



**FY 2016 RESULTS  
CONFERENCE CALL**

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**BERLIN, 22 MARCH 2017**

# Disclaimer

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# Agenda

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# Highlights FY 2016 and Onwards

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**Operations:  
lefitolimod  
(MGN1703)  
  
EnanDIM®**

**New strategy “Next Level” implemented** and brought forward

➔ Partnering discussions ongoing

**Clinical study program advanced:**

➔ Progress in patient recruitment for pivotal study

➔ Continuation of TEACH study in HIV based on good results from initial phase: extension phase started in June 2016

➔ Collaboration with MD Anderson Cancer Center, US, Texas: first combination trial with checkpoint inhibitor started in July 2016

➔ Promising preliminary data on EnanDIM® in a murine tumor model

**Financials**

➔ Financials characterized by study progress

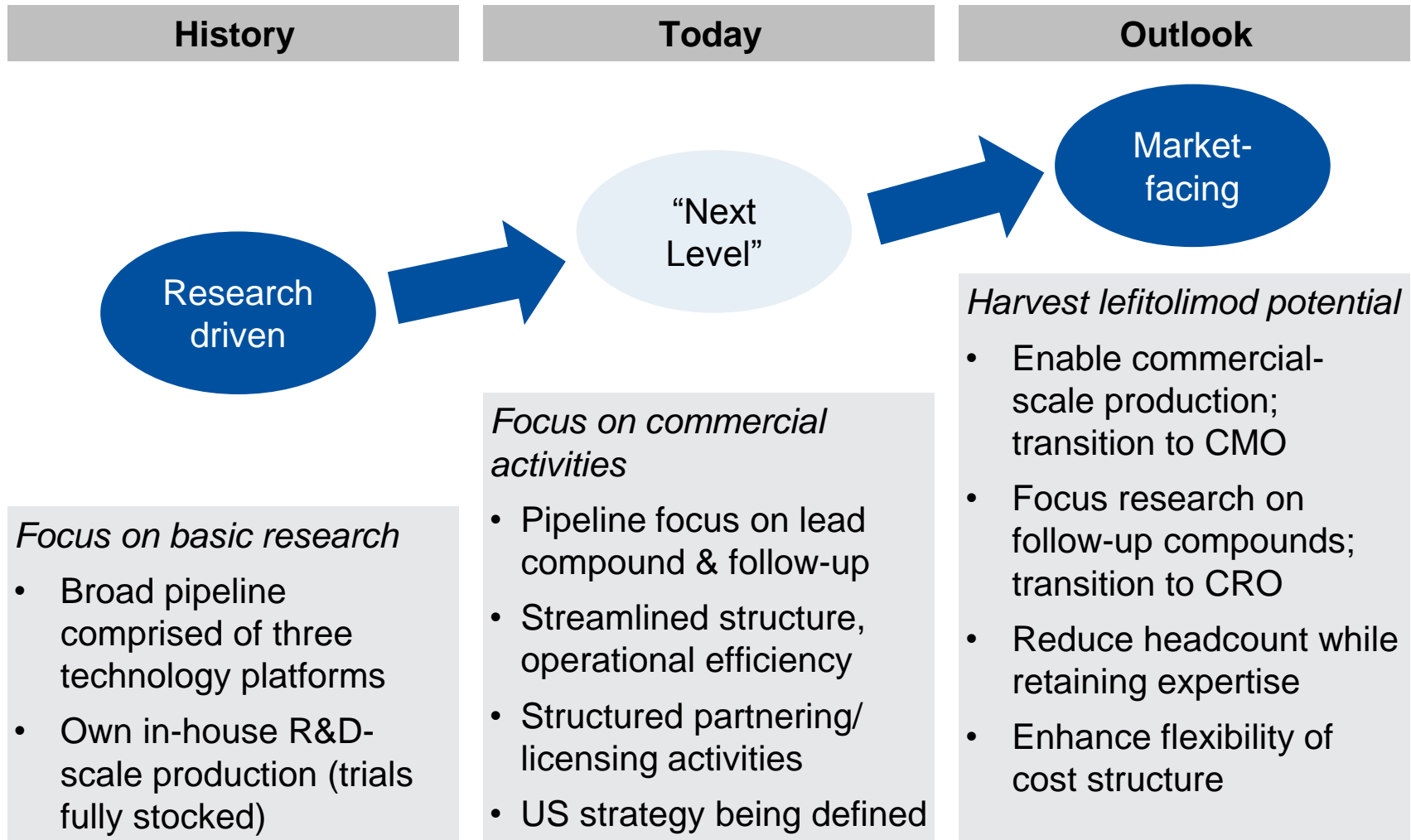
➔ Liquid funds decreased in line with study progress

➔ Capital increase in Oct 16; issuance of two convertible bonds Nov 16/Jan 17

**Executive Board**

➔ New CFO started 1 Apr 2016; new CMO to start 1 May 2017

# Next Level Strategy: Transition to Commercial Enterprise



# Advanced Immunotherapy Pipeline: Late-Stage Lefitolimod & Follow-Up EnanDIM®

	Indication <sup>(1)</sup>	PC	Ph I	Ph II	Ph III	Timeline <sup>(2)</sup>	Exclusivity <sup>(3)</sup>	
Lefitolimod	Metastatic colorectal cancer (mCRC)	[Bar spanning PC, Ph I, Ph II]					LPI: first months '17 Data: '19 Filing: '19/'20	EU: 2030 US: 2028
						IMPALA (MGN)		
	Small-cell lung cancer (SCLC)	[Bar spanning PC, Ph I]					Data: '17	EU: 2030 US: 2028
						IMPULSE (MGN)		
	Advanced solid malignancies (+ ipilimumab)	[Bar spanning PC]					LPI: '18 Data: '19	EU: 2036 US: 2036
						MD Anderson		
	Human immunodeficiency virus (HIV)	[Bar spanning PC]					LPI: '16 Data: '17	EU: 2036 US: 2036
						TEACH (Aarhus)		
EnanDIM®	Cancer/ infect. diseases	[Bar spanning PC]					Pre-clinical	EU: 2035 US: 2035
MGN1601	Renal cell carcinoma (RCC)	[Bar spanning PC, Ph I]					Ph I / II data available backup compound	EU: 2036 <i>orphan drug status</i> US: 2038
						ASET (MGN)		

**Notes:** (1) Pipeline overview excludes MIDGE platform | (2) **Timeline** Denotes latest estimated timeline of upcoming milestones | (3) **Exclusivity** Denotes estimated minimum market exclusivity horizon based on patent and data protection

# HIV Program: Phase I (Ongoing)

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- Collaboration agreement with Aarhus University Hospital, DK
- First trial of lefitolimod (MGN1703) in HIV patients
- Aarhus University Hospital conducts the trial; MOLOGEN provides lefitolimod (MGN1703); funding received from the American Foundation for AIDS research (amFAR)
- Extension phase: More patients to be treated for 6 months based on broad activation of immune system induced by lefitolimod as shown in first phase
  - Activation of plasmacytoid dendritic cells (pDC), natural killer cells (NK) and T cells in HIV patients during antiretroviral therapy (ART)
  - Lefitolimod (MGN1703) could play a role in “kick & kill“ concept of HIV eradication
  - First patients of extension phase enrolled
- Final results expected mid-2017

The HIV program explores potential expansion of applications of lefitolimod

# Combination program: Phase I (Ongoing)

## Lefitolimod (MGN1703) and Ipilimumab (Yervoy®)

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- Collaboration with MD Anderson Cancer Center, Texas, US
- First combination trial of lefitolimod (MGN1703) with checkpoint inhibitor, commercially available ipilimumab (Yervoy®), manufactured by Bristol-Myers Squibb Co.
- MD Anderson Cancer Center conducts the trial; MOLOGEN provides lefitolimod (MGN1703) and funding for the trial
- Phase I trial in 50-60 patients with advanced solid malignancies, mainly melanoma

The combination program explores further potential expansion of applications of lefitolimod



# Key Financials 2016

In € million	FY 2016	FY 2015	Δ
R&D expenses	17.0	16.8	1%
EBIT	-21.0	-20.5	2%
Cash flows from operating activities	-19.3	-15.1	28%
Cash flows from financing activities	15.2	26.2	-42%
Monthly cash burn	1.7	1.4	21%

In € million	31 Dec 2016	31 Dec 2015	Δ
Total assets	21.4	26.4	-19%
Cash & cash equivalents	20.5	24.6	-17%
Equity ratio	55%	74%	-26%

- Slightly increased R&D expenses and related cash outflows due to advanced study program
- Next-level strategy including upscaling: increased R&D expenses in the mid- and long-term

# Refinancing - Current Shareholder Structure

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## Capital measures

- Capital increase: Oct 2016 (~11 m new shares to now ~34 m shares) €13.60 m
  - Convertible bond: Nov 2016 (8 years, 6% interest rate) €2.54 m
  - Convertible bond: Jan 2017 (8 years, 6% interest rate) €4.99 m
- 

**Total gross proceeds** ~ **€21.10 m**

## → Cash reach until early 2018



# Key Data of Convertible Bonds

	2016/2024	2017/2025
Amount	€ 2.54 million	€ 4.99 million
Issue date	25 Nov 2016	20 Jan 2017
Maturity date	29 Oct 2024	20 Jan 2025
Coupon	6%	6%
Price	EUR 10,000	EUR 10
Interest payment date	Quarterly	Quarterly
Conversion price	EUR 1.50	EUR 1.60
ISIN	DE000A2BPDY4	DE000A2DANN4
Listing	no	no
Holder at issuance date	Global Derivate Trading (GDT)	approx. 73% subscribed by GDT

# Outlook 2017

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- Advance product development
  - Focus on lead compound lefitolimod and successor molecules EnanDIM<sup>®</sup>
    - IMPALA: Finalize patient recruitment short-term
    - IMPULSE: Present study results in Q2
    - TEACH study results extension phase by mid-year
    - Ongoing recruitment for combination study with ipilimumab (Yervoy<sup>®</sup>)
    - Advance pre-clinical study program for EnanDIM<sup>®</sup>
- Production: Execute tech transfer and start upscaling
- Partnering discussions / Out-licensing activities to accelerate
- Ensure financing beyond early 2018
- R&D expenses will further increase due to study progress; operating results below FY 2016 expected - dependent on financing structure

# Financial Calendar 2017 and Contact Details

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**22 March 2017**

Full Year Report 2016

**28 April 2017**

Annual General Meeting

**11 May 2017**

Quarterly Statement as of 31 March 2017

**10 August 2017**

Half-Yearly Financial Report as of 30 June 2017

**9 November 2017**

Quarterly Statement as of 30 September 2017



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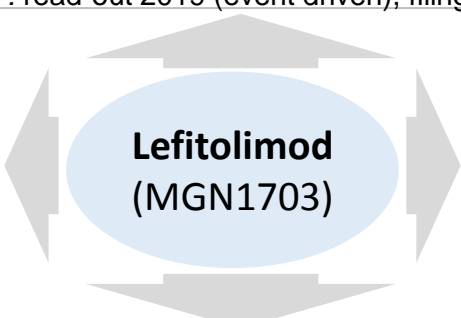
# Multi-Billion Dollar Markets: Ongoing Clinical Trials

## HIV: Phase I

- Two-stage single-center “TEACH” trial
  - Aarhus Univ. Hospital (DEN)
- *Status*: started Jun-2015
  - Stage 1 successfully completed (15 patients)
  - Stage 2 first patient Jun-2016 (target: 15 patients)
- *Aim*: to define value in kick and kill concept in HIV / infectious diseases
- *Target*: read out 2017

## mCRC: Phase III

- Pivotal multicenter (122) EU (8 countries) study “IMPALA”
- *Status*: started Sep-14 targeting 540 patients
- Patient recruitment on track
- *Aims*: to compare OS vs. local gold-standard treatment & to enable regulatory approval
- *Targets*<sup>(1)</sup>: read-out 2019 (event driven), filing 2019/ 2020



**Lefitolimod  
(MGN1703)**

## SCLC: Phase II

- Multicenter (41) EU (4 countries) study “IMPULSE”
- *Status*: started Mar-14 with recruitment of 100 patients completed Oct-15
- *Aims*: to compare OS vs. local gold-standard treatment, to inform development pathway in SCLC, to further support safety data base
- *Target*<sup>(1)</sup>: read-out 2017

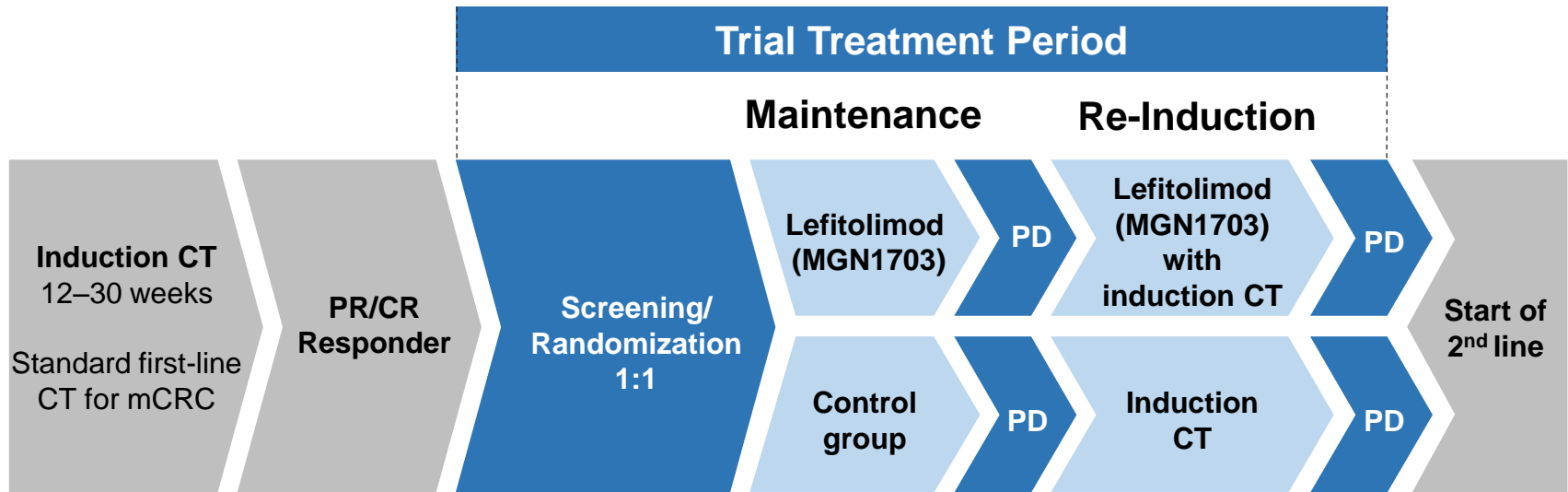
## Solid tumours: Phase I

- Single-center proof-of-concept trial combining lefitolimod with checkpoint inhibitor ipilimumab (Yervoy®)
  - MD Anderson (US)
  - 50-60 patients envisaged
- *Status*: started Jul 2016 (first patient in)
- *Aim*: to inform development pathway in combination treatments
- *Target*: read-out 2019

MOLOGEN is developing its lead compound in various directions

# mCRC Program: Phase III (Ongoing)

## Pivotal IMPALA Study

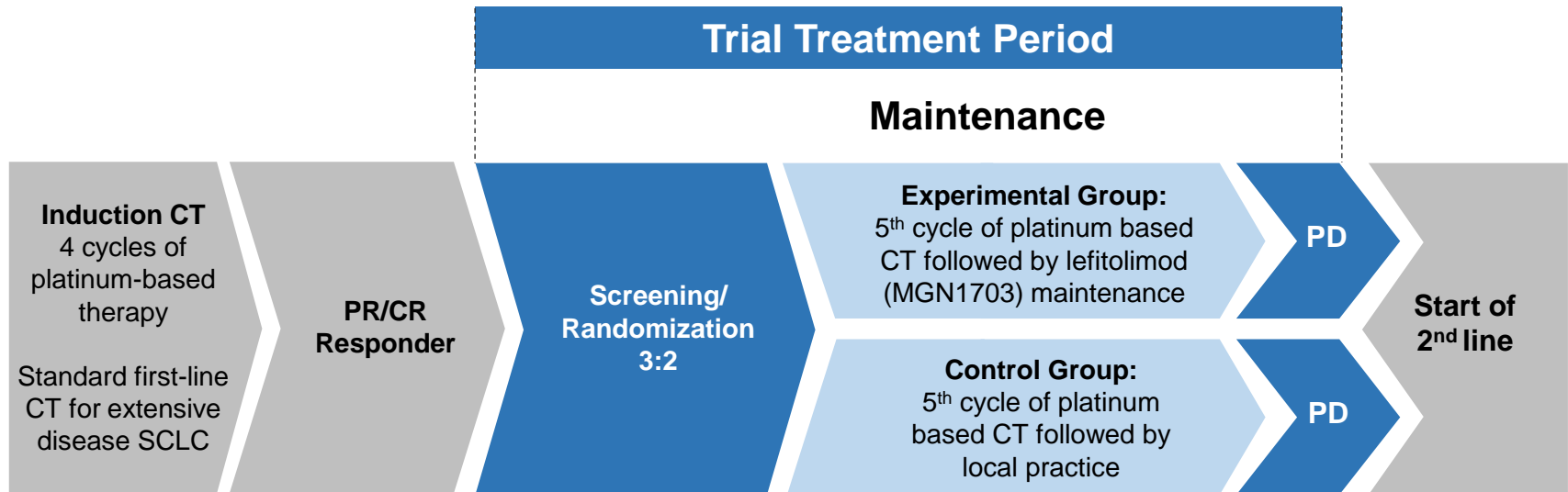


- Primary endpoint overall survival (OS)
- Open-label, randomized, controlled, two-arm, multinational phase III trial
- 540 patients in around 120 sites in eight European countries, including Top 5 European pharma markets
- Biomarkers used as stratification factors: CEA level and NKT activation



# SCLC Program: Phase II (Ongoing)

## Randomized IMPULSE Study



- Primary endpoint overall survival (OS)
- 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
- Patient enrollment completed: End of October 2015

# Key Financials Q4 2016

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In € million	Q4 2016	Q4 2015	Δ	FY 2016
R&D expenses	6.5	6.4	2%	17.0
EBIT	-6.7	-7.2	-7%	-21.0
Cash flows from operating activities	-5.4	-6.1	-11%	-19.3
Cash flows from financing activities	15.7	0.1	>100%	15.2
Monthly cash burn	1.9	2.0	-5%	1.7

# Quarterly Key Financials

in € million	Q4 2016	Q3 2016	Q2 2016	Q1 2016	FY 2016	Q4 2015	Q3 2015	Q2 2015	Q1 2015	FY 2015
R&D expenses	6.5	3.4	3.4	3.7	17.0	6.4	5.2	2.8	2.4	16.8
EBIT	-6.7	-4.5	-5.3	-4.5	-21.0	-7.2	-6.4	-3.7	-3.2	-20.5
CF from operating activities	-5.4	-4.7	-4.8	-4.4	-19.3	-6.1	-4.3	-2.5	-2.2	-15.1
CF from financing activities	15.7	-0.5	0.0	0.0	15.2	0.1	0.0	26.8	-0.7	26.2
Monthly cash burn	1.9	1.7	1.6	1.5	1.7	2.0	1.5	1.4	1.0	1.4



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