

# MOLOGEN AG

Germany / Pharmaceutical/Biotechnology  
 Primary Exchange: Frankfurt  
 Bloomberg: MGN GR  
 ISIN: DE000A2LQ900

IMPALA readout  
 preview

**RATING**  
**BUY**

**PRICE TARGET**  
**€ 25.20**

Return Potential 475.3%  
 Risk Rating High

## GOOD CHANCE THAT IMPALA WILL MEET ITS PRIMARY ENDPOINT

Topline results of IMPALA, the pivotal phase III study of Mologen's flagship drug candidate, lefitolimod, in therapy of mCRC chemotherapy responders, are due in August. The primary endpoint of the trial is overall survival (OS). Evaluation will be based on metrics including median OS, hazard ratio and p value. In the phase II IMPACT trial (final results published in 2013), median OS for chemotherapy responders in the experimental group was 24.5 months. The meaningfulness of the IMPACT trial was reduced by small sample size. Meanwhile, in the IMPACT trial, experimental arm patients were treated solely with lefitolimod whereas in IMPALA the experimental arm comprises a maintenance phase (treatment with lefitolimod alone) and in the event of progressive disease, a reinduction phase (treatment with lefitolimod and induction chemotherapy). The incorporation of a reinduction phase suggests that median OS will be longer in IMPALA than IMPACT. On the basis of results of trials similar to IMPALA, management expects median OS in the IMPALA control arm of 22 months. IMPACT overall survival data for chemotherapy responders were promising (again subject to the sample size caveat). The hazard ratio was 0.40 while the p value of 6.9% would presumably have reached the targeted 5% level with a larger number of patients. We continue to think there is a circa 70% probability that IMPALA will meet its primary endpoint. Our pipeline valuation model for the first time includes lefitolimod in combination with virus-neutralising antibodies for the HIV indication as well as lefitolimod in combination with Yervoy in the indication solid tumours. However, the impact of this on our valuation is outweighed by the narrowing of the scope of the Oncologie deal as well as higher dilution than we previously modelled. We lower our price target from €28.9 to €25.2 but maintain our Buy recommendation.

**IMPALA comprises 549 patients in eight European countries** Maintenance therapy of mCRC patients follows chemotherapy-based induction therapy, which usually has to be halted for several months because of toxicity (p.t.o.)

### FINANCIAL HISTORY & PROJECTIONS

	2015	2016	2017	2018	2019E	2020E
Revenue (€m)	0.04	0.07	0.05	3.05	0.10	42.50
Y-o-y growth	230.0%	89.7%	-36.5%	6383.0%	-96.7%	n.a.
EBIT (€m)	-20.54	-20.98	-18.71	-11.30	-14.97	25.08
EBIT margin	n.a.	n.a.	n.a.	-370.9%	n.a.	100.0%
Net income (€m)	-20.54	-21.00	-19.28	-11.88	-15.40	24.64
EPS (diluted) (€)	-4.95	-4.25	-2.80	-1.50	-1.30	1.81
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€m)	-15.18	-19.30	-19.11	-13.70	-13.57	25.94
Net gearing	-126.1%	-155.4%	22.5%	260.0%	12.6%	-132.7%
Liquid assets (€m)	24.59	20.52	6.52	8.02	6.79	32.72

### RISKS

Risks to our price target include but are not limited to development, partnering, financial, and regulatory risks.

### COMPANY PROFILE

MOLOGEN is a biopharmaceutical company based in Berlin specialising in the clinical development of innovative DNA-based and cell-based drugs in the fields of oncology and infectious diseases. The company's furthest developed product is lefitolimod for the treatment of metastatic colorectal carcinoma, small cell lung cancer and HIV. In addition a combination study of lefitolimod with Yervoy is being performed.

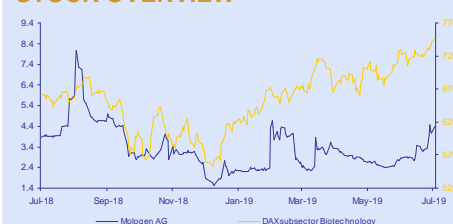
### MARKET DATA

As of 22 Jul 2019

Closing Price	€ 4.38
Shares outstanding	12.33m
Market Capitalisation	€ 53.99m
52-week Range	€ 1.54 / 8.08
Avg. Volume (12 Months)	44,026

Multiples	2018	2019E	2020E
P/E	n.a.	n.a.	2.4
EV/Sales	17.4	530.6	1.2
EV/EBIT	n.a.	n.a.	2.1
Div. Yield	0.0%	0.0%	0.0%

### STOCK OVERVIEW



### COMPANY DATA

As of 31 Mar 2019

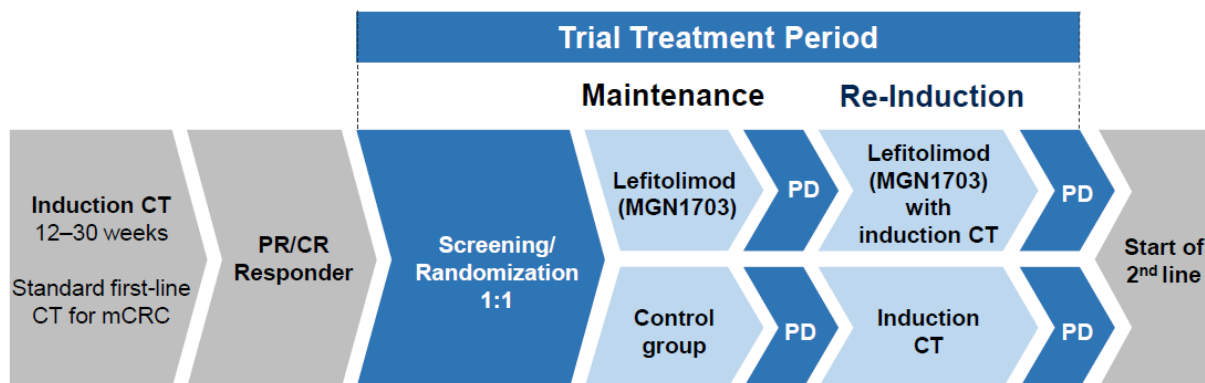
Liquid Assets	€ 6.21m
Current Assets	€ 8.01m
Intangible Assets	€ 0.01m
Total Assets	€ 8.04m
Current Liabilities	€ 5.80m
Shareholders' Equity	€ -3.28m

### SHAREHOLDERS

Global Derivative Trading GmbH	25.0%
Deutsche Balaton AG	5.0%
SIGNAL Krankenvers. a.G.	4.0%
Baloise Holding AG	4.0%
Free float	62.0%

The IMPALA study comprises 549 patients in eight European countries including the five largest European markets. The fact that all the trial sites are in Europe is not expected to have negative implications for approval in the U.S. because there is no FDA requirement for U.S. sites. The IMPALA trial is unblinded and patients were randomised 1:1 to the treatment arm and the control arm. As figure 1 below shows, patients in the experimental arm first receive lefitolimod as a single agent maintenance therapy and then reinduction with lefitolimod and chemotherapy.

**Figure 1: IMPALA study**



Source: Mologen AG

**IMPACT recruited only 59 patients vs. target of 129** The design of the IMPALA trial was informed by Mologen's IMPACT phase II trial with Lefitolimod. Mologen recruited for IMPACT between 2010 and 2012 and published preliminary results of the trial in May 2012. In the course of the double-blinded IMPACT trial, 59 patients were randomised in a 2:1 ratio to receive lefitolimod MGN1703 (n = 43) or placebo (n = 16). Recruitment was halted in May 2012 before the recruitment target of 129 patients could be reached. The primary reason for stopping the trial was slow recruitment, which could not be accelerated, despite several attempts by the sponsor. We gather from talking to Mologen's management that IMPACT recruitment was slowed due to patient concern over possible allocation to the placebo arm of the trial. The primary endpoint of IMPACT was progression-free survival (PFS), measured from the date of randomisation to progression on maintenance therapy. The main secondary endpoint was OS measured from the date of randomisation.

**IMPACT showed median OS of 22.6 months in lefitolimod patients** Investigator assessment of the primary endpoint showed a hazard ratio (HR) of 0.55 (confidence interval 0.3–1.0; p = 0.04). Median PFS was 2.8 months (95 % confidence interval 2.8–4.1) with lefitolimod and 2.6 months (95 % confidence interval 2.5–2.8) with placebo. An independent assessment of the primary endpoint showed HR of 0.56 (95 % CI 0.29–1.08; p = 0.07). On the basis of the standard significance level of 5.0%, IMPACT's primary endpoint was reached according to the investigator assessment but not according to the independent assessment. The difference in p values between the two assessments was attributable to a higher number of censored patients in the independent assessment compared with the investigator assessment and hence a higher degree of statistical uncertainty and a higher p value. PFS is defined as the time elapsed between treatment initiation and metastatic tumour progression - not local or regional progression. The independent assessment censored thirteen patients whereas the investigator assessment censored only five because eight relapses identified by the investigator assessment could not be confirmed as such by the independent investigators. OS data were immature after a median follow-up of over 17 months, with more than 50% of patients censored. Measured from randomisation, median

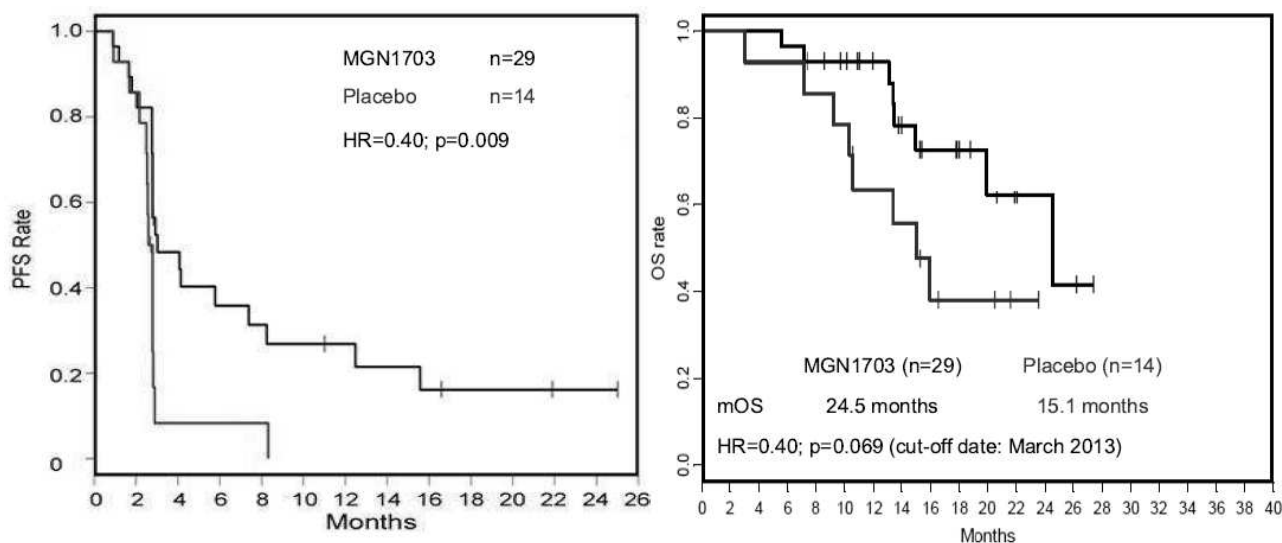
OS was 22.6 months (95% CI 14.9–not reached [NR]) with lefitolimod and 15.1 months (95% CI 10.6–NR) with placebo (HR 0.63; 95% CI 0.3– 1.5;  $p = 0.2886$ ).

The IMPACT trial showed that patients who derived the greatest benefit from treatment with lefitolimod were those who:

- achieved greater than median tumour size shrinkage during induction therapy (chemotherapy responders);
- had normalised carcinoembryonic antigen (CEA) concentration following induction therapy;
- had elevated activated natural killer (NK) T cells.

**IMPACT median OS was 24.5 months in chemotherapy responders** Mologen produced Kaplan-Meier curves for the subgroup of patients (lefitolimod  $n = 29$ ; placebo  $n = 14$ ) who responded to induction therapy. For PFS HR was 0.40 (all patients: 0.55/0.56) and  $p$  was 0.009 (all patients: 0.04/0.07). With regard to OS, the subgroup showed median overall survival of 24.5 months vs. 15.1 months (all patients: 22.6 months vs. 15.1 months). Meanwhile HR and  $p$  were 0.40 and 0.069 respectively (all patients: 0.63 and 0.2886 respectively). The  $p$  value for the subgroup was thus 190 basis points away from statistical significance.

**Figure 2: PFS/OS Kaplan-Meier curves for IMPACT chemotherapy responders subgroup**



Source: Mologen AG

IMPACT trial  $p$  values were calculated using the log rank test which produces a value for chi squared. Assuming a drug is efficacious, chi squared rises in line with the number of patients. Meanwhile chi squared is positively related to statistical significance. The median OS data for the subgroup did not reach statistical significance, but we believe that this was attributable to the smaller than planned study size rather than lefitolimod's lack of efficacy.

**Maintenance plus reinduction with chemotherapy in both IMPALA trial arms** The IMPALA trial's official title is "Evaluation of an Immunomodulatory Maintenance Treatment in Patients With Metastatic Colorectal Cancer With Tumour Reduction During Induction Treatment". Mologen has thus incorporated the conclusions of IMPACT with regard to the greater efficacy of lefitolimod with induction therapy responders into the IMPALA study design. The primary endpoint is OS instead of PFS, as OS is the standard primary endpoint in phase III cancer trials. PFS is a secondary endpoint.



Another big change is that, as figure 1 shows, both arms of the trial incorporate reinduction with chemotherapy in the event of progressive disease. In addition, maintenance in the control arm is not placebo but “usual maintenance therapy according to local investigator’s practice e.g. treatment break, reduced treatment, continued treatment and other.” In a further move to reflect the insights gained from IMPACT, IMPALA patients will also be stratified by CEA and NKT levels.

**Figure 3: Selected drugs indicated for maintenance therapy in mCRC**

Product brandname	Company	Mode of action	2018 sales (USDm)	Indications
Avastin	Roche	VEGF inhibitor	6,996	mCRC with intravenous 5-fluorouracil-based chemotherapy for first or second line treatment, non squamous non-small cell lung cancer, metastatic breast cancer, glioblastoma, metastatic renal cell carcinoma
Erbix	Eli Lilly/Merck KGaA	EGFR inhibitor	1,595	mCRC after failure of both irinotecan- and oxaliplatin-based regimens or in patients who are intolerant of irinotecan-based regimens, squamous cell carcinoma of the head and neck
Keytruda	Merck & Co.	PD-1 inhibitor	7,171	metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumours that have progressed or CRC that has progressed following prior treatment with fluoropyrimidine, oxaliplatin and irinotecan, metastatic melanoma
Opdivo	Bristol-Myers Squibb	PD-1 inhibitor	6,735	metastatic non-small cell lung cancer, Hodgkin Lymphoma, squamous cell head and neck cancer
Vectibix	Amgen	EGFR inhibitor	691	urothelial carcinoma, gastric cancer, cervical cancer
Xeloda	Roche	nucleoside metabolic inhibitor with antineoplastic activity	436	microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) mCRC
Yervoy	Bristol-Myers Squibb	CTLA4 inhibitor	1,330	metastatic melanoma, adjuvant treatment of melanoma
				metastatic non-small cell lung cancer, renal cell carcinoma
				Hodgkin Lymphoma, squamous cell head and neck cancer
				urothelial carcinoma, hepatocellular carcinoma
				mCRC with disease progression on or following fluoropyrimidine oxaliplatin, and irinotecan chemotherapy regimes
				mCRC first line as monotherapy when treatment with fluoropyrimidine is preferred, patients with Dukes' C colon cancer, metastatic breast cancer
				in combination with Opdivo for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) mCRC, metastatic melanoma, cutaneous melanoma with pathologic involvement of regional lymph nodes

Source: companies

### We believe mCRC maintenance therapy market is worth several billion USD annually

Figure 3 shows selected drugs currently indicated for the maintenance setting in mCRC. Several of these drugs are used in indications other than mCRC maintenance. The pharmaceutical companies do not break down individual product sales by indication, but we believe the mCRC maintenance market is worth several billion USD annually. The most valuable drug in the space is Avastin. mCRC is the first indication for which Avastin received FDA approval in 2004.

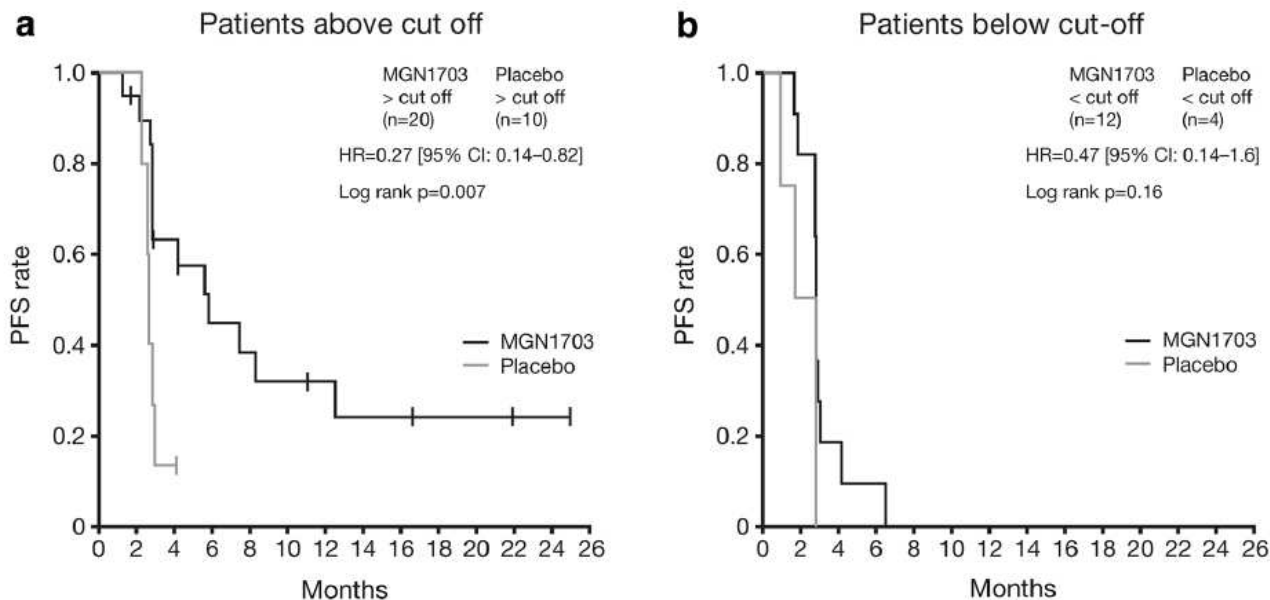
### Checkpoint inhibitors currently cover only 5% of mCRC maintenance market

CRC is very heterogenous at the genomic level. Several genomic biomarkers such as microsatellite instability (MSI) and KRAS mutational status are used to guide therapy. Microsatellites are repeated sequences of DNA. MSI results from the inability of mismatch repair proteins to correct a DNA replication error. MSI is associated with several cancers besides CRC. In CRC MSI incidence varies by disease stage. Incidence in stages I and II is 20% but in mCRC only 4-5%. The FDA approved Keytruda for maintenance therapy of MSI mCRC tumours in May 2017 and granted accelerated approval to Opdivo in the same indication two months later. In 2018, the FDA granted accelerated approval to Yervoy for use in combination with Opdivo in MSI mCRC tumours. KRAS is a gene which controls cell proliferation. In its mutated state, cells can proliferate and often develop into cancer. Mutated KRAS genes are found in 30-40% of CRC tumours and are associated with poor response to anti-EGFR (epidermal growth factor receptor) therapies such as Erbix and Vectibix.



**Mologen may analyse IMPALA patient data for KRAS mutation status** Mologen's management tell us that they have no evidence that KRAS status interferes with lefitolimod's mode of action. They will also use available information on patients' KRAS mutation status for analysis of this group in so far as the size of the relevant data set allows for meaningful evaluation.

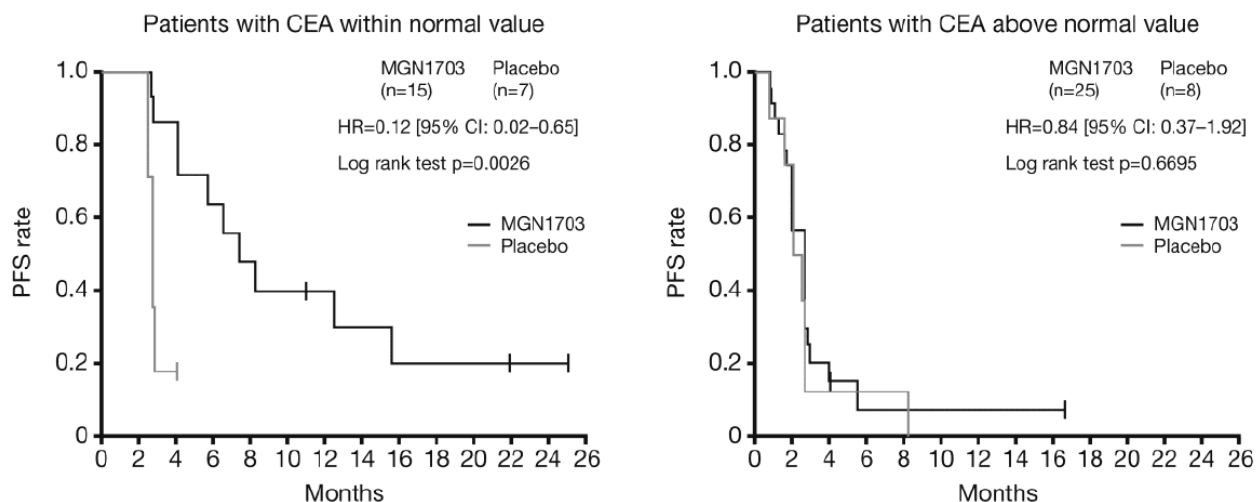
**Figure 4: IMPACT patients above and below 3.08% NKT cell cut-off**



Source: Mologen AG

IMPALA patients will also be stratified by NKT and CEA levels. As figure 4 shows, the IMPACT trial produced NKT cell count data for 46 of 59 participants. Blood samples from the remaining 13 patients were found to be of insufficient quality to perform this analysis. Of these 46 patients, 30 (nearly two thirds) had NKT cell count  $\geq$  3.08% while the remainder had NKT cell count  $\leq$  3.08%. PFS data from the patients with NKT cell count  $\geq$  3.08% were better than the data for both the chemotherapy responders subgroup and the overall trial population ( $p=0.007$  vs 0.009 and 0.04 respectively).

**Figure 5: IMPACT patients with normal and above normal CEA values**



Source: Mologen AG



The IMPACT trial also generated CEA values for 55 of its 59 participants. CEA levels were determined locally at the trial centres and data for four of the 59 patients could not be verified and so was not included in the analysis of the trial's results. 22 of the 55 patients (40%) had CEA at normal levels while the remainder had CEA above normal levels. PFS data from the patients with CEA at normal levels were again better than the data for both the chemotherapy responders subgroup and the overall trial population ( $p=0.0026$  vs  $0.009$  and  $0.04$  respectively).

The NKT and CEA data are for PFS (the primary end point of IMPACT) rather than OS (the primary end point of IMPALA) and Mologen also did not carry out any analysis as to the extent of the overlap between NKT cell count  $\geq 3.08\%$ , CEA normal level patients and chemotherapy responders in the IMPACT trial. However, in our view, the numbers suggest that lefitolimod should also be able to generate clinically and statistically significant median OS improvement in these subgroups.

#### **Mologen/Oncologie designing combi trials of lefitolimod with check point inhibitors**

In August 2018 Mologen and Oncologie announced a global assignment and co-development agreement for lefitolimod. However, subsequent negotiations failed, and in November 2018 the scope of the agreement between Mologen and Oncologie reverted to the deal previously announced between the two companies in February 2018. This entails a licensing agreement for Greater China as well as a global co-development agreement. Mologen and Oncologie are currently designing combination trials of lefitolimod with check point inhibitors. The conclusion in June of a USD80m Series B financing is contributing to the financing of these efforts from the Oncologie side.

#### **Plans for lefitolimod in ES-SCLC include biomarker evaluation, combination studies**

The IMPULSE phase II trial of lefitolimod in 103 patients with extensive-stage small cell lung cancer (ES-SCLC) did not meet its primary endpoint of overall survival. This is not surprising as ES-SCLC is a very challenging indication. However, the study did demonstrate an overall survival benefit in comparison to the control arm in two important subgroups – patients with a low count of activated B cells (hazard ratio 0.53, 95% confidence interval 0.26-1.08) and patients with reported Chronic Obstructive Pulmonary Disease (hazard ratio 0.48, 95% confidence interval 0.20-1.17). The former group comprised 38 (43%) of a total of 88 patients for whom B cell data was available. The latter group numbered 25 of the 103 participants in the study. The B cell-related data is particularly interesting as it has positive implications for lefitolimod's efficacy against cancers other than SCLC. The sizes of the subgroups in the IMPULSE study are reflective of the overall patient population. Subject to the availability of financing, Mologen's future plans for lefitolimod in the ES-SCLC indication entail the conduct of preclinical studies in order to further evaluate B-cell biomarkers, combination studies with different immuno-oncological approaches and inclusion of a comprehensive panel of biomarkers.

#### **Lefitolimod could be combi partner in HIV for vaccines/monoclonal antibodies**

In August 2017 Mologen published results of the extension phase of the TEACH study of lefitolimod with HIV patients on ART (antiretroviral therapy). The study enrolled 12 patients and was carried out in cooperation with Aarhus University Hospital in Denmark. One of the primary endpoints of the study was quantification of the size of the HIV reservoir. Lefitolimod combined with ART did not show any detectable impact on the size of the viral reservoir. However, the intervention did demonstrate sustained increases in activation of important immune cells (CD4 and CD8 cells) and also triggered maturation of other important immune cells (B cells) towards antibody producing cells. Lefitolimod was also safe and well tolerated in HIV patients on ART. Although the trial did not demonstrate the desired effect on the viral reservoir, the results do suggest that lefitolimod could be an important partner in combination with other HIV therapies such as monoclonal antibodies or vaccines.



### Gilead-financed combi trial of lefitolimod with HIV patients to start later this summer

In January 2017, Aarhus University received a grant of USD2.75m from Gilead Sciences to fund the phase IIa TITAN trial of lefitolimod in combination with innovative virus-neutralising antibodies in HIV positive patients using ART. The virus-neutralising antibodies have been developed by Rockefeller University, New York, US. The trial, to be known as TITAN, is scheduled to start later this summer.

**Extension of phase I combination trial with Yervoy planned** Mologen presented results of the first part of an ongoing phase I trial of lefitolimod with the immune checkpoint inhibitor Yervoy in patients with advanced solid tumours at the SITC (The Society for the Immunotherapy of Cancer) in Washington D.C. in November 2018. The first part of the study, which is being undertaken in cooperation with the MD Anderson Cancer Center at the University of Texas, ascertained the tolerable dosage of lefitolimod in combination with Yervoy. It also established lefitolimod's safety in combination with Yervoy. In addition, the results showed an increase in cytotoxic T cells in tumour biopsies thus suggesting that the beneficial lefitolimod-mediated modulation of the tumour microenvironment already established in a murine model also applies to humans. A planned extension of the phase I trial will collect further data on the efficacy of lefitolimod in combination with Yervoy.

**Figure 6: Changes to our forecasts**

in €m	2019E			2020E		
	Old	New	Delta	Old	New	Delta
Revenue*	7.00	0.10	-98.6%	42.50	42.50	-99.8%
EBIT	-12.87	-14.97	-	25.65	25.08	-2.2%
margin	neg.	neg.	-	neg.	neg.	-
Net income	-13.53	-15.40	-	24.99	24.64	-1.4%
margin	neg.	neg.	-	58.8%	58.0%	-
EPS (in €)	-1.14	-1.30	-	2.09	1.81	-13.3%

\* including other operating income and upfront/milestone payment(s)

Source: First Berlin Equity Research estimates

### We reduce our price target from €28.9 to €25.2 but maintain Buy recommendation

Figure 6 above shows changes to our forecasts. The €7m in revenue in our old 2019 revenue forecast related to expected funding for the IMPALA trial following a global assignment and co-development agreement for lefitolimod concluded between Mologen and Oncologie in August 2018. However, as mentioned above, subsequent negotiations failed, and in November 2018 the scope of the agreement between Mologen and Oncologie reverted to the license deal for Greater China and global co-development agreement previously announced in February 2018. We continue to assume the conclusion of a partnership and a milestone payment of €42.5m in 2020 following the readout from the IMPALA trial. Mologen's cash position at the end of Q1/19 was €6.5m. In April a rights issue raised gross proceeds of €4.2m. Cashburn is currently running at €1.3m a month which suggests that Mologen will require further financing this autumn. We have assumed a €5m equity issue. Our pipeline valuation model for the first time includes lefitolimod in combination with virus-neutralising antibodies for the HIV indication (phase IIa TITAN trial due to start later this summer) as well as lefitolimod in combination with Yervoy in the indication solid tumours (phase I extension trial about to start). However, the impact of this on our valuation is outweighed by the narrowing of the scope of the Oncologie deal as well as the additional dilution caused by a smaller than expected capital raise last October and the alteration of convertible bond terms. We have lowered our price target from €28.9 to €25.2 but maintain our Buy recommendation.



Figure 7: Changes to our pipeline valuation model

	Old	New	Delta
<b>PACME PV</b>	<b>€336.4M</b>	<b>€691.8M</b>	<b>105.6%</b>
<b>Costs PV (4)</b>	<b>€209.5M</b>	<b>€366.6M</b>	<b>75.0%</b>
<b>NPV</b>	<b>€126.9M</b>	<b>€325.2M</b>	<b>156.3%</b>
<b>Milestones PV</b>	<b>€183.6M</b>	<b>€38.0M</b>	<b>-79.3%</b>
<b>Proforma net cash</b>	<b>€25.1M</b>	<b>€15.9M</b>	<b>-36.6%</b>
<b>Fair Value</b>	<b>€335.6M</b>	<b>€379.1M</b>	<b>13.0%</b>
<b>Share Count</b>	<b>11,595K</b>	<b>15,048K</b>	<b>29.8%</b>
<b>Price Target</b>	<b>€28.94</b>	<b>€25.19</b>	<b>-13.0%</b>

Source: First Berlin Equity Research estimates; Mologen AG

Figure 8: Pipeline valuation

Compound	Project <sup>1)</sup>	Present Value	Patient Pop	Treatment Cost	Market Size	Market Share	Peak Sales	PACME Margin <sup>2)</sup>	Discount Factor	Patent Life <sup>3)</sup>	Time to Market
Lefitolimod	mCRC-EU	€181M	188K	€35,000	€6,580M	10%	€851M	12%	15.0%	10	3 Years
Lefitolimod	mCRC-US	€168M	119K	€58,333	€6,942M	10%	€863M	12%	15.0%	10	3 Years
Lefitolimod	mCRC-PRC	€15M	419K	€11,550	€4,839M	10%	€751M	2%	20.0%	10	3 Years
Lefitolimod	SCLC-EU	€24M	30K	€25,000	€750M	50%	€466M	12%	150%	6	6 Years
Lefitolimod	SCLC-US	€17M	19K	€41,667	€792M	50%	€402M	12%	150%	4	6 Years
Lefitolimod	SCLC-PRC	€3M	71K	€8,250	€586M	50%	€402M	2%	20.0%	10	6 Years
Lefitolimod	mab HIV combi EU	€61M	800K	€10,000	€8,000M	10%	€1,143M	12%	15.0%	9	8 Years
Lefitolimod	mab HIV combi US	€110M	1,100K	€13,000	€14,300M	10%	€2,042M	12%	15.0%	9	8 Years
Lefitolimod	mab HIV combi PRC	€2M	700K	€3,300	€2,310M	10%	€330M	2%	20.0%	9	8 Years
Lefitolimod	Yervoy combi EU	€60M	1,693K	€24,000	€40,636M	2%	€1,138M	12%	15.0%	9	8 Years
Lefitolimod	Yervoy combi US	€49M	1,069K	€31,200	€33,368M	2%	€934M	12%	15.0%	9	8 Years
Lefitolimod	Yervoy combi PRC	€1M	1,141K	€7,920	€9,038M	2%	€253M	2%	20.0%	9	8 Years
<b>PACME PV</b>		<b>€692M</b>			<b>€128,140M</b>		<b>€9,576M</b>				
<b>Costs PV<sup>4)</sup></b>		<b>€367M</b>									
<b>NPV</b>		<b>€325M</b>									
<b>Milestones PV</b>		<b>€38M</b>									
<b>Proforma net cash</b>		<b>€16M</b>									
<b>Fair Value</b>		<b>€379M</b>									
<b>Proforma share count</b>		<b>15,048K</b>									
<b>Price Target</b>		<b>€25.19</b>									

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues. This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining patent life after the point of approval

4) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research estimates





## INCOME STATEMENT

All figures in EUR '000	2015	2016	2017	2018	2019E	2020E
<b>Net product revenues</b>	39	74	47	47	100	0
<b>Milestone &amp; upfront payments</b>	0	0	0	3,000	0	42,500
<b>Total revenue</b>	39	74	47	3,047	100	42,500
<b>Cost of materials</b>	11,681	11,780	9,752	6,529	6,000	7,500
<b>Gross profit</b>	-11,642	-11,706	-9,705	-6,482	-5,900	-7,500
<b>PACME (incl. milestone &amp; upfront payments)</b>	-11,642	-11,706	-9,705	-3,482	-5,900	35,000
Depreciation	121	408	49	38	45	49
Personnel costs	5,074	5,453	5,093	5,053	5,600	5,600
Other operating income (expense)	-3,702	-3,418	-3,860	-2,727	-3,425	-4,275
<b>Operating income (EBIT)</b>	-20,539	-20,985	-18,707	-11,300	-14,970	25,076
Net financial result	3	-18	-574	-583	-435	-434
<b>Pre-tax income (EBT)</b>	-20,536	-21,003	-19,281	-11,883	-15,404	24,642
<b>Net income / loss</b>	-20,536	-21,003	-19,281	-11,883	-15,404	24,642
<b>Basic EPS (in EUR)</b>	-4.95	-4.25	-2.80	-1.50	-1.30	1.81
<b>EBITDA</b>	-20,418	-20,577	-18,658	-11,262	-14,925	25,125
<b>Ratios</b>						
EBIT margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	71.6%
EBITDA margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	71.8%
Net margin on PACME	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
<b>Expenses as % of PACME</b>						
Personnel costs	n.m.	n.m.	n.m.	n.m.	n.m.	16.0%
<b>Y-Y Growth</b>						
Total revenues	225.0%	89.7%	-36.5%	6383.0%	-96.7%	42400.0%
Operating income	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Net income/ loss	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.



## BALANCE SHEET

All figures in EUR '000	2015	2016	2017	2018	2019E	2020E
<b>Assets</b>						
<b>Current assets, total</b>	<b>25,981</b>	<b>21,300</b>	<b>8,061</b>	<b>9,339</b>	<b>7,526</b>	<b>33,661</b>
Cash and cash equivalents	24,592	20,520	6,523	8,021	6,785	32,723
Short-term Investments	0	0	0	0	0	0
Receivables	0	33	13	0	10	10
Inventories	28	13	16	701	30	128
Other current assets	1,361	734	1,509	617	701	801
<b>Non-current assets, total</b>	<b>414</b>	<b>62</b>	<b>44</b>	<b>18</b>	<b>25</b>	<b>31</b>
Property, plant & equipment	239	25	27	16	22	28
Goodwill & other intangibles	175	37	17	2	3	4
Other assets	0	0	0	0	0	0
<b>Total assets</b>	<b>26,395</b>	<b>21,362</b>	<b>8,105</b>	<b>9,357</b>	<b>7,551</b>	<b>33,692</b>
<b>Shareholders' equity &amp; debt</b>						
<b>Current liabilities, total</b>	<b>6,886</b>	<b>7,404</b>	<b>7,502</b>	<b>4,749</b>	<b>6,000</b>	<b>7,500</b>
Short-term debt	8	3	9	11	0	0
Accounts payable	6,390	6,530	4,400	2,640	4,000	5,500
Other current liabilities	488	871	3,093	2,098	2,000	2,000
<b>Long-term liabilities, total</b>	<b>6</b>	<b>2,121</b>	<b>5,474</b>	<b>5,553</b>	<b>6,200</b>	<b>6,200</b>
Convertible bond	0	2,119	5,419	5,553	6,200	6,200
Long term debt	0	0	0	0	0	0
Deferred revenue	6	2	55	0	0	0
<b>Shareholders' equity</b>	<b>19,503</b>	<b>11,837</b>	<b>-4,871</b>	<b>-945</b>	<b>-4,649</b>	<b>19,992</b>
<b>Total consolidated equity and debt</b>	<b>26,395</b>	<b>21,362</b>	<b>8,105</b>	<b>9,357</b>	<b>7,551</b>	<b>33,692</b>
<b>Ratios</b>						
Current ratio (x)	3.77	2.88	1.07	1.97	1.25	4.49
Quick ratio (x)	3.77	2.88	1.07	1.82	1.25	4.47
Net gearing	-126.1%	-155.4%	n.a.	260.0%	12.6%	-132.7%
Book value per share (€)	4.36	1.74	-0.71	-0.10	-0.34	1.47
Net cash	24,584	18,398	1,095	2,457	585	26,523
Return on equity (ROE)	n.m.	n.m.	n.m.	n.m.	n.m.	321.2%



## CASH FLOW STATEMENT

All figures in EUR '000	2015	2016	2017	2018	2019E	2020E
<b>EBIT</b>	<b>-20,539</b>	<b>-20,985</b>	<b>-18,707</b>	<b>-11,300</b>	<b>-14,970</b>	<b>25,076</b>
Depreciation and amortization	121	408	49	38	45	49
<b>EBITDA</b>	<b>-20,418</b>	<b>-20,577</b>	<b>-18,658</b>	<b>-11,262</b>	<b>-14,925</b>	<b>25,125</b>
Changes in working capital	4,786	1,127	-705	-2,597	1,839	1,303
Other adjustments	546	198	251	173	-435	-434
<b>Operating cash flow</b>	<b>-15,086</b>	<b>-19,252</b>	<b>-19,112</b>	<b>-13,686</b>	<b>-13,521</b>	<b>25,994</b>
CAPEX	-95	-44	6	-9	-51	-56
<b>Free cash flow</b>	<b>-15,181</b>	<b>-19,296</b>	<b>-19,106</b>	<b>-13,695</b>	<b>-13,572</b>	<b>25,937</b>
<b>Debt financing, net</b>	<b>-2</b>	<b>-5</b>	<b>0</b>	<b>0</b>	<b>-11</b>	<b>0</b>
<b>Equity financing, net</b>	<b>26,207</b>	<b>12,706</b>	<b>477</b>	<b>12,787</b>	<b>9,000</b>	<b>0</b>
<b>Convertible bond</b>	<b>0</b>	<b>2,535</b>	<b>4,976</b>	<b>2,854</b>	<b>0</b>	<b>0</b>
Changes in other financial assets	0	-18	0	0	0	0
Other Changes in Cash	5	6	-344	-448	3,347	0
<b>Net cash flows</b>	<b>11,029</b>	<b>-4,072</b>	<b>-13,997</b>	<b>1,498</b>	<b>-1,236</b>	<b>25,937</b>
Cash, start of the year	13,563	24,592	20,520	6,523	8,021	6,785
<b>Cash, end of the year</b>	<b>24,592</b>	<b>20,520</b>	<b>6,523</b>	<b>8,021</b>	<b>6,785</b>	<b>32,723</b>
<b>EBITDA/share</b>	<b>-4.90</b>	<b>-4.16</b>	<b>-2.73</b>	<b>-1.42</b>	<b>-1.26</b>	<b>1.85</b>
<b>Y-Y Growth</b>						
Operating cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
Free cash flow	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.
EBITDA/share	n.m.	n.m.	n.m.	n.m.	n.m.	n.m.

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Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	9 January 2013	€12.14	Buy	€26.70
2...20	↓	↓	↓	↓
21	22 November 2017	€13.10	Buy	€65.50
22	5 June 2018	€4.60	Buy	€28.50
23	11 September 2018	€4.78	Buy	€28.90
24	Today	€4.38	Buy	€25.20

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Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy <sup>1</sup>	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

<sup>1</sup> The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

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