



**15. DVFA  
HERBSTKONFERENZ / SCC**

**DR. MARIOLA SÖHNGEN – CEO**

**FRANKFURT, 6. SEPTEMBER 2017**

# Disclaimer

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# MOLOGEN Snapshot

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- Based in Berlin, Germany; founded 1998
- Approx. 50 employees
- One of the pioneers in immunotherapies
- Focus on family of TLR9 agonists:
  - Lead product: immunotherapy with lefitolimod
  - Next-generation technology EnanDIM®
- Highly attractive markets: A multi-billion US\$ market
- Network with scientific institutions and experts



Lefitolimod



EnanDIM®

Aarhus University Hospital

THE UNIVERSITY OF TEXAS  
MDAnderson  
~~Cancer Center~~

CHARITÉ  
UNIVERSITÄTSMEDIZIN BERLIN

Freie Universität  Berlin

**MDC** MAX DELBRÜCK CENTER  
FOR MOLECULAR MEDICINE  
BERLIN-BUCH

# MOLOGEN Summary Highlights

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Advanced immunotherapy player

- Late stage phase III product in mCRC

Safe & well tolerated lead product

- Safety data from more than 400 treated patients

Multi-billion dollar target markets

- In attractive indications like mCRC, SCLC, HIV, combination treatments

Value-generating milestones reached

- Phase II SCLC and phase I/II HIV read outs published; phase III mCRC recruitment finished

Binding term sheet signed with the Chinese iPharma Ltd. for

- Collaboration regarding the development, manufacture and commercialization of lefitolimod in specific Asian territories and a potential co-development

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

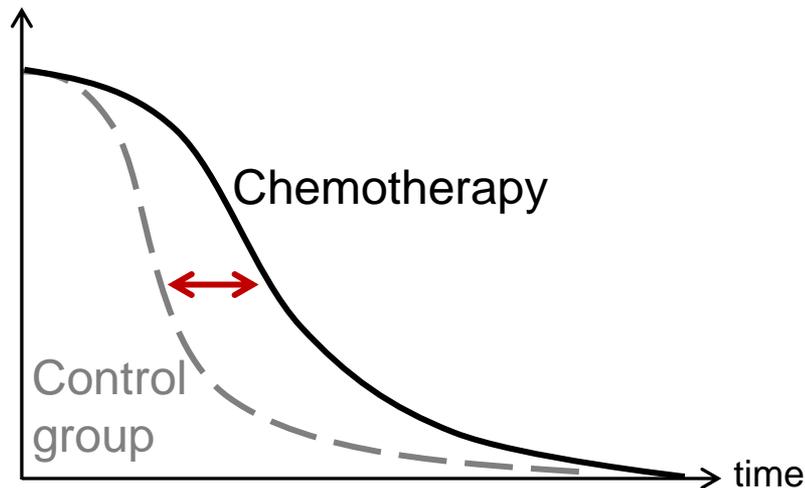
	Indication <sup>(1)</sup>	PC	Ph I	Ph II	Ph III	Timeline <sup>(2)</sup>	Exclusivity <sup>(3)</sup>	
Lefitolimod	Metastatic colorectal cancer (mCRC)	[Bar spanning PC, Ph I, Ph II]					LPI: 05/17 Data: '19 Filing: '19/'20	EU: 2030 US: 2028
						IMPALA (MGN)		
	Small-cell lung cancer (SCLC)	[Bar spanning PC, Ph I, Ph II]					04/17: top-line results	EU: 2030 US: 2028
						IMPULSE (MGN)		
	Advanced solid malignancies (+ ipilimumab)	[Bar spanning PC, Ph I]				LPI: '18 Data: '19	EU: 2036 US: 2036	
						MD Anderson		
	Human immunodeficiency virus (HIV)	[Bar spanning PC, Ph I, Ph II]					08/17: results of extension phase	EU: 2036 US: 2036
						TEACH (Aarhus)		
EnanDIM®	Cancer/ infect. diseases	[Bar in PC]					Pre-clinical	EU: 2035 US: 2035
MGN1601	Renal cell carcinoma (RCC)	[Bar spanning PC, Ph I, Ph II]					Ph I / II data available backup compound	EU: 2036 <i>orphan drug status</i> US: 2038
						ASET (MGN)		

# Cancer Immunotherapy Value Proposition: Improve Long-Term Overall Survival

## Traditional Chemotherapy

- Fast effect in many patients
- Effect not lasting

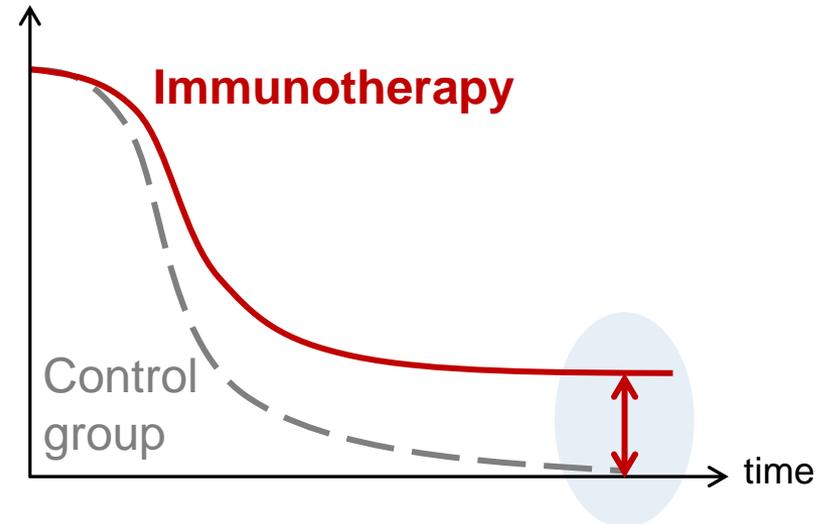
Patients alive in %



## Immunotherapy

- Needs time to be effective
- Long-lasting effect in a subgroup of patients

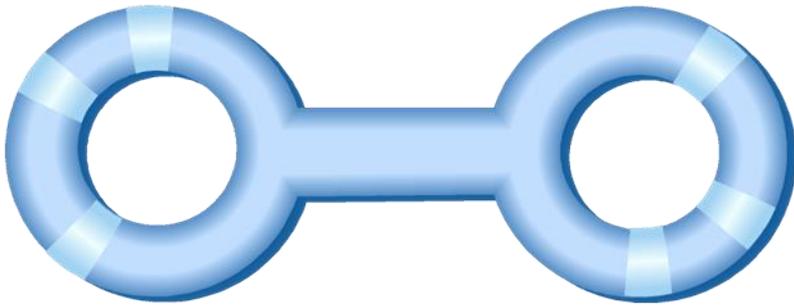
Patients alive in %



- Immunotherapies target improving OS at the long end of the curve

# Safe and Well Tolerated Immunotherapy: “Best in Class” TLR9 Agonist Lefitolimod

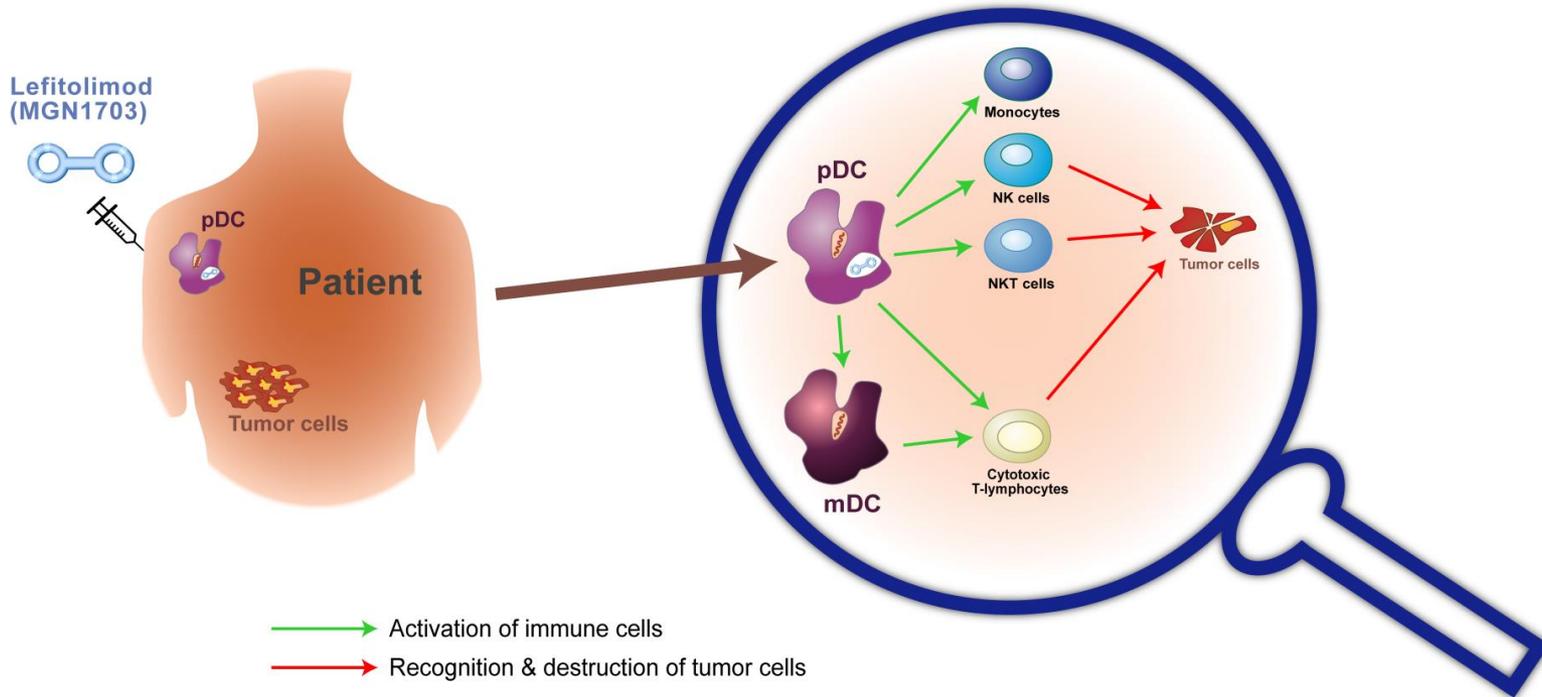
## Molecular Structure



## Commentary

- Immunologic activation and good safety profile due to molecular composition
    - Safety established in ~400 patients to date
  - High dosing over long periods of time – as required to trigger clinical benefit – possible without major toxic effects
  - Clinical strategy optimized for lefitolimod TLR9 activation pattern
- 
- Lefitolimod is geared to success given its combination of safety and tolerability by design with large potential for clinical benefit

# Safe and Well Tolerated Lead Product: Mode of Action in Oncology



- The patient's immune system generally polices the development of cancer cells – occasionally, cells evade that system, developing into cancer
- Lefitolimod reactivates the patient's own immune system for anti-cancer surveillance
- Lefitolimod can work safely alongside other treatments leveraging the body's own immune surveillance system

# Planned Collaboration with Chinese iPharma Ltd. (1/3)

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- 25 August 2017: MGN & iPharma signed binding term sheet that defines the framework for a collaboration
- iPharma is a China-based drug development company focusing on innovative approaches and assets in immunotherapy via in-licensing those programs and further developing the assets for the Chinese market and globally
  - Strong support for development program of lefitolimod, especially in China and other Asian regions
  - Preparation for market entry in China with high market potential
  - MGN to receive upfront and milestone payments, royalties and an equity investment under the final contract
  - Homing in on key objective:



 Licensing deal for main product candidate lefitolimod expected

# Two Parts of the Final Contract: To be signed by the end of 2017 (2/3)

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## License agreement (incl. sublicense rights) for:

- Development, manufacturing and commercialization for lefitolimod in oncology in China including Hong Kong and Macao, Taiwan and Singapore
- Under the licensing agreement MGN to receive an upfront payment, milestone payments, royalties and an equity investment

## Co-development agreement

- Both parties to jointly develop lefitolimod in one or more mutually agreed indications in oncology in the defined Asian territory and on a global level
- Combination studies with checkpoint inhibitors planned
- Indications and development plan to be mutually agreed and subject to further funding
- Parties to share economic returns from joint development pursuant to their contributions

Unleash Asian market potential of lefitolimod and further develop product candidate in oncology

## Financials of the Final Contract in Detail (3/3)

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Under the terms of the final agreement MGN to receive:

- Upfront payment of EUR 3 million
- Equity investment in MGN amounting to EUR 2 million within a period of 12 months following the execution of the final license agreement
- Further milestones - development milestones for predefined development steps and the market approval of the compound as well as commercial milestones due upon reaching certain sales thresholds
  - Total package can amount to over EUR 100 million and would be paid over several years after having reached the milestones.
- In addition MGN would receive low double digit royalties on net sales
- All costs relating to development, registration, marketing and commercialization of lefitolimod in the defined territory would be covered by iPharma

# IMPULSE: Positive Results in Two Subgroups of Patients Treated with Lefitolimod

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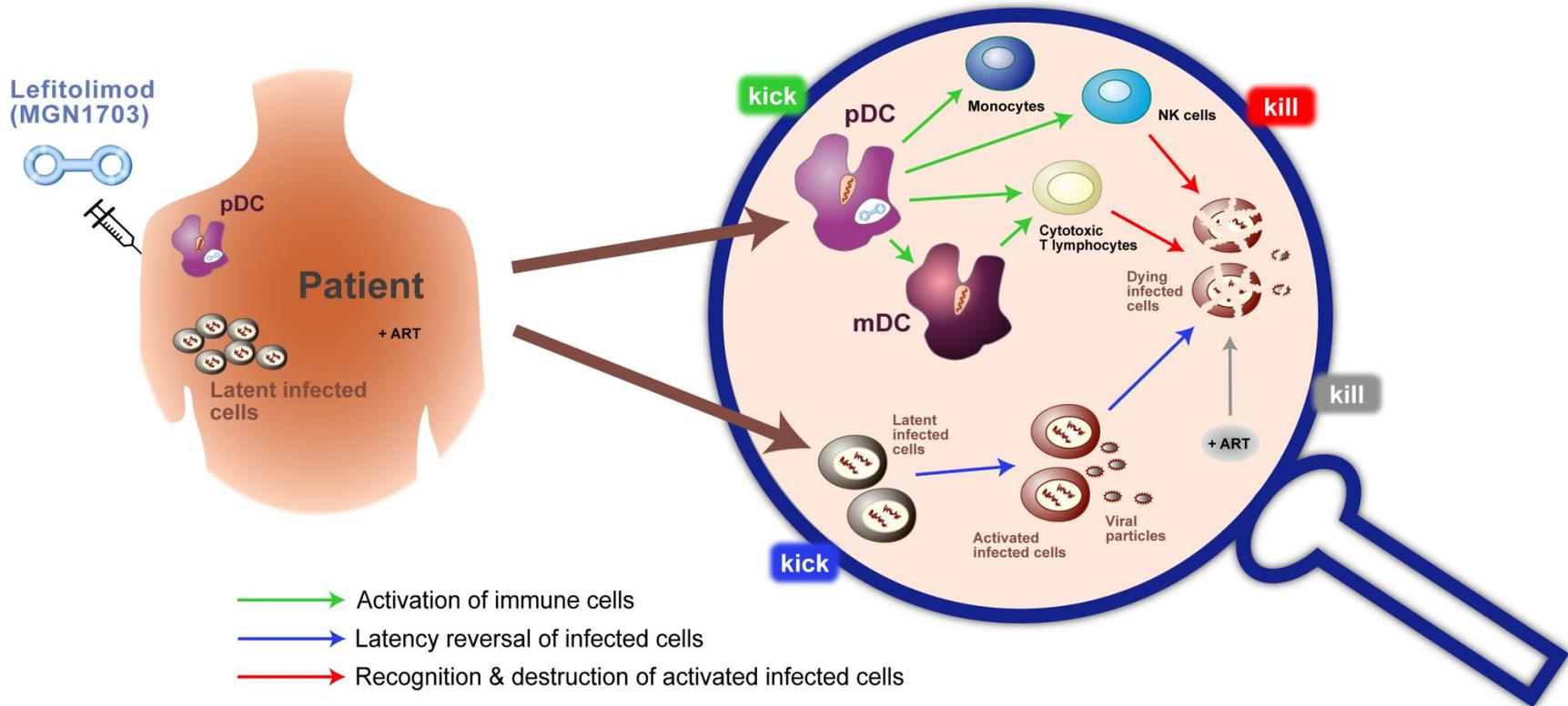
IMPULSE: Exploratory phase II controlled, two-arm, multinational trial with 102 patients with extensive disease small cell lung cancer (SCLC) to evaluate efficacy and safety of lefitolimod in comparison to control group (standard therapy)

- Primary endpoint “overall survival” (OS) not met in the overall study population in this challenging indication
- Positive results in two pre-defined and clinically relevant **subgroups of patients**:  
Notably, an overall survival (OS) benefit was shown in comparison to the control arm (local standard of care):
  1. Patients with a **low count of activated B cells**, an important immune parameter:  
Hazard ratio “HR”: 0.59; 95% confidence interval “CI”: 0.29–1.21
  2. Patients with reported **Chronic Obstructive Pulmonary Disease (COPD)**, a frequent underlying disease:  
Hazard ratio “HR”: 0.54; 95% confidence interval “CI”: 0.21–1.38



Results provide significant guidance for defining patient populations most likely to benefit from lefitolimod

# Safe and Well Tolerated Lead Product: Mode of Action in HIV



- Patients on ART are cleared from actively-infecting HI viruses, but T cells keep the remaining virus load in its latent stage (no immune response against the virus)
- Lefitolimod as “kick & kill” agent kicks the virus from latency into active infection, and reactivates immune surveillance to kill infected cells by NK cells and CTL

# TEACH EXTENSION PHASE: Results

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- Sustained increases in activation of important immune cells (CD4 and CD8 T cells) were observed throughout the dosing period of 24 weeks.
- Lefitolimod triggered maturation of other important immune cells (B cells) towards antibody-producing cells.
- After interruption of ART, one of the nine patients who participated in that study part showed viral control for more than 20 weeks, whereas the interval until viral rebound is generally two weeks.
- The intervention had no detectable effects on the size of viral reservoir in peripheral blood in the total study population of 12 patients, which was defined as the primary endpoint of the extension phase of the study.
- 24 weeks of lefitolimod treatment was safe and well tolerated in HIV patients on ART, corroborating the favourable safety profile already seen in cancer patients. The most common related adverse events study population were: neutropenia, injection site reaction, fatigue, dizziness, and headache. The majority of adverse events were of mild or moderate intensity with no life-threatening or fatal events. There were no discontinuations due to adverse events and no related serious adverse events.



Although lefitolimod alone on top of ART did not show the desired effect on the viral reservoir, lefitolimod could be an important combination partner for other interventions aiming at HIV cure, such as monoclonal antibodies or vaccines

# Grant by Gilead for Combination Study in HIV with Lefitolimod

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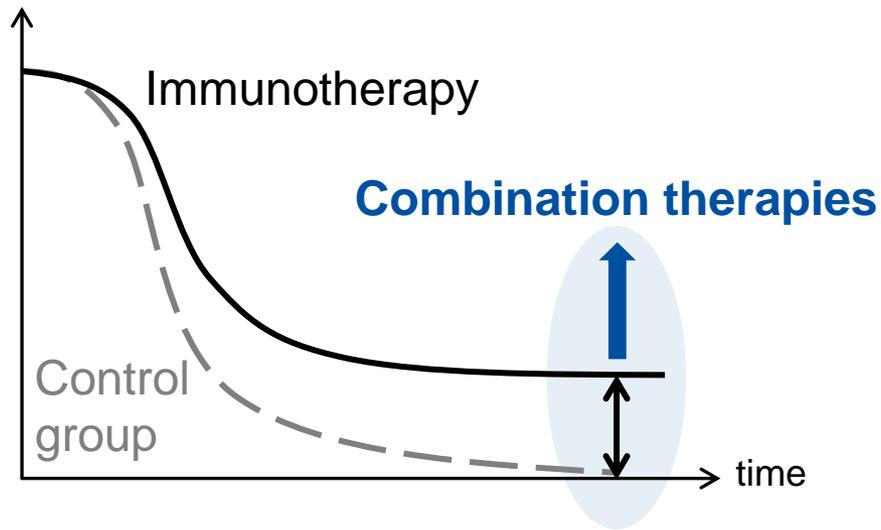
- Aarhus University Hospital received 2.75 US\$ from Gilead to fund clinical study in HIV-positive patients on antiretroviral treatment (ART)
  - Evaluating combination of lefitolimod with novel virus-neutralizing antibodies
- Rationale for the study
  - Coordinated mode of action of the compounds could generate a more effective eradication of the HIV reservoir compared to standard HIV treatment regimens, i.e. ART
- Promising potential for the combination of lefitolimod with virus-neutralizing antibodies

New use of “kick & kill” concept with virus-neutralizing antibodies

# Safe and Well Tolerated Lead Product: Combination Therapies Represent the Next Opportunity

## Combination Therapy Potential

Patients alive in %



## Commentary

- Combination treatments aim to combat a disease through various synergistic ways
- Expected to play integral role in future new immunotherapy approaches or breakthrough outcomes
- Increased research – and business development – across the market
- Lefitolimod uniquely positioned as potential “combination partner of choice”

- Combination therapies are the latest advancement in the fight against several global diseases including cancer & HIV

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

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Best in class TLR9 agonist and most advanced in mCRC (pivotal trial)

Long-term treatment

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

Superior safety and tolerability

Suitable for mono- and combination therapy

Patient selection via biomarker



Blockbuster potential

# Follow-Up Molecules EnanDIM<sup>®</sup>: Next-Generation TLR9 Agonists

## Linear DNA-structure



- Linear molecules
  - Simple, cost-effective production
- Stability through chemically modified structure
  - Usually unfavorable risk / benefit ratio

## Lefitolimod



- Stability through closed, dumbbell-shaped structure
  - Complex production
- Only natural DNA components
  - Good safety and tolerability profile

## EnanDIM<sup>®</sup>



- Linear molecules; stability through specific feature
  - Simple, cost-effective production
- No chemical modifications
  - Good safety and tolerability profile expected

- New family of linear TLR9 agonists, combining safety of molecules containing only natural DNA components with simple production process of linear molecules
  - Allow drug differentiation on molecular level
- Broad immune activation and anti-tumor effect shown in pre-clinical models
- Potential application in cancer and in anti-infective therapies

# Key Financials Q2/H1 2017

In € million	Q2 2017	Q2 2016	Δ	H1 2017	H1 2016	Δ
R&D expenses	4.1	3.4	21%	8.0	7.1	13%
EBIT	-5.4	-5.3	2%	-10.5	-9.8	7%
CF from operating activities	-5.2	-4.8	8%	-11.2	-9.2	22%
CF from financing activities	-0.1	0.0	-	4.8	0.0	-
Monthly cash burn	1.8	1.6	13%	1.9	1.5	27%

In € million	30 June 2017	31 Dec 2016	Δ
Total assets	15.1	21.4	-29%
Cash & cash equivalents	14.2	20.5	-31%
Equity	1.8	11.8	-85%
Equity ratio	12%	55%	-78%

- R&D mainly driven by study progress
- Issuance of convertible bonds reflected in CF from financing activities in H1 2017

# Refinancing - Current Shareholder Structure

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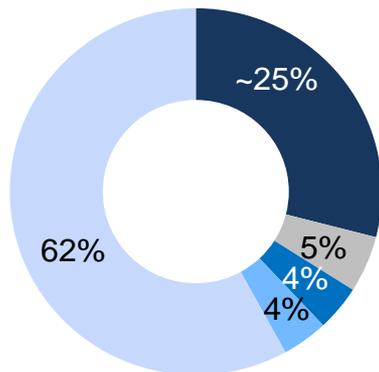
## Capital Measures

- Capital increase: (~11 m new shares); Oct 2016 €13.60 m
  - Convertible bond 2016/2024 (8 years, 6% interest rate); Nov 2016 €2.54 m
  - Convertible bond 2017/2025 (8 years, 6% interest rate); Jan 2017 €4.99 m
- 

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

→ **Cash reach until early 2018 according to current planning**

Shareholder Structure as at June 2017 (estimates)



- Global Derivative Trading GmbH, DE
- Deutsche Balaton Aktiengesellschaft, DE
- Baloise Holding AG, DE
- Deutscher Ring Krankenversicherungsverein a.G., DE
- Freefloat

# Outlook 2017

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- Advance product development
  - Focus on lead compound lefitolimod and successor molecules EnanDIM®
    - 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®)
    - Advance pre-clinical study program for EnanDIM®
- 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

# Appendix

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# 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



**Claudia Nickolaus**

Head of Investor Relations &  
Corporate Communications

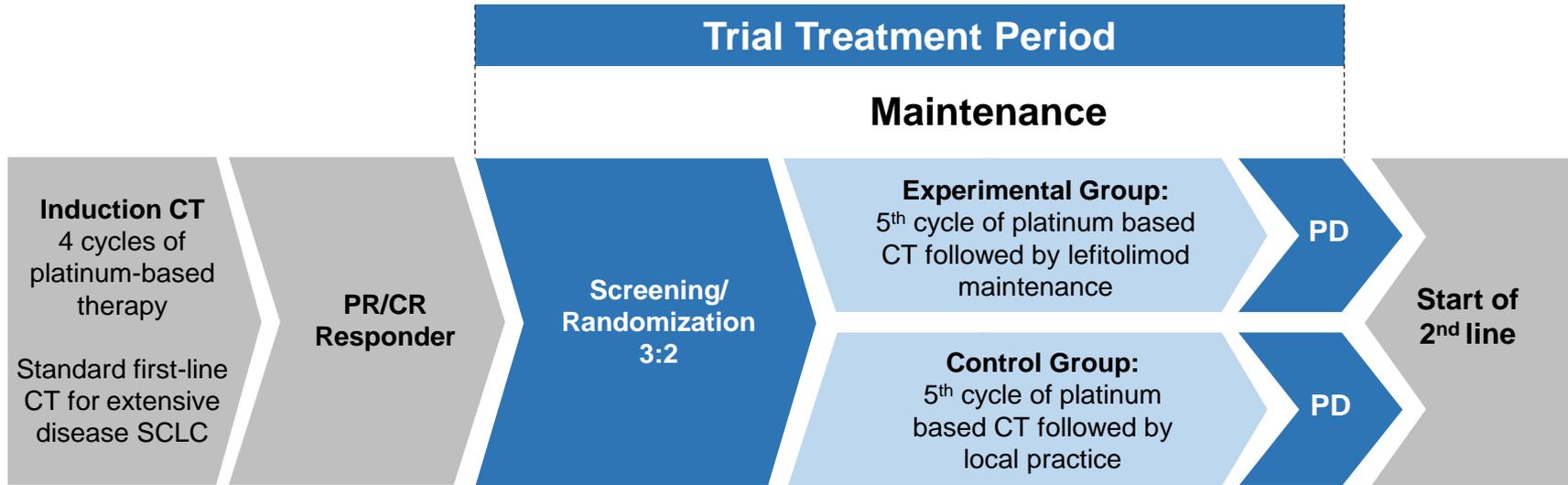
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# IMPULSE: Exploratory Phase II Randomized Study in Small Cell Lung Cancer (SCLC)



## Study design

- Controlled, two-arm, multinational trial with 102 pts in Belgium, Austria, Germany and Spain
- Biomarkers used as stratification factors: NSE level and NKT activation

## Efficacy

- Primary endpoint: overall survival (OS)
- Secondary endpoints: progression-free survival (PFS), best objective response rate (ORR), quality of life (QOL), biomarkers

## Safety



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