100,000 to 10,000,000 transduced T cells per kg body weight
- Progression between dose cohorts will be decided by an independent Data and Safety Monitoring Board (DSMB).
- Multi-center study at three sites (University of Regensburg, Würzburg and Erlangen, Germany)

Phase II



40 treated + 40 control patients

- 2 of 3 indications to be carried into Phase II after a positive DSMB assessment and PEI/ethics committee vote
- 40 HLA-A*02:01 and PRAME positive patients to be treated with MDG1011 (20 per indication)
- Another 40 patients, PRAME positive but HLA-A*02:01 negative, serve as control groups (20 control patients per indication)

MDG1011 – Patient recruitment and treatment procedure

- Two tests are the main enrollment criteria for the clinical trial:
 - Patients need to have **suitable HLA status (HLA-A*02:01)**
 - Patients' tumor cells need to **express the PRAME antigen**
- After a patient is enrolled, an apheresis is performed and MDG 1011 is produced (i.e. introduction of PRAME TCR, expansion, quality testing)
- In the early stages of this clinical development, Medigene expects a production time of about six weeks from the beginning of an apheresis process until completion of the cell product
- One week before the one-time infusion of T cell therapy product MDG1011, the patient has to undergo a preparative chemotherapy (Cyclophosphamide and Fludarabine)
- In the Phase I of this trial, patients will be sequentially included in compliance with requirements imposed by the authorities to ensure patient safety

DC vaccine clinical trial

Recent DC vaccine data from AACR 2018

Data on the successful production of AML DC vaccine :

- 20 patients with a median age of 59 years (range 24 - 73 years) were recruited
- Successful production runs of dendritic cells for vaccination were achieved for all 20 AML patients
- Aliquots prepared to deliver 5-10 million cells per vaccine dose
- An additional apheresis for a second production run in order to generate sufficient vaccine doses was needed for only 4 out of the 20 patients

→ Feasible and robust production protocol for high numbers of mature, clinical grade DCs from heavily pretreated, post-remission AML patients

IIT study presented by Oslo University Hospital:

- Clinical data for DC vaccine in 20 prostate cancer patients
- Seventy-five percent of the patients remain without biochemical relapse with a mean observation time of 47.5 (range 29-82) months
- 5 of 20 patients received DCs generated with Medigene's proprietary maturation cocktail
- The 5 patients given the new type of DCs have not experienced PSA relapse

→ Adjuvant dendritic cell vaccines in high-risk prostate cancer patients following radical surgery may reduce the incidence of biochemical relapse

Financial Report 3M-2018

Financial overview for the first 3 months of 2018

€2.8 m

Total revenues increased by 6%

+20%

Increase in R&D expenses due to progress in clinical programs

€1.4 m

Revenues from immunotherapies increased

€49.1 m

Liquid assets & time deposits

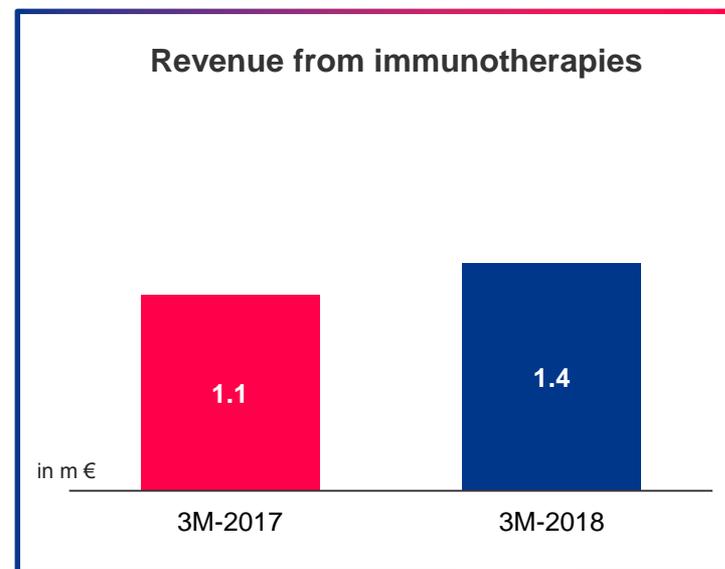
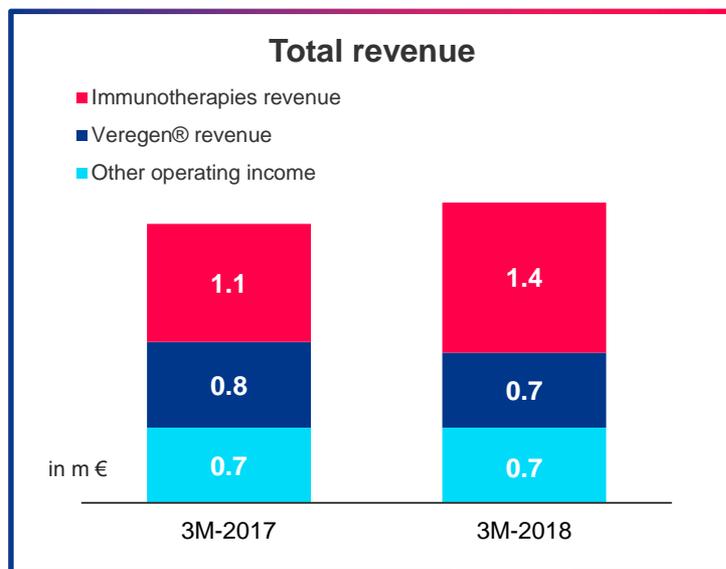
€3.2 m

EBITDA loss



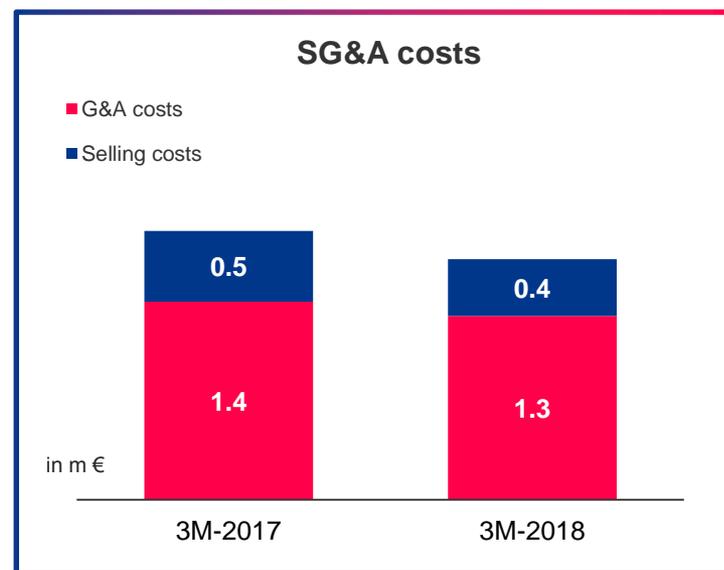
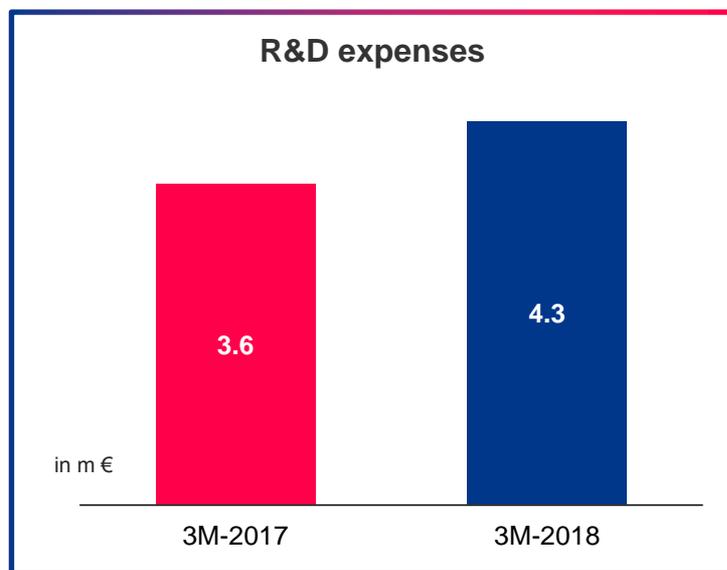
Financial guidance 2018 met

Increasing revenues from TCR collaboration



- Revenue of €1.4 m from bluebird bio (2017: €1.1 m) – revenue recognition of upfront payment and R&D reimbursement

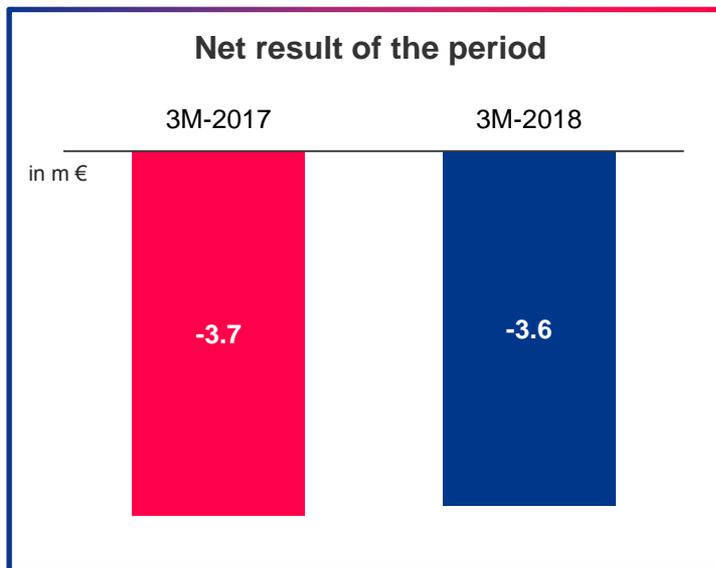
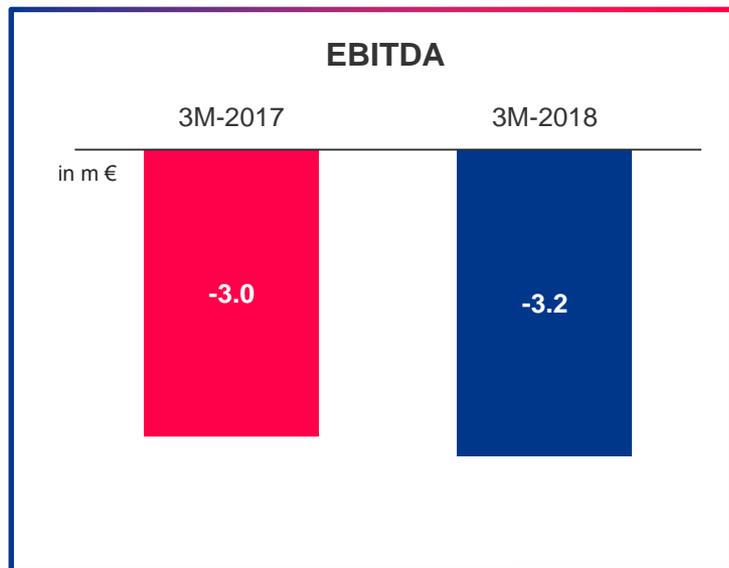
Increase in R&D expenses by 20%



- Ongoing DC clinical trial
- Ongoing clinical trial for MDG1011

- Decrease by 12%, mainly due to less cost of sales for Veregen

Minor changes in EBITDA and net loss



Financial guidance 2018

	3M 2018	GUIDANCE 2018
Total revenue	€2.8 m	€7.5-9.5 m
R&D expenses	€4.3 m	€22-24 m
EBITDA loss	€3.2 m	€21-23 m
Cash usage		€21-26 m

- Medigene has sufficient financial resources for beyond the planning horizon of two years
- No milestone payments or cash inflows are included from existing or future partnerships or transactions

Outlook 2018

MDG1011, Medigene's first TCR trial:

- Treatment of first patient
- Treatment of first dose cohorts

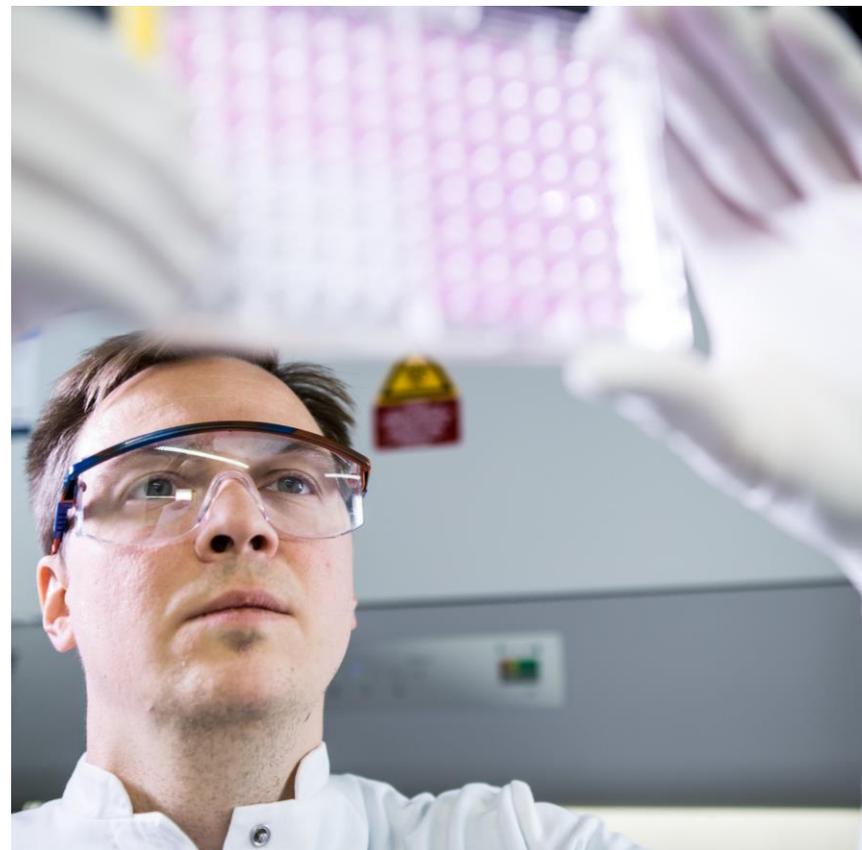
DC trial in AML, Oslo:

- Presentation of preliminary data on certain aspects of the trial
- Final read-out in 2019

TCR IIT, Berlin:

- Clinical trial authorization
- Study start

Progress in bluebird collaboration



Questions & Answers



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