EDISON

Mologen

Interims, valuation update

Lefitolimod trial readouts hint at future potential

Pharma & biotech

In the last six months, mixed readouts in the Phase II SCLC trial (IMPULSE) and the Phase Ib/IIa HIV trial (TEACH) weighed on the stock. Full data packages presented in the next 12 months may yet highlight potential in these indications. Our valuation is adjusted to take into account both the current trial data and visibility of the long-term strategy in certain geographical regions. While long-term potential lies in the lefitolimod Phase III mCRC trial (IMPALA, readout expected in 2019), Mologen has additionally signed a binding term sheet with Chinese iPharma, which could provide €100m+ in revenues over several years and boost the cash position. We value Mologen at €253m.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (x)	Yield (%)
12/15	0.0	(20.5)	(0.99)	0.0	N/A	N/A
12/16	0.0	(20.8)	(0.84)	0.0	N/A	N/A
12/17e	0.0	(21.4)	(0.62)	0.0	N/A	N/A
12/18e	0.0	(15.9)	(0.46)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Top-line TEACH and IMPULSE data read out

Top-line data from TEACH, an exploratory, non-randomised Phase Ib/IIa trial testing lefitolimod in HIV-positive patients, failed the primary endpoint of reduction in viral reservoir in 12 patients receiving both antiretroviral therapy and lefitolimod. However, an increased duration of viral control above what is typically expected was observed in one patient out of nine after stopping ART (further analysis ongoing). Full data will likely be presented next March at the Conference on Retroviruses and Opportunistic Infections (CROI). Data were presented at ESMO from the exploratory Phase II IMPULSE trial in small cell lung cancer (SCLC), which demonstrated that it did not meet the primary endpoint of overall survival. However, it showed potential, non-statistically significant advantage in two subgroups. SCLC is a difficult disease to treat and any benefit hints at potential for lefitolimod.

iPharma collaboration and H117 results

Signed deal terms with iPharma look to aid the development, manufacturing and commercialisation of lefitolimod, particularly in China. Mologen would be eligible to receive a €3m upfront payment, milestone payments of up to €100m, as well as low double-digit royalties and a €2m equity investment (within 12 months following execution of the final licensing agreement). Net cash of €7.6m (gross cash €14.2m) was reported as of 30 June. Monthly cash burn for H117 was €1.9m and current cash reach is expected into Q118.

Valuation: Increased to €253m (€7.36/share)

We now value Mologen at €253m (€7.36/share) vs €252m (€7.33/share) previously. Alterations to our model and valuation predominately relate to the development strategy in certain geographical regions, the removal of MG1601 from our valuation and the addition of the iPharma deal. We note that an improved liquidity situation and better visibility on future developments would have a positive effect on our valuation.

25 September 2017

Price	**€3.00**
Market cap	**€103m**
Net cash (€m) at 30 June 2017	7.6
Shares in issue	34.3m
Free float	62%
Code	MGN
Primary exchange	Frankfurt (Prime Standard)
Secondary exchange	N/A

Share price performance

%	1m	3m	12m
Abs	45.6	(23.1)	115.7
Rel (local)	41.4	(21.9)	82.8
52-week high/low		€4.56	€1.17

Business description

Mologen is a German biopharmaceutical company developing novel biopharmaceuticals. Lead product lefitolimod (TLR9 agonist) is being evaluated in metastatic colorectal cancer maintenance, small cell lung cancer maintenance, HIV and a combination trial in advanced solid malignancies.

Next events

Q3 results	9 November 2017
TEACH full data presented	March 2018
IMPALA data	Mid-2019

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Edison profile page

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Investment summary

Company description: Lefitolimod the focus

Mologen is predominantly focused on commercialising its lead candidate, lefitolimod, which is currently in three ongoing trials: a Phase III study (IMPALA) for the maintenance treatment of metastatic colorectal cancer, ongoing maximum 24-month follow-up for the Phase II IMPULSE trial and a Phase I combination study in advanced malignancies. Top-line data from the exploratory Phase II trial (IMPULSE) for small cell lung cancer (SCLC) and the exploratory Phase Ib/IIa trial (TEACH) in HIV recently read out. Both trials missed the primary endpoints, but encouraging data in certain subsets were observed. Development of MGN1601, a therapeutic cancer cell vaccine, which completed a Phase I/II study (ASET) for kidney cancer, has been put on hold and the company is looking to divest/spin off the MIDGE technology platform. The company is based in Berlin and currently has c 50 employees.

Valuation: rNPV of €253m or €7.36/share

Our valuation of Mologen has increased slightly to €253m (€7.36/share) vs €252m (€7.33/share) previously. Due to the current uncertainty with regard to the clinical development of MGN1601 and near-term liquidity concerns, we have removed it from our valuation; however, fresh funding and reactivation of the programme could prompt us to reverse this decision. We have altered the regions in which we believe lefitolimod will launch as a result of having no visibility on the current strategy or funding in Japan. We have now included the iPharma deal in our valuation; we have assumed that mCRC is the first indication pursued, with a standard development cycle. However, to reflect uncertainties in the Chinese market and as the deal has yet to be completed, we use a probability of success of 5%. We now value only lefitolimod in the CRC and SCLC indications in the EU, US and China markets.

Sensitivities: Funding needed, out-licensing deal

The key sensitivities relate to the clinical performance of lefitolimod and Mologen's ability to secure the additional financing and/or a partner (in the EU/US) to complete the full clinical programme. Mixed recent results from the exploratory IMPULSE and HIV trials mean additional funding may not come or will do so at less favourable terms. In the long term, IMPALA data will have a major bearing on lefitolimod's chance of regulatory approvals and commercial success. We have made assumptions about the potential market opportunity available to lefitolimod, which do not currently include significant stratification of patient populations. Lefitolimod may be most active in certain subgroups, which could reduce the target patient pool. However, confirmed activity in a patient subset may result in a higher treatment price, greater reimbursement rates and more favourable economic terms from any partnership. It should also be noted that success or failure of lefitolimod in one indication may not translate across to other indications.

Financials: Cash reach to Q118

Gross cash at 30 June 2017 of €14.2m, combined with an average cash burn of €1.9m per month in H117, will see Mologen into Q118. Mologen has raised gross proceeds of €21.1m in the last 12 months through an equity increase and the issue of two capital bonds to fund it through key inflection points including the IMPULSE and HIV data readouts. The capital increase in October 2016 issued 11.3m new shares, raising €13.6m gross (€12.7m net). Subsequently, two convertible bonds have been placed: one in November 2016 (€2.54m) and another in January 2017 (€4.99m). Each has an eight-year maturity date and a 6% coupon, paid quarterly. Our model assumes an illustrative €30m will be raised in debt in 2018 to fund the company, although we would expect funding to be raised before Q118 to ensure the financial stability of the company.

Lefitolimod: A broad immune stimulator

Lefitolimod is an immune surveillance reactivator (TLR9 agonist), which broadly activates the immune system and is believed to enable it to increase the recognition and combat of abnormal cells. It is being developed as both a maintenance treatment for use after effective induction chemotherapy in cancer patients and as a treatment for HIV.

The first line of defence against infection is the innate immune system, which comprises a set of receptors that recognise foreign DNA, reacting instantly to produce cytokines and other inflammatory mediators and to stimulate, among others, natural killer (NK) and NK T-cells. The innate immune system ultimately links through to the adaptive immune system, which is highly specific to a target antigen and creates immunological memory after the initial response. The majority of immunotherapies (approved and in development) target the adaptive immune system. In primarily targeting the innate system and, to a lesser extent, the adaptive, Mologen's approach could complement these, and combination therapy approaches could prove synergistic.

iPharma collaboration highlights potential in Asia

Mologen has announced that it has signed a binding term sheet with iPharma, a Chinese drug development company. The term sheet defines the framework of the final agreement (yet to be signed, expected by year end), which will consist of two key components. The first is an exclusive licence in China (including Hong Kong and Macao), Taiwan and Singapore to develop, manufacture and commercialise lefitolimod (full costs covered by iPharma). Mologen would be eligible to receive a €3m upfront payment, milestone payments of up to €100m, as well as low double-digit royalties and a €2m equity investment (within 12 months following execution of the final licensing agreement). Asia remains a major untapped market for many western companies; according to data from the World health Organisation, there were 607,000 cases of colorectal cancer (lefitolimod's lead indication) in Asia in 2012, 253,000 of which were in China

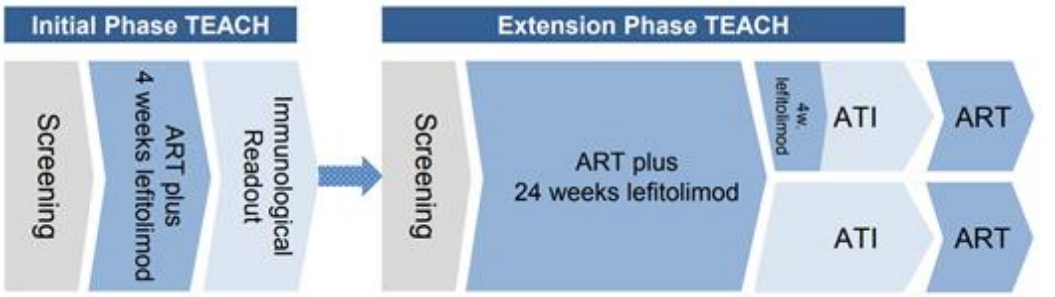
The second component will be a co-development agreement in one or more mutually agreed indications in oncology. Further information on what this agreement would involve has not yet been clarified. The overall collaboration has the potential to provide Mologen with both an ongoing revenue stream (from a significant non-EU/US market) and a development partner for new indications.

TEACH data: More questions arise

Mologen recently announced that its exploratory Phase Ib/IIa trial, TEACH, missed the primary endpoint of reducing viral load in the second part of the trial, whereas in the first part of the trial, the primary endpoint of increasing the proportion of activated natural killer cells was met. The trial was designed to test whether lefitolimod could stimulate the immune system in HIV patients and reduce their viral load.

The study was split into two parts (Exhibit 1). In the first part of the study lefitolimod was given twice weekly (60mg) to 15 patients over a four-week period. The primary endpoint was to measure changes in the proportion of activated NK cells, with other secondary endpoints looking at changes in virological and immunological data among others. The primary endpoint was met and lefitolimod was demonstrated to aid in broadly activating the immune system. On the back of these data an extension phase was undertaken.

Exhibit 1: Teach trial design



Source: Mologen

12 patients received lefitolimod in combination with antiretroviral therapy (ART) for 24 weeks. Nine consenting patients were then split into two groups, where one group received an extra four weeks of lefitolimod alone. After treatment in both groups, patients underwent antiretroviral treatment interruption until their viral load rebounded. This procedure is utilised to determine the size and any reduction that has occurred in the reservoir of latent infected cells.

Lefitolimod and ART did not achieve its primary endpoint of reducing viral load. However, other beneficial findings were observed including:

- sustained activation of CD4 and CD8 cells throughout the dosing period;
- maturation of B-cells towards antibody-secreting effector cells;
- viral control in one out of nine patients after interruption of ART for 20 weeks; and
- safe and well tolerated in patients for 24 weeks, corroborating what has been observed in cancer patients.

The company expects to present full data at a conference in H118 and a further study is planned to start next year. At the beginning of this year, Aarhus University Hospital announced that it had received a $2.75m grant from Gilead. The grant is to fund a clinical trial with lefitolimod in combination with novel virus-neutralising antibodies developed by the Rockefeller University. The two unique modes of action are hoped to act in a “kick-and-kill” manner, where the latent virus is woken up (“kick”) in the infected cells before being subsequently “killed” by the activated immune system; lefitolimod is believed to aid in both the “kick” and “kill” stages.

IMPALA: Opportunities in metastatic colorectal cancer remain

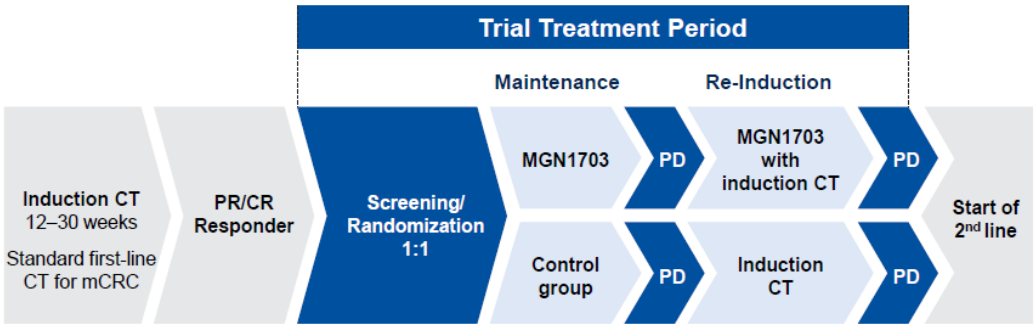
Lefitolimod is being tested in a Phase III trial as a maintenance treatment in metastatic colorectal cancer patients. If successful, it could become a practice-changing additional treatment that is used alongside current mainstream treatments. Colorectal cancer is both the third most common cancer diagnosed and the third leading cause of cancer-related deaths in both men and women in the US (source: cancer.org). The American Cancer Society estimates that there will be approximately 95,520 new cases of colon cancer and 39,910 cases of rectal cancer in the US in 2017. A cure is not possible for most patients with metastatic colorectal cancer (mCRC), although for those with limited involvement of other organs, surgery may be curative. For others, chemotherapy, often in combination with biological agents (VEGF and EGFR inhibitors), can improve symptoms and prolong life. However, the five-year survival rate of mCRC is just 11%.

According to clinicaltrials.gov, there are currently 40 Phase III trials in mCRC that are active, indicating the unmet clinical need. Catching the headlines recently has been a wave of immunotherapy approvals. In July 2017, the FDA granted Opdivo (nivolumab) accelerated approval for mismatch repair deficient and microsatellite instability-high metastatic colorectal cancer (following treatment with fluoropyrimidine, oxaliplatin, and irinotecan).

Other recent approvals include Taiho Oncology's Lonsurf (trifluridine/tipiracil), which was approved for refractory mCRC in September 2015. In the pivotal trial, median overall survival of 7.1 months in the trifluridine/tipiracil plus best supportive care (BSC) arm was observed (vs 5.3 months for BSC and placebo). Lilly's Cyramza (ramucirumab, approved in April 2015), a VEGF inhibitor, was approved for use in combination with the chemotherapy combination FOLFIRI (irinotecan with 5FU and folinic acid) in mCRC that has progressed after first-line treatment; in the pivotal trial median overall survival of 13.3 months for patients on the FOLFIRI plus ramucirumab arm was observed (vs 11.7 months for FOLFIRI plus placebo). Capecitabine, an orally administered chemotherapeutic agent, is one of the most commonly prescribed treatments for CRC, while Avastin (Roche), a VEGF inhibitor, tends to lead sales among biologics (approximately CHF3.4bn in H117 across all indications). Avastin demonstrated an overall survival of 20.3 months when used alongside bolus-IFL compared to 15.6 months for bolus-IFL alone. Combinations of target therapies (tyrosine kinase inhibitors [TKIs], monoclonal antibodies and immunotherapies) and chemotherapy are increasingly becoming the best approach to treating the complex and constantly mutating disease that is cancer. We note that limited therapies exist in the target mCRC maintenance population following first-line treatment.

IMPALA, a Phase III trial testing lefitolimod as a maintenance treatment in 540 metastatic colorectal cancer patients (Exhibit 2) has completed enrolment (concluded in May 2017) and top-line data are expected in 2019. The trial is being conducted across 120 centres in eight European countries. It is a randomised, non-blinded, two arm study, with a primary endpoint of overall survival (OS) and secondary endpoints of progression-free survival (PFS), tolerability, safety and quality of life (QoL).

Exhibit 2: IMPALA Phase III study design



Source: Mologen. Note: PD = progressive disease, CT = chemotherapy treatment, PR = partial response, CR = complete response, mCRC = metastatic colorectal cancer.

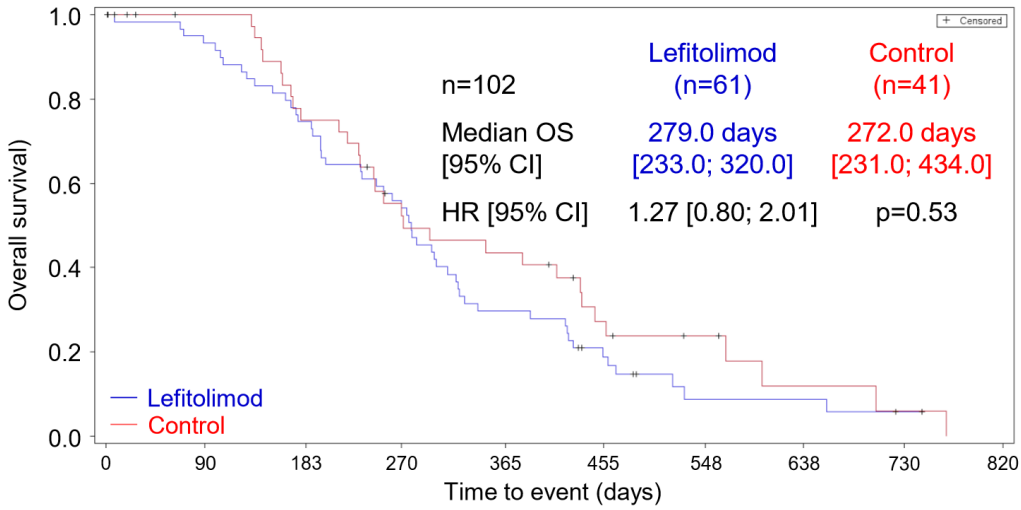
IMPULSE: Data package presented at ESMO 2017

Small cell lung cancer (SCLC) is a difficult disease to treat and over the last couple of decades few advances have been made. While chemotherapy agents like Etoposide and Cisplatin still lead first-line treatments, it is hoped that new immunotherapies could provide benefit. A recent 1,132-patient Phase III trial being conducted by Bristol-Myers Squibb (BMS) tested the immune checkpoint inhibitor (ICI) ipilimumab (Yervoy) in combination with chemotherapy for the treatment of SCLC and demonstrates the difficulty in treating this disease. Median overall survival in the treatment arm (chemo plus ipilimumab) was 11.0 months compared with 10.9 months for the placebo arm (chemo plus placebo); as such, no significant benefit was observed.

IMPULSE is an exploratory randomised, controlled, two-arm, Europe-based study assessing lefitolimod as a maintenance therapy post-induction chemo in metastatic SCLC (n=102). Enrolled patients must have achieved at least a partial response following platinum-based, first-line therapy. Participants in the trial were split between two treatments arms, with one arm receiving lefitolimod while the other arm receives local standard of care. With 102 patients enrolled in the trial (61 in the treatment arm, 41 in the control arm), it is the largest single data package on lefitolimod to date.

The data package from IMPULSE was recently presented at ESMO 2017. Lefitolimod missed its primary endpoint of overall survival in the total study population. Median OS (Exhibit 3) was 279.0 days (95% confidence interval [CI]: 233.0, 320.0) in the lefitolimod arm compared with 272.0 days (95% CI: 231.0, 434.0) in the control arm. The hazard ratio was 1.27 (95% CI: 0.80, 2.01; p=0.53).

Exhibit 3: Overall survival in the intent to treat population

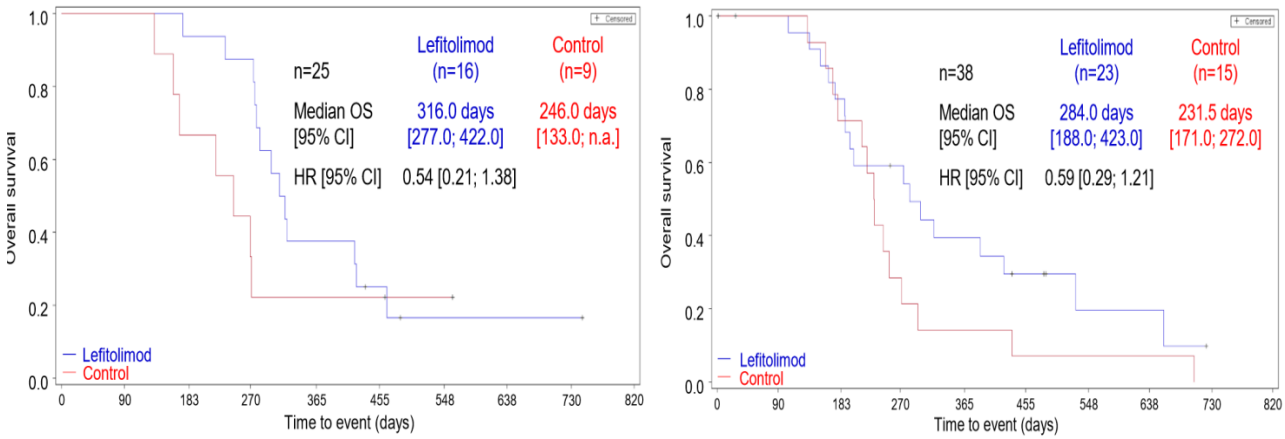


Source: Mologen

However, the data hinted at benefit in certain subgroups (Exhibit 4); lefitolimod demonstrated benefit in 38 patients with a low count of activated B-cells (hazard ratio: 0.59; 95% CI: 0.29-1.21). Patients were analysed before the start of lefitolimod treatment via flow cytometry in a central laboratory to determine activated B-cells, defined as the proportion of CD86+ to CD19+ B-cells. 88 patients were able to be evaluated (out of 102) and 38 (43.2%) of them fell below the cut-off of 15.4% of activated B-cells, as determined by a Cox Regression model. Mologen hypothesises that activated B-cells, specifically regulatory B-cells, inhibit a lefitolimod-triggered response.

There was an enhanced benefit in another subgroup population of 25 patients with chronic obstructive pulmonary disease (hazard ratio 0.54; 95% CI: 0.21-1.38). The large confidence intervals reported in both subgroups indicate the low powering of the subgroup analysis; as such, further trials and data will be needed to confirm the observations. We note that SCLC is a difficult indication to treat and the five-year relative survival rate in stage 1 patients is 31%, dropping off to 2% in stage 5 patients. Subsequently, the response in the subgroups is a positive development, but at this stage only exploratory in nature.

Exhibit 4: Overall survival in subgroups – reported COPD (left), activated B-cells (right)



Source: Mologen

The most common adverse events (AEs) reported were cough (25% vs 7.7% in control group) and headache (21.7% vs 5.1% in control group). The most common grade 3 event was headache, which occurred in two lefitolimod-treated patients (3.3%). In general, the side effect profile further reinforced the favourable safety profile of lefitolimod. Median and mean duration of treatment was 72 days and 113.1 days, respectively. The mean age in the treatment arm was 63.9 (vs 64.6 in control) with min-max ages of 49-80 (vs 51-82 in the control arm). 42 patients (70%) in the treatment arm (data only available for ECOG analysis in 99 patients) had an ECOG status of 1 (vs 21 [53.8%] in control arm) and 18 patients (30%) had a status of 0 (vs 18 [46.2%] in the control arm). Final readout is expected in Q118, approximately 24 months after patient enrolment.

The potential for combinations with lefitolimod

Patient recruitment is currently ongoing in a Phase I trial testing lefitolimod in combination with ipilimumab (Yervoy) for patients with advanced solid tumours. The trial consists of dose escalation and dose expansion cohorts. The primary endpoint is maximum tolerated dose with secondary outcomes measuring tumour response. The trial is expected to enrol 60 patients with potential data readout by 2019.

In other preclinical work, Mologen's lead candidate, lefitolimod (TLR9 agonist), demonstrated promising efficacy in mouse models when used in combination with a PD-1 or a PD-L1 immune checkpoint inhibitor (ICI). In an A20 lymphoma model, mean tumour growth inhibition (TGI) of 45.9% for PD-1 antibody-treated and 49.8% for lefitolimod-treated mice was observed. However, when used in combination the TGI increased dramatically to 99.1%, and consequently, at 60 days survival was 100% compared with approximately 33% for the PD-1 antibody and lefitolimod when used as monotherapies. In a separate colon carcinoma (CT26) mouse model, lefitolimod and a PD-L1 combination demonstrated a mean TGI of 48.4% compared with 27.6% for lefitolimod alone. The PD-L1 ICI had no effect on tumour growth when used as a monotherapy. This early preclinical data highlights the potential of ICI combinations with lefitolimod. However, clinical data are needed in what is now a hotly contested sector.

Financing constraints put rest of the pipeline on hold

Mologen's strategy is now focused on the development and commercialisation of lefitolimod; thus focus on the remaining product candidates has now shifted (Exhibit 5). While the development of MGN1601 is now on hold, successful out-licensing of lefitolimod could lead to the resumption of its development programme. The MIDGE platform, which currently consists of two preclinical product candidates (MGN1331 and MGN1333) and Mologen expects to divest or spin off a Phase I product candidate (MGN1404). The preclinical EnanDIM product candidate will be advanced to Phase I only if funding is available.

EnanDIM: Next-generation product candidate

EnanDIM (Enantiomeric, DNA-based, ImmunoModulator) is a technology platform that consists of innovative, linear, DNA-based TLR9 agonists. The EnanDIM platform aims to provide the safety and durability of lefitolimod with the ease of production of linear DNA. The use of linear single-stranded DNA in the body is problematic as degradation by enzymes means limited lifetimes. To counter this, the EnanDIM family of molecules contains the stereoisomeric form (the same molecular formula and bonding, but differs in three-dimensional orientation) of the ribose molecules at the end of the backbone. These cannot be recognised by DNA-degrading enzymes. Mologen plans to advance the preclinical assets into the clinic.

The benefits of combining a TLR9 agonist with checkpoint inhibitors was highlighted by recent data demonstrating the effect that EnanDIM compounds had on a colon carcinoma CT26 mouse model.

EnanDIM532 and a PD-1 antibody demonstrated 28.3% and 57.0% TGI, respectively, when utilised as monotherapies, while the combination of both reduced tumour growth substantially, represented by 74.7% TGI.

MGN1601: On hold, ready for future development

MGN1601, a Phase II-ready asset, has its development on hold as resources are focused on the commercialisation of lefitolimod. Development would be reinitiated on the successful out-licensing of lefitolimod. MGN1601 is a therapeutic cancer vaccine specific to renal cell carcinoma (RCC), cultured from a tumour cell line from one patient and genetically modified using the MIDGE technology. This makes the product unique and difficult to copy by a potential generic competitor. The MIDGE-transfected cells are also combined with lefitolimod (used as an adjuvant, at a lower dose) and the product can be stored and shipped frozen, providing an off-the-shelf cancer vaccine.

MGN1601 was evaluated in a small, open-label, single-arm Phase I/II study (ASET). The trial treated 19 patients with advanced RCC who had failed prior systemic therapies (intent-to-treat, ITT). 10 patients completed the study per protocol (PP; intradermal injections of 10m cells per dose, administered once-weekly for four weeks, then bi-weekly until 12 weeks). Overall, two patients achieved disease control (1x partial response; 1x stable disease) after 12 weeks and continued treatment in an extension phase (starting at week 24 through to 120 weeks). Subsequently, one patient had PD after 60 weeks, while the other completed all five further vaccinations and was still in tumour remission after 120 weeks. Median OS was 24.8 weeks in the ITT population and 115.3 weeks in the PP group. The two patients still alive at week 120 were in the PP group. The safety profile was favourable.

Exhibit 5: Mologen development pipeline

Product	Technology/mechanism	Target	Status	Notes
Lefitolimod (MGN1703)	Immune Surveillance Reactivator. TLR9 agonist; dSLIM (double-stem loop immunomodulator) is a dumbbell-shaped, DNA-based construct.	Metastatic colorectal cancer (mCRC); maintenance therapy (post-chemo induction).	Phase III (IMPALA) started Q314; 540 patients enrolled; OS primary endpoint. Phase II (IMPACT) complete; 59 patients.	IMPALA is an open-label, randomised (1:1), controlled, two-arm, multinational study (120 sites across the EU); full recruitment completed, initial data in FY19.
		Small-cell lung cancer (SCLC); maintenance therapy (post-chemo induction).	Phase II (IMPULSE) initiated Q214; 100 patients; OS (at 12 months) primary endpoint.	IMPULSE is an exploratory, open-label, randomised (3:2), controlled, two-arm, multinational EU study; full recruitment completed. Top-line data demonstrated the primary endpoint of overall survival was missed. However, a benefit was seen in certain subgroups.
		Human immunodeficiency virus (HIV).	Phase I (TEACH) initiated Q215; 15 patients; NK cell activation primary endpoint for expansion study.	TEACH is an exploratory, non-randomised interventional study. Top-line results from the extension study demonstrated that a reduction in viral load was not achieved (primary endpoint); however, in the first part of the trial, the primary endpoint of increasing the proportion of activated natural killer cells was met.
		Advanced solid malignancies	Phase I initiated Q316. 60 patients; maximum tolerated dose primary endpoint. Data expected in 2019	Lefitolimod will be tested in combination with the CTLA-4 immune checkpoint inhibitor ipilimumab. The first patient has been enrolled with end of recruitment by 2018. Initial data readout expected by 2019.

Product	Technology/mechanism	Target	Status	Notes
MGN1601	Cell-based cancer vaccine; genetically modified tumour cells transfected with four vectors: GM-CSF, IL-7, CD80 and CD154 (CD40L), and combined with dSLIM (MGN1703).	Metastatic renal cell carcinoma (mRCC).	Phase I/II (ASET) complete; 19 patients.	Mologen has placed this asset on hold and will potentially reinitiate development on successful out-licensing of lefitolimod.
EnanDIM	Next-generation TLR9 agonists; linear DNA construct with structural feature to protect against degradation.	Oncology and anti-infectives	Preclinical model experiments that confirm broad immune activation.	Designed to combine the chemically unmodified DNA components of MGN1703 with the ease of production advantages of linear molecules. Potential patent life extension of the franchise.

Source: Mologen; Edison Investment Research. Note: MIDGE = minimalistic immunogenically defined gene expression; proprietary platform, also classified as a DNA vector. EnanDIM = Enantiomeric, DNA-based, ImmunoModulator.

Valuation

We now value Mologen at €253m (€7.36/share) vs €252m (€7.33/share) previously. The valuation is based on a risk-adjusted, sum-of-the-parts DCF model, applying a standard 12.5% discount rate and including estimated end-2017 net debt of €2.8m.

We have retained our probability of success for lefitolimod in HIV at 15%. While recent trial data have cast doubt on our initial optimism, we believe that next year's combination trial with novel virus-neutralising antibodies (run by the Danish Aarhus University Hospital, developed by the Rockefeller University, New York and funded by Gilead) could yet prove successful.

We assume that lefitolimod will be out-licensed in oncology indications (in the EU and US) in 2018 and will be out-licensed for HIV post Phase II. We do not include upfront fees and/or milestones, which would be expected on securing a partner and successful commercialisation of the product, providing potential upside to our valuation.

While the IMPALA trial is based in Europe, combining the data with those from the Phase I combination trial running in the US (at MD Anderson Cancer Center) should be (based on expert regulatory advice that Mologen has recieved) sufficient for approval in the US. Our model still expects that a Phase III trial in SCLC will initiate next year; we believe this would combine both US and EU centres and launch in 2022. However, any delay in securing funding or partners would push back this launch.

We no longer value the opportunities in Japan for CRC or SCLC as we have no visibility on the current strategy or funding in this region and believe data packages from other regions would not be approved by the Japanese authorities, and thus additional data from further trials would be needed.

We have added the recently announced collaboration with China-based iPharma to our valuation. For valuation purposes, we have assumed that it follows a standard development cycle and would launch in 2022. Our key assumptions can be seen in Exhibit 6.Our probability of success is lower than what would typically be expected and reflects the challenges inherent in the Chinese market, notably its focus on generics, significantly lower prices, limited healthcare insurance and lower penetration of targeted therapies. Additionally, we draw attention to the difficulties many companies have recently had in moving funds out of China following new rules brought in by the Chinese government. As the deal is yet to be finalised and the exact development strategy is yet to be clarified, we have for now assumed a probability of success of 5%.

Finally, due to the aforementioned limited financial headroom and the uncertainty about the clinical development of MGN1601, we have removed it from our valuation (it contributed €0.45/share to our previous €7.33/share valuation). However, fresh funding and reactivation of the programme could prompt us to reverse this decision.

Exhibit 6: Summary of rNPV valuation assumptions

Product	Status	Market launch	NPV (€m)	Peak sales ($m)	Probability of success	Royalty estimate	rNPV (€m)	rNPV share (€)	Key assumptions
Lefitolimod – CRC – US	Phase III-ready	2021	106	308	65%	25%	70.7	2.06	~135,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2026); $40,000 treatment price; 2028 market exclusivity
Lefitolimod – CRC – EU	Phase III	2020	233	589	65%	25%	150.6	4.40	~345,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 25% peak share (2026); $30,000 treatment price; 2030 market exclusivity
Lefitolimod – SCLC – US	Phase II-ready	2022	23	124	15%	15%	3.7	0.11	~225,000 lung cancer cases/yr; 15% SCLC; 75% advanced SCLC; 70% chemo response; 15% peak share (2027); $40,000 price; 2028 market exclusivity
Lefitolimod – SCLC – EU	Phase II	2022	15	130	15%	15%	0.3	0.01	~310,000 lung cancer cases/yr; 15% SCLC; 75% advanced SCLC; 70% chemo response; 15% peak share (2028); $30,000 price; 2030 market exclusivity
Lefitolimod – HIV – worldwide	Phase I	2025	64	405	15%	15%	6.5	0.19	~ 36.7m cases (prevalence), 46% treated, 5% peak share (2034), $20,000 price, patent expiry 2036 (expected – not yet granted)
Lefitolimod & ICI – ASM (SCLC used as model) – worldwide	Phase I	2028	57	511	15%	10%	7.9	0.23	~ 1.8m lung cancer cases worldwide, 12.50% SCLC, 5% peak share (2033), $30,000 price, patent expiry 2036 (expected – not yet granted)
Lefitolimod – mCRC – China	Phase I	2028	64	203	5%	15%	16.4	0.48	~200,000 CRC cases/yr; 25% metastatic + 5% regional; 60% chemo response; 10% will receive additional treatment, 1% peak share (2033), €5,000, patent expiry unknown.
Portfolio value			794				256.03	7.47	
Net cash/(debt)							(2.8)	(0.11)	As at 31 December 2017 (estimated).
Total							**253.2**	**7.36**	34.3m shares outstanding

Source: Edison Investment Research

Sensitivities

The key sensitivities relate to the clinical performance of lefitolimod and Mologen's ability to secure the additional financing and/or a partner (in the EU) to complete the full clinical programme. Recent mixed results from the IMPULSE and HIV trials mean additional funding may not come or will be available at less favourable terms. In the long term, IMPALA data will have a major bearing on lefitolimod's chance of regulatory approvals and commercial success. We have made assumptions about the potential market opportunity available to lefitolimod, which do not currently include significant stratification of patient populations. Lefitolimod may be most active in certain subgroups, which could reduce the target patient pool. However, confirmed activity in a patient subset may result in a higher treatment price, greater reimbursement rates and more favourable economic terms from any partnership. It should also be noted that the success or failure of lefitolimod in one indication may not translate across to other indications.

Financials

Gross cash at 30 June 2017 was €14.2m (net cash €7.6m). Our model suggests that current cash is sufficient to fund operations into early 2018; a funding gap remains in respect of the IMPALA study (primary endpoint estimated 24 months after the final patient is recruited) and combination readout. Our model includes €30m of illustrative debt in 2018; however, funding is likely to be needed before Q118 to ensure financial stability. We currently have no visibility on near-term funding possibilities.

In terms of operating costs for H117, the company reported that H117 R&D expenses increased 13% from €7.1m (H116) to €8.0m. This translated to a small increase in operating loss (EBIT) of €10.5m vs €9.8m in H116. We expect R&D costs to remain broadly similar for the rest of FY17 and this is reflected in a forecast EBIT loss of €21.0m in FY17.

We anticipate personnel expenses to remain stable as increased outsourcing offsets the lower headcount (we forecast €5.2m in FY17 vs €5.5m in FY16). We currently assume that lefitolimod will be out-licensed in oncology indications in FY18; as such, a reduction in costs is expected, mainly in the cost of materials (€7.4m in FY18e from €12.4m in FY17e). We note that the terms of any potential future licensing deal for lefitolimod will heavily influence financing needs, while a delay or failure to achieve out-licensing could materially affect Mologen's long-term financial position.

To fund the company through inflection points in 2017, Mologen has raised gross proceeds of €21.1m, through a capital increase and the issue of two convertible bonds. The capital increase in October 2016 raised €13.6m gross (€12.7m net) via the issue of 11.3m new shares. Subsequently, two convertible bonds have been placed: one in November 2016 (€2.54m) and another in January 2017 (€4.99m); each has an eight-year maturity date and a 6% coupon, paid quarterly. The €2.54m bond has a conversion price of €1.50, while the €4.99m bond can be converted at €1.60. Mologen's largest shareholder, Global Derivative Trading (GDT), subscribed fully to the €2.54m bond and to approximately 73% of the €4.99m bond.

We maintain our forecast net loss for FY17 of €21.4m.

Exhibit 7: Financial summary

€000s	2014	2015	2016	2017e	2018e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	12	39	74	40	40
Cost of Sales	0	0	0	0	0
Gross Profit	12	39	74	40	40
Research and development (cost of materials)	(8,687)	(11,681)	(11,780)	(12,369)	(7,421)
Selling, general & administrative (personnel expenses)	(5,113)	(5,074)	(5,453)	(5,180)	(4,662)
Other operating income/expense	(3,199)	(3,702)	(3,418)	(3,444)	(3,444)
EBITDA	(16,987)	(20,418)	(20,577)	(20,953)	(15,488)
Operating Profit (before GW and except.)	(17,059)	(20,499)	(20,813)	(20,956)	(15,494)
Intangible Amortisation	(38)	(40)	(172)	(19)	(17)
Exceptionals/Other	0	0	0	0	0
Operating Profit	(17,097)	(20,539)	(20,985)	(20,974)	(15,511)
Net Interest	19	3	(18)	(424)	(423)
Other	0	0	0	0	0
Profit Before Tax (norm)	(17,040)	(20,496)	(20,831)	(21,380)	(15,917)
Profit Before Tax (FRS 3)	(17,078)	(20,536)	(21,003)	(21,399)	(15,934)
Tax	0	0	0	0	0
Deferred tax	0	0	0	0	0
Profit After Tax (norm)	(17,040)	(20,496)	(20,831)	(21,380)	(15,917)
Profit After Tax (FRS 3)	(17,078)	(20,536)	(21,003)	(21,399)	(15,934)
Average number of shares outstanding (m)	16.8	20.7	24.7	34.3	34.3
EPS – normalised (c)	(1.01)	(0.99)	(0.84)	(0.62)	(0.46)
EPS – FRS 3 (c)	(1.02)	(0.99)	(0.85)	(0.62)	(0.47)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	440	414	62	97	121
Intangible Assets	206	175	37	33	20
Tangible Assets	234	239	25	64	101
Other	0	0	0	0	0
Current Assets	14,613	25,981	21,300	5,019	19,268
Stocks	30	28	13	13	13
Debtors	0	0	33	33	33
Cash	13,563	24,592	20,520	4,239	18,488
Other	1,020	1,361	734	734	734
Current Liabilities	(1,747)	(6,886)	(7,404)	(7,404)	(7,404)
Creditors	(1,747)	(6,886)	(7,404)	(7,404)	(7,404)
Short term borrowings	0	0	0	0	0
Long Term Liabilities	(8)	(6)	(2,121)	(7,072)	(37,072)
Long term borrowings	0	0	(2,119)	(7,070)	(37,070)
Other long term liabilities	(8)	(6)	(2)	(2)	(2)
Net Assets	13,298	19,503	11,837	(9,360)	(25,087)
CASH FLOW					
Operating Cash Flow	(15,602)	(15,095)	(19,270)	(20,751)	(15,280)
Net Interest	3	0	0	(424)	(424)
Tax	(6)	12	0	0	0
Capex	(93)	(95)	(57)	(56)	(47)
Acquisitions/disposals	0	0	13	0	0
Financing	14,495	26,207	12,706	0	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	(1,203)	11,029	(6,608)	(21,232)	(15,751)
Opening net debt/(cash)	(14,765)	(13,563)	(24,592)	(18,401)	2,831
HP finance leases initiated	0	0	0	0	0
Exchange rate movements	1	0	1	0	0
Other	0	0	416	0	0
Closing net debt/(cash)	(13,563)	(24,592)	(18,401)	2,831	18,582

Source: Mologen accounts, Edison Investment Research

Contact details	Revenue by geography
Fabeckstr. 30, 14195 Berlin, Germany +49 (0)30 84 17 88 0 www.mologen.com	N/A

Management team

Chief Executive Officer: Dr Mariola Söhngen	Chief Financial Officer: Walter Miller
Dr Söhngen joined Mologen on 1 November 2015, assuming the role of CEO. She is the co-founder of Paion and Paion Deutschland, and served as MD at both. She also held the position of CMO of Paion from 2004 to 2015. Before founding Paion she worked for Grünenthal and Ferrer Internacional. She has a medical degree, a PhD in medicine, a diploma in pharmaceutical medicine and a Master's in business communication.	Mr Miller joined Mologen on 1 April 2016, assuming the role of CFO. He was most recently the CFO of Nuvisan, an international contract research organisation (CRO). He has also held various managerial positions at Santhera Pharmaceuticals, initially VP of finance and commercial operations in Germany and subsequently in Switzerland. He was also a member of the group's management team. He started his career at Isra Vision Parsytec in Aachen, Germany.
Chief Medical Officer: Dr Matthias Baumann	
Dr Baumann joined Mologen in May 2017, assuming the role of CMO. From 2011 to 2017 he served as chief medical officer and member of the executive board of NOXXON Pharma, a Berlin-based biotech company focused on novel cancer therapies. From 2002 to 2010 he served as chief scientific officer and MD of FOCUS Clinical Drug Development. Before this he served in various research and development roles at Roche and Boehringer Mannheim.	

Principal shareholders	(%)
Global Derivative Trading	<25%
Deutsche Balaton Aktiengesellschaft	5%
Signal Krankenversicherung	4%
Baloise Holding	4%

Companies named in this report

Bristol-Myers Squibb ,Gilead, Lilly, Roche

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