

# THE POWER OF *IMMUNO* THERAPIES

FY 2014 Results Conference Call

Dr. Matthias Schroff – Chief Executive Officer

Berlin, 25 March 2015

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# Agenda

## **Achievements FY 2014**

Product Pipeline

Key Financials FY 2014 and Outlook 2015

Appendix

## Achievements 2014

Capital increase to start IMPALA study



Start IMPALA – Registration study



Start IMPULSE – Randomized study



Present positive clinical data at scientific congresses



EnanDim - New generation of lead product MGN1703



Guidance 2014 met



## Summary MGN1703: Most Advanced Product

Phase II study **IMPACT** colorectal cancer: Outstanding long-term responses

Pivotal phase III study **IMPALA** in colorectal cancer

- Patient enrolment started in September 2014
- Switch maintenance therapy to prolong overall survival
- Study design is based on findings of the phase II IMPACT study

Randomized study **IMPULSE** in small cell lung cancer

- Patient enrolment started in March 2014
- Switch maintenance therapy to prolong overall survival
- Indication with high unmet medical need

Investigational New Drug (**IND**) application approved in the US

- Safety and tolerability study in the US completed in 2013
- Prerequisite for US application for marketing authorization

# MGN1703 – Milestones for Various Clinical Trials

2014	2015	2016	2017 / 2018
<b>Metastatic Colorectal Cancer (mCRC)</b>			
IMPALA (Phase III trial) First patient in, PEP: OS	IMPACT (Phase II trial) OS data expected	IMPALA Recruitment completed	IMPALA Primary analyses (OS), Filing/Approval
<b>Small Cell Lung Cancer (SCLC)</b>			
IMPULSE (randomized, controlled trial) First patient in, PEP: OS	IMPULSE Recruitment completed	IMPULSE Primary analyses (OS)	

OS overall survival | PEP primary endpoint

## ASET Trial with MGN1601: Promising Data

ASET phase I/II study (12/2010 – 08/2013):

- Open-label, proof-of-principle, multi-center phase I/II trial
- 19 patients with advanced renal cell carcinoma who failed prior systemic therapies



- Primary endpoint met: Favorable safety and tolerability profile
- Promising overall survival data in subgroup of patients
- Identification of potential biomarkers

# Conclusion: Late-Stage Products with Unique Profile and Huge Market Potential

## MGN1703

First-line maintenance

Long-term treatment

Usable for various indications (mCRC, SCLC,...)

Superior safety and tolerability

Suitable for mono- and combination therapy

Patient selection via biomarker

## MGN1601

Promising phase I/II data in renal cancer

EMA: Orphan Drug Status; 10 yrs. market exclusivity

Blockbuster potential

Attractive market potential



## EnanDIM<sup>®</sup>: New Generation of Immunomodulators

- New class of linear TLR9 agonists
  - ➔ Combines advantages of molecules containing only natural DNA components with benefits from linear molecules
  - ➔ Specific structure protects against degradation - no chemical modifications needed
- Broad immune activation shown in preclinical trials
- Potential application in the fields of cancer and anti-infective therapies

## Key Financials FY 2014: Ongoing High R&D Expenses Due to Advanced Study Programs

[in € million]	Dec 31 2014	Dec 31 2013	Δ
Cash & cash equivalents	13.6	14.8	-8%
Balance sheet total	15.1	15.9	-
Equity ratio	88%	94%	-6%

- Balance sheet almost unchanged: high cash consumption due to extended R&D compensated by cash inflow from capital increase

[in € million]	2014	2013	Δ
R&D expenses	13.3	7.9	68%
EBIT	-17.1	-10.9	57%
Cash flow from operating activities	-15.6	-8.9	75%
Cash flow from financing activities	14.5	-	-
Monthly cash burn	1.4	0.8	75%

- IMPALA and IMPULSE studies main drivers of increased R&D costs
- Monthly cash burn increased accordingly
- Cash flow from financing activities includes capital increase

## FY 2015: Qualitative Outlook

- Development of product pipeline well on track
  - ➔ Intensify clinical development of MGN1703:
    - Registration study IMPALA: Continue patient recruitment
    - Randomized study IMPULSE: Finalize patient recruitment
  - ➔ MGN1601: plan and prepare continuative study in renal cancer
- Continue partnering discussions
- Increase of R&D expenses due to studies with MGN1703, mainly IMPALA

## Corporate Calendar and Contact Details

- **May 12, 2015**  
Quarterly Report as of March 31, 2015
- **August 13, 2015**  
Quarterly Report as of June 30, 2015
- **November 12, 2015**  
Quarterly Report as of Sep 30, 2015



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## Appendix

Product Pipeline

Further information on trials

Quarterly Key Financials

# Advanced Product Pipeline with Strong Focus on Cancer Immunotherapies

Preclinical	Phase I	Phase II	Phase III / Approval
<b>EnanDIM</b> Oncology & Anti-infectives	<b>MGN1703<sup>1</sup></b> Other solid tumors	<b>MGN1703<sup>1</sup></b> Small cell lung cancer	<b>MGN1703<sup>1</sup></b> Colorectal cancer
<b>MGN1331</b> Leishmaniasis	<b>MGN1601</b> Renal cancer		
<b>MGN1333</b> Hepatitis B	<b>MGN1404<sup>2</sup></b> Malignant melanoma		

- Oncology
- Infectious diseases
- Oncology & Infectious diseases

<sup>1</sup> IND (Investigational New Drug) filed in US; safety trial in US completed

<sup>2</sup> Collaboration with Max-Delbrueck-Center for Molecular Medicine and Charité Universitaetsmedizin, Berlin

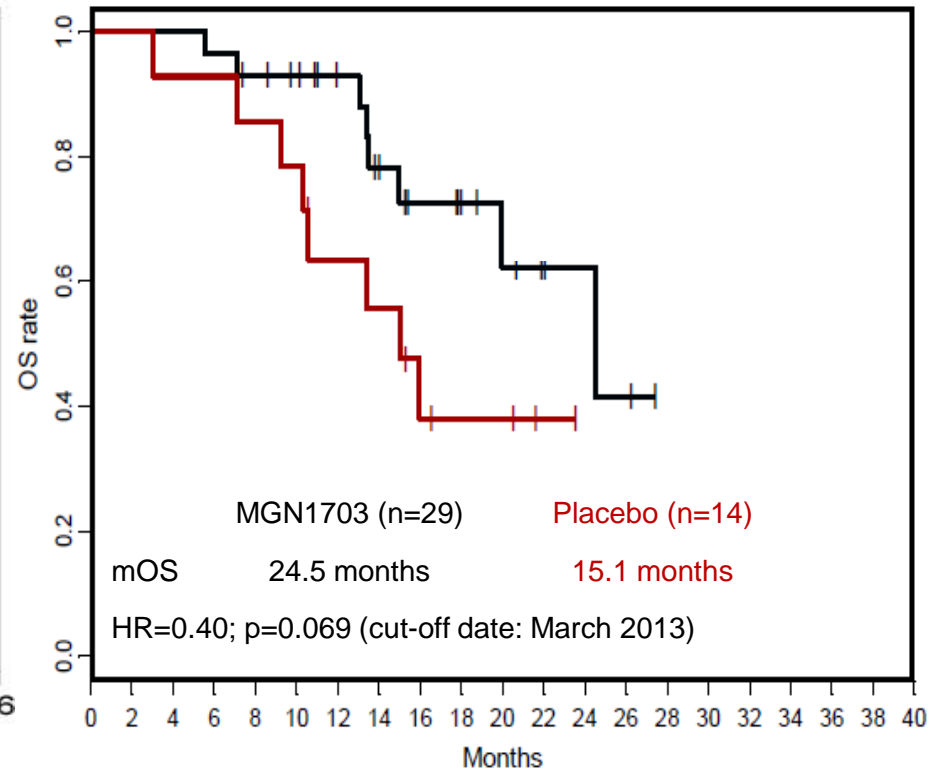
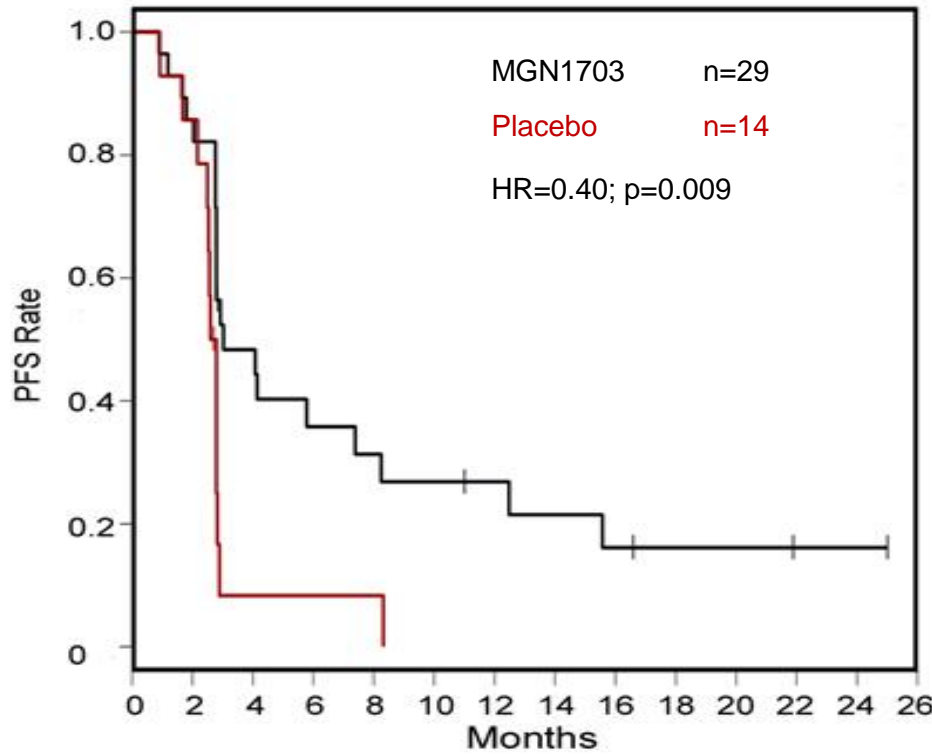
# IMPACT - Phase II Study in Colorectal Cancer Generated Outstanding Long-Term Responses

- Primary endpoint met: Progression free survival
- Secondary endpoint “Overall Survival”: Results are not yet mature (too many patients alive), median OS 22.6 (MGN1703) vs. 15.1 months
- Predictive biomarkers identified: Tumor reduction by induction therapy, CEA level, presence of activated NKTs
- Follow-up of four patients who continued MGN1703 treatment in compassionate use programs since no relapse at end of study:
  - ➔ Three patients progression-free in excess of 37- 45 months as of September 2014
  - ➔ Excellent safety and tolerability, also when treated long-term

Findings from subgroup analyses were used to optimize the phase III study design

# IMPACT - PFS and OS Benefit in Patients Relevant for Phase III

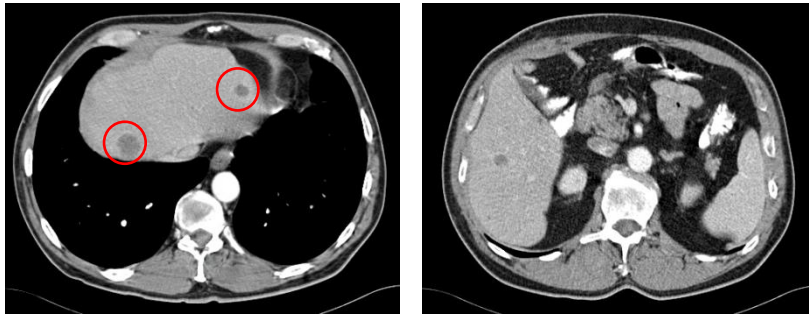
- Responders to prior induction therapy show encouraging PFS and OS benefit (shown from start of maintenance therapy, time of induction therapy is not included)
- Data on OS still preliminary due to lack of events [patients alive]



HR hazard ratio | IT induction therapy | mOS median overall survival | PFS progression-free survival

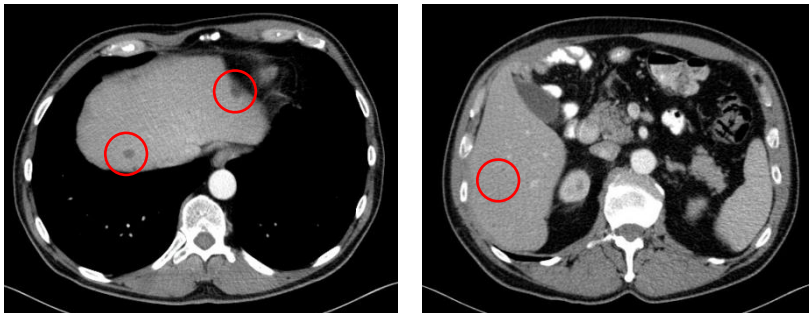


# IMPACT - Sustained Efficacy



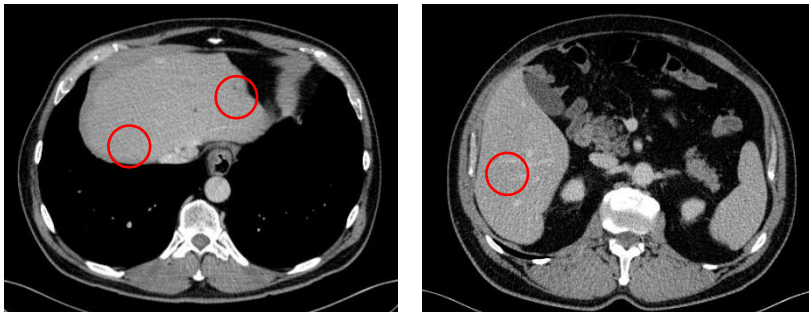
## Patient 049 - At initial diagnosis (04/2010)

- Colon carcinoma with multiple liver metastases



## After induction chemotherapy (12/2010)

- 06/2010 - 11/2010:  
9 courses of CT (FOLFIRI) + Bevacizumab  
(biologic)
- 12/2010: Response to induction CT: PR\*

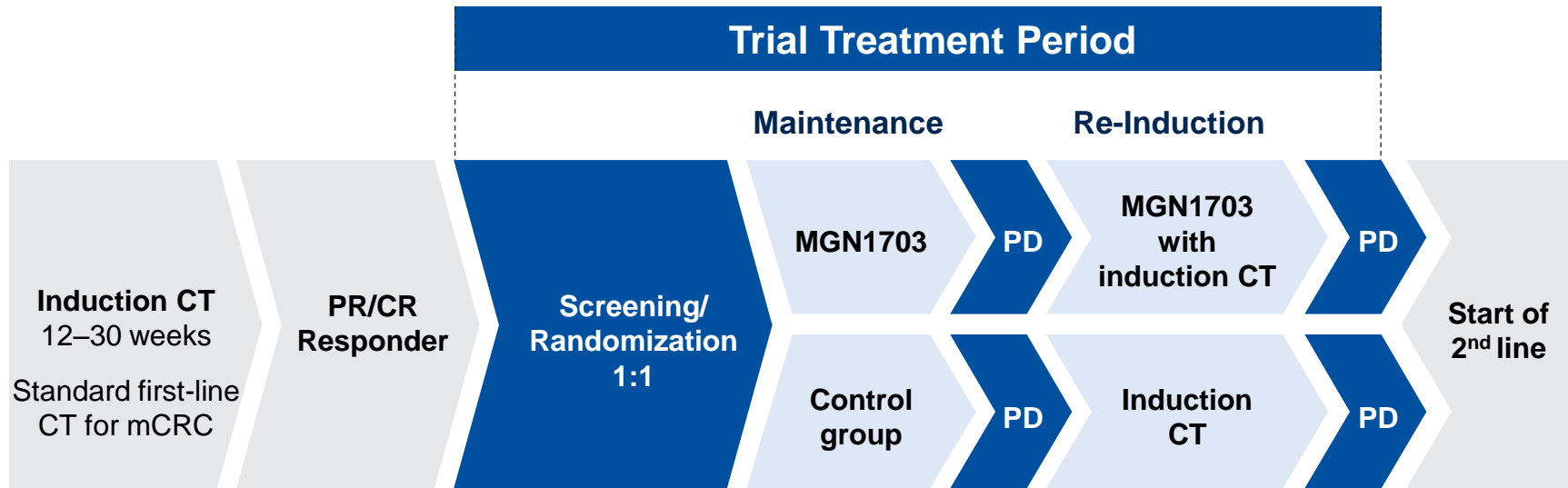


## During MGN1703 maintenance (04/2012)

- Since 12/2010: MGN1703 maintenance therapy
- New PR\* after 9 months
- Still ongoing PR (40 months as of January 2015)
- Good medical condition, mild local skin reactions,  
no further toxicities

CT chemotherapy | PR partial response | \*confirmed by two independent radiologists

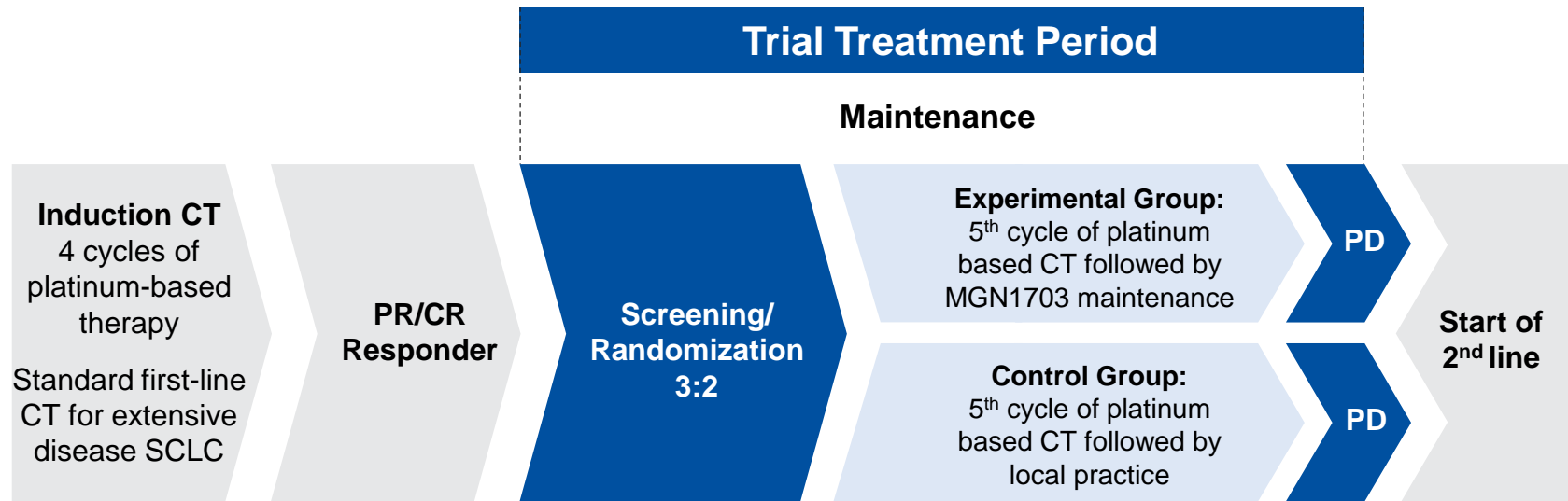
# IMPALA - mCRC Pivotal Phase III Study Started in Sep 2014



- Primary endpoint: Overall survival
- Open-label, randomized, controlled, two-arm, multinational phase III trial
- 540 patients in more than 100 sites in eight European countries, including Top 5 European pharma markets
- Biomarkers used as stratification factors: CEA level and NKT activation

CR complete response | CEA carcinoembryonic antigen - a tumor marker for colorectal cancer | CT chemotherapy | mCRC metastatic colorectal cancer | NKT Natural Killer T cells | PR partial response | PD progressive disease

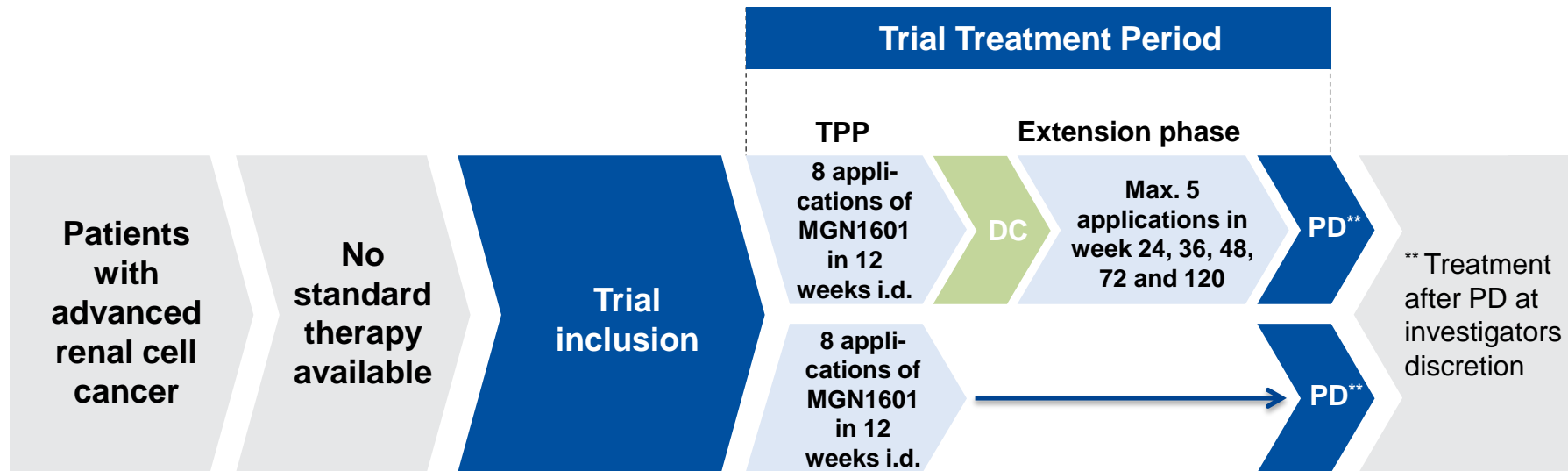
# IMPULSE - SCLC Randomized Study Started in Mar 2014



- Primary endpoint: Overall survival
- Randomized, controlled, two-arm, multinational trial with 100 patients in Belgium, Austria, Germany and Spain
- Biomarkers used as stratification factors: NSE level and NKT activation

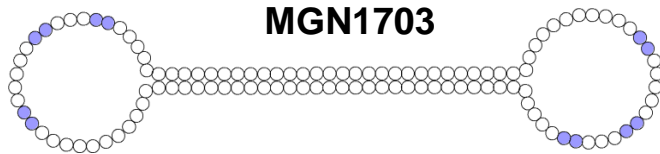
CR complete response | CT chemotherapy | NKT Natural Killer T cells | NSE neuron specific enolase - a tumor marker for lung cancer | PD progressive disease | PR partial response | SCLC small cell lung cancer

# MGN1601 - ASET Study Design



- Primary endpoints met: safety and tolerability
- Open-label, proof-of-principle, multi-center phase I/II trial
- 19 patients with advanced renal cell carcinoma who failed prior systemic therapies
- Orphan drug designation from EMA
- Start: December 2010 – primary completion date: August 2013

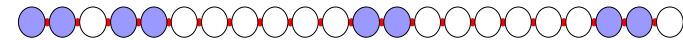
# EnanDIM - Combining Advantages of Two Types of Agonists: Linear and not Chemically Modified Structure



**MGN1703**

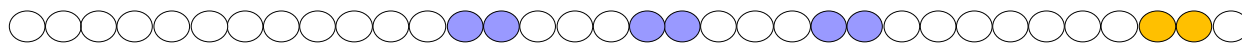
- Closed, dumbbell-shaped structure
- Only natural DNA components
- Good safety and tolerability profile
- One additional production step

**Linear DNA-structure**



- Linear molecules
- Easy and cost-effective production
- Chemically modified structure (•)

## EnanDIM® = Enantiomeric DNA-based ImmunoModulator



- Linear molecules
- No chemical modifications
- Good safety and tolerability profile expected
- Easy and cost-effective production

**New structural feature:**  
Protection against degradation

DNA sequence essential for function (so-called “CG motifs”)

## Quarterly Key Financials

[in € million]	Q4 2014	Q3 2014	Q2 2014	Q1 2014	Q4 2013	Q3 2013	Q2 2013	Q1 2013	2014	2013
R&D expenses	2.8	4.6	3.0	2.9	3.4	1.7	1.4	1.4	13.3	7.9
EBIT	-3.8	-5.4	-3.8	-4.1	-4.2	-2.5	-2.0	-2.2	-17.1	-10.9
Cash flow from operating activities	-4.1	-5.0	-3.3	-3.2	-2.8	-2.3	-1.8	-2.0	-15.6	-8.9
Cash flow from financing activities	-0.2	-	-0.1	14.8	-	-	-	-	14.5	-
Monthly cash burn	1.4	1.7	1.1	1.4	0.9	0.8	0.6	0.7	1.4	0.8

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