



IMPULSE – SCLC

Analysts' Investors' Conference Call

**KEY RESULTS
PRIMARY ANALYSIS**

BERLIN, 24 APRIL 2017

IMPULSE: Positive Results in Two Subgroups of Patients Treated with lefitolimod

IMPULSE: Exploratory phase II controlled, two-arm, multinational trial with 102 patients to evaluate efficacy and safety of lefitolimod

- Positive results in two pre-defined and clinically relevant **subgroups of patients**: Notably, a strong 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
- Additional, potentially promising subgroups will be explored
- In this highly challenging indication the primary endpoint OS was not met in the overall study population



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

Favorable Safety Profile of Lefitolimod

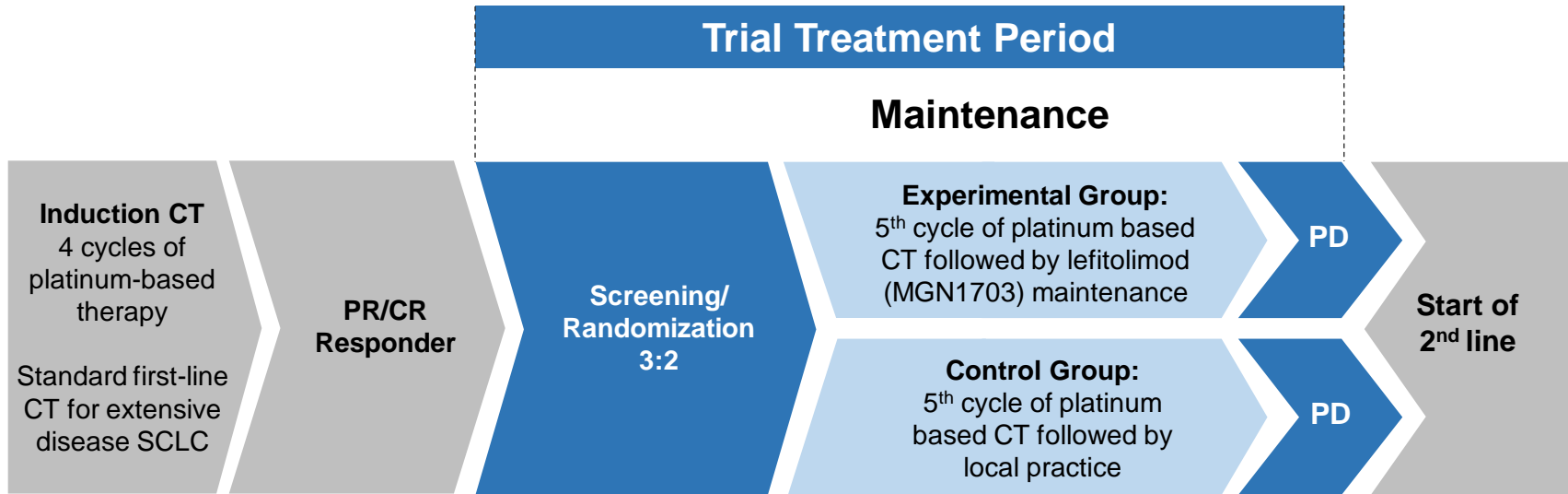
The most common adverse events (AE) in the IMPULSE population were:

Adverse events	Lefitolimod	Control Group
Cough	25.0%	7.7%
Asthenia	13.3%	17.9%
Headache	21.7%	5.1%
Nausea	11.7%	20.5%
Back pain	13.3%	12.8%

Next Steps

- Extensive evaluation of the data is ongoing
- More detailed results will be presented at international scientific congresses
- Positive study results are important asset in ongoing partnering discussions
- Final read out probably in the first quarter 2018; approximately 24 months following the recruitment of the last patient

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

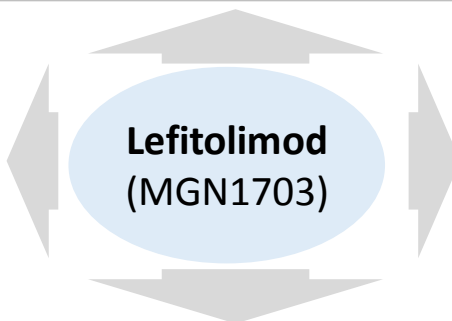
Lefitolimod: Clinical Trials

HIV: Phase I

- Two-stage single-center “TEACH” trial
 - Aarhus University Hospital (DEN)
- *Status*: started Jun-2015
 - Stage 1 successfully completed (13 patients)
 - Stage 2 first patient Jun-2016 (13 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; target 540 patients
- Patient recruitment to be finalized shortly
- *Aims*: to compare OS vs. local standard of care & to enable regulatory approval
- *Targets*⁽¹⁾: read-out 2019 (event driven), filing 2019/ 2020



SCLC: Phase II

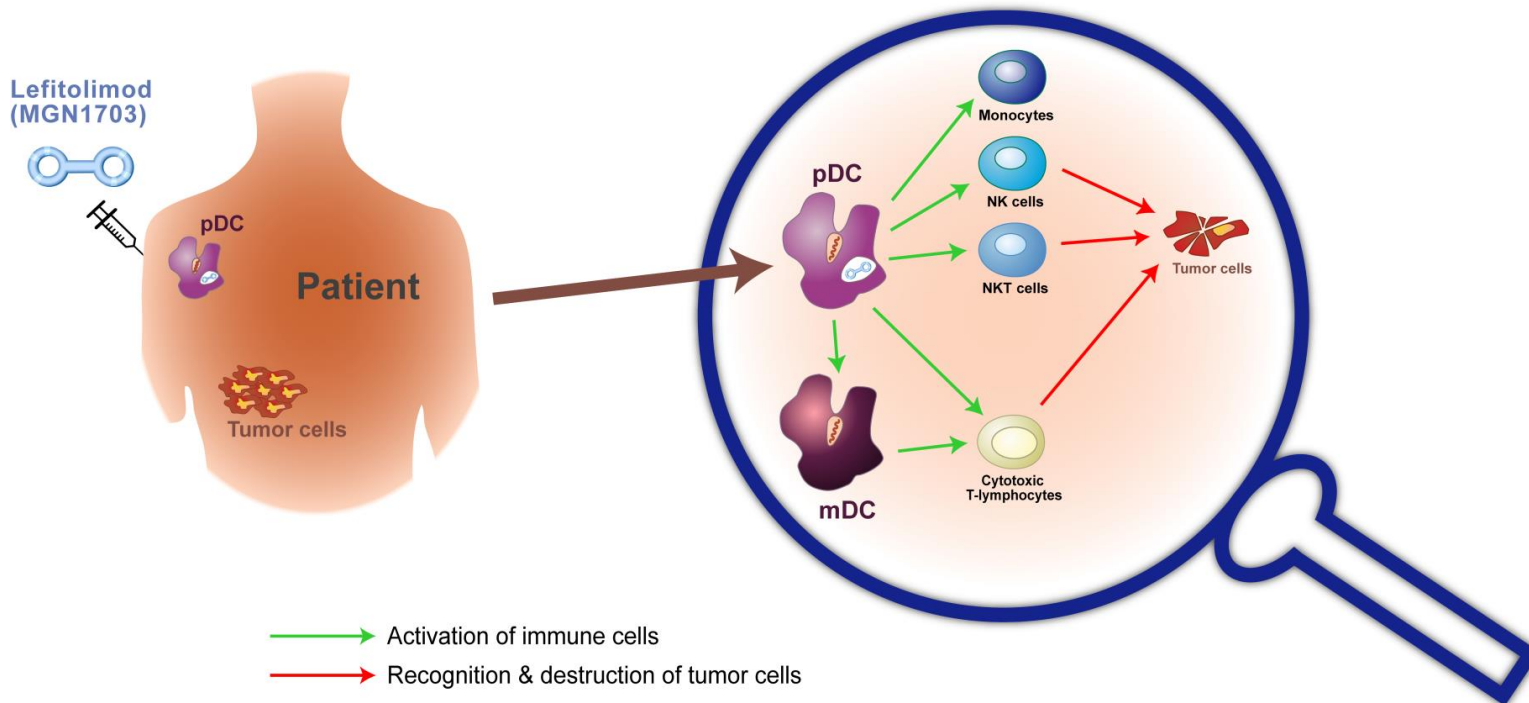
- Multicenter (41) EU (4 countries) study “IMPULSE”
- *Status*: started Mar-14 with recruitment of 102 patients completed Oct-15
- *Aims*: to compare OS vs. local standard of care, to inform development pathway in SCLC, to further support safety data base
- *Apr-17*: Positive results in two pre-defined subgroup of pts.

Solid Tumors: 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

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

IMPULSE: Main Inclusion and Exclusion Criteria

Main inclusion criteria

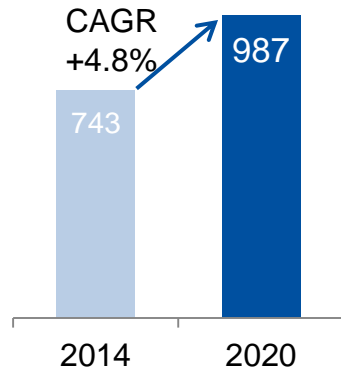
- Extensive disease SCLC confirmed by histology or cytology
- Completion of 4 cycles of first-line platinum-based chemotherapy, with
- Documented evidence of tumor response (PR or CR)
- ECOG performance status 0 or 1

Main exclusion criteria

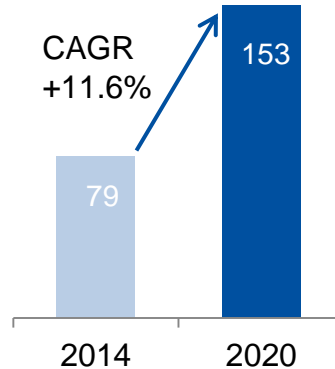
- Prior or current other malignancy within last 3 years
(except superficial bladder cancer, basal or squamous-cell carcinoma of the skin)
- History of carcinomatous meningitis
- Prior or current paraneoplastic syndrome related to SCLC
- History of autoimmune disease or immune deficiency

Multi-Billion US\$ Markets in Oncology: Strong Fundamentals and Significant Unmet Needs

WW Prescription Drugs¹



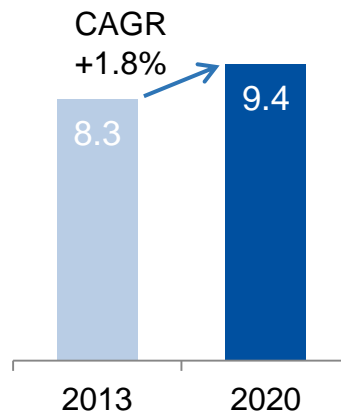
WW Oncology Drugs¹



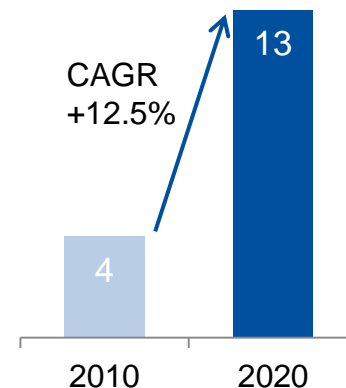
Sales in US\$ bn

- Oncology is expected to be among the largest and fastest growing therapeutic areas worldwide
- Cancer immunotherapies represent a huge market potential: ~US\$ 35 bn

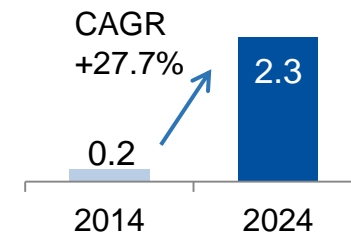
Colorectal Cancer²



Lung Cancer³



SCLC⁴





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