

INDEPENDENT RESEARCH
UPDATE

29th November 2016

Healthcare

Bloomberg	MOR GR
Reuters	MORG.DE
12-month High / Low (EUR)	60.8 / 33.2
Market capitalisation (EURm)	1,254
Enterprise Value (BG estimates EURm)	905
Avg. 6m daily volume ('000 shares)	125.9
Free Float	92.0%
3y EPS CAGR	
Gearing (12/15)	-78%
Dividend yield (12/16e)	NM

YE December	12/15	12/16e	12/17e	12/18e
Revenue (EURm)	106.20	51.96	75.00	8.59
EBIT (EURm)	17.17	-67.24	-64.81	-151.86
Basic EPS (EUR)	0.57	-1.78	-1.71	-4.01
Diluted EPS (EUR)	0.57	-1.78	-1.71	-4.01
EV/Sales	9.14x	17.41x	12.75x	124.38x
EV/EBITDA	47.1x	NS	NS	NS
EV/EBIT	56.6x	NS	NS	NS
P/E	75.4x	NS	NS	NS
ROCE	16.0	-52.7	-47.6	-104.9



Morphosys

We want MORE!

Fair Value EUR65 (price EUR43.00)


BUY

With LLY's solanezumab's recent failure in Alzheimer's disease, a period of significantly negative news flow is now behind us. The stock has lost c.1% since our initiation of coverage... And yet 1/ the downside has been materially reduced with Guselkumab's recent filing for approval in plaque psoriasis; 2/ we believe the next ASCO Congress might prompt us to (positively) reconsider our estimates for both anetumab ravtansine and utomilumab. **BUY** reiterated.

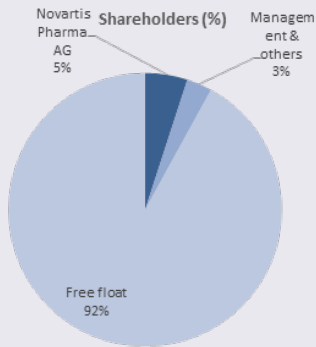
■ **Guselkumab (anti-IL23p19) story significantly de-risked.** The overall potential downside has been substantially reduced in our view thanks to 1/ the presentation of impressive Phase III results in plaque psoriasis, along with promising Phase II data in psoriatic arthritis; 2/ Janssen's recent filing for approval in its primary indication. Furthermore, guselkumab's addressable market could be expanded to novel indications like Crohn's disease and ulcerative colitis in our view.

■ **Towards a rich ASCO 2017.** We believe the next ASCO Congress could trigger a further re-rating; especially if positive data were to be published for 1/ anetumab ravtansine (anti-mesothelin ADC) in ex-mesothelioma indications (which we haven't included in our estimates so far); 2/ utomilumab (anti-CD137) in some solid tumours, knowing that BMS has recently presented some quite promising data for urelumab (another CD137 mAb) in combination with nivolumab in melanoma irrespectively of PD-L1 expression. Note also that the first data from the L-MIND (MOR 208 + lenalidomide in R/R patients with DLCBL) are likely be presented.

■ **BUY reiterated with a FV of EUR65.** The stock has lost c.1% since our initiation... And yet, the risk-reward is much more attractive now that 1/ the downside has been significantly reduced thanks to the positive news flow related to guselkumab; 2/ there is significant upside potential to our current base-case (c.50%). Note also that our FV could be increased by +EUR6 should 1/ guselkumab be approved for the treatment of plaque psoriasis (+EUR4), and 2/ positive Phase I/II data be published for anetumab in a range of selected solid tumours (+EUR2).

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Morphosys



Simplified Profit & Loss Account (EURm)	2014	2015	2016e	2017e	2018e	2019e	2020e
Revenues	64.0	106	52.0	75.0	8.6	18.5	108
Change (%)	-%	66.0%	-51.1%	44.3%	-88.5%	115%	484%
Adjusted EBITDA	(1.8)	20.6	(63.2)	(60.8)	(148)	(149)	(69.7)
EBIT	(6.0)	17.2	(67.2)	(64.8)	(152)	(153)	(73.7)
Change (%)	-%	-%	-492%	-3.6%	-134%	-0.5%	-51.7%
Financial results	1.6	3.4	0.0	0.0	0.0	0.0	0.0
Pre-Tax profits	(4.4)	20.6	(67.2)	(64.8)	(152)	(153)	(73.7)
Exceptionals	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Tax	(1.3)	5.7	(20.2)	(19.4)	(45.6)	(45.8)	(22.1)
Net profit	(3.1)	14.8	(47.1)	(45.4)	(106)	(107)	(51.6)
Restated net profit	(3.1)	14.8	(47.1)	(45.4)	(106)	(107)	(51.6)
Change (%)	-%	-%	-417%	-3.6%	-134%	-0.5%	-51.7%

Cash Flow Statement (EURm)	2014	2015	2016e	2017e	2018e	2019e	2020e
Operating cash flows	(26.3)	(46.5)	(43.1)	(41.4)	(102)	(103)	(47.6)
Change in working capital	(12.1)	(22.9)	(9.4)	0.0	0.0	0.0	0.0
Capex, net	20.5	8.8	10.0	10.0	10.0	10.0	10.0
Financial investments, net	(6.5)	112	0.0	0.0	0.0	0.0	0.0
Dividends	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net debt	(303)	(283)	(349)	(298)	(185)	(72.6)	(15.0)
Free Cash flow	(34.7)	(32.3)	(43.6)	(51.4)	(112)	(113)	(57.6)

Balance Sheet (EURm)	2014	2015	2016e	2017e	2018e	2019e	2020e
Tangible fixed assets	3.6	3.5	9.5	15.5	21.5	27.5	33.5
Intangibles assets	46.0	79.6	79.6	79.6	79.6	79.6	79.6
Cash & equivalents	303	283	349	298	186	72.8	15.2
current assets	19.6	17.2	5.7	5.7	5.7	5.7	5.7
Other assets	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total assets	426	400	461	416	309	203	151
L & ST Debt	0.25	0.23	0.23	0.23	0.23	0.23	0.23
Others liabilities	77.4	37.1	35.1	35.1	35.1	35.1	35.1
Shareholders' funds	349	363	426	380	274	167	116
Total Liabilities	426	400	461	416	309	203	151
Capital employed	91.8	92.8	89.4	95.4	101	107	113

Ratios	2014	2015	2016e	2017e	2018e	2019e	2020e
Operating margin	(9.30)	16.17	(129)	(86.41)	(1,768)	(825)	(68.13)
Tax rate	29.71	27.85	30.00	30.00	30.00	30.00	30.00
Net margin	(4.79)	13.97	(90.58)	(60.49)	(1,238)	(577)	(47.69)
ROE (after tax)	(0.88)	4.09	(11.06)	(11.93)	(38.80)	(63.91)	(44.62)
ROCE (after tax)	(3.34)	15.98	(52.67)	(47.57)	(105)	(99.50)	(45.50)
Gearing	(86.73)	(77.94)	(82.01)	(78.28)	(67.67)	(43.42)	(12.98)
Pay out ratio	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Number of shares, diluted	26.19	26.24	26.65	26.76	26.76	26.76	26.76

Data per Share (EUR)	2014	2015	2016e	2017e	2018e	2019e	2020e
EPS	(0.12)	0.57	(1.78)	(1.71)	(4.01)	(4.03)	(1.94)
Restated EPS	(0.12)	0.57	(1.78)	(1.71)	(4.01)	(4.03)	(1.94)
% change	-%	-%	-412%	-4.0%	-134%	-0.5%	-51.7%
BVPS	13.32	13.82	15.97	14.21	10.24	6.25	4.32
Operating cash flows	(1.01)	(1.77)	(1.62)	(1.55)	(3.82)	(3.84)	(1.78)
FCF	(1.32)	(1.23)	(1.64)	(1.92)	(4.20)	(4.22)	(2.15)
Net dividend	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Source: Company Data; Bryan, Garnier & Co ests.

Company description

Morphosys is a biopharmaceutical company focused on the development of monoclonal antibodies

1. Why invest now?

1.1. Multiple upcoming catalysts leading to further upgrades

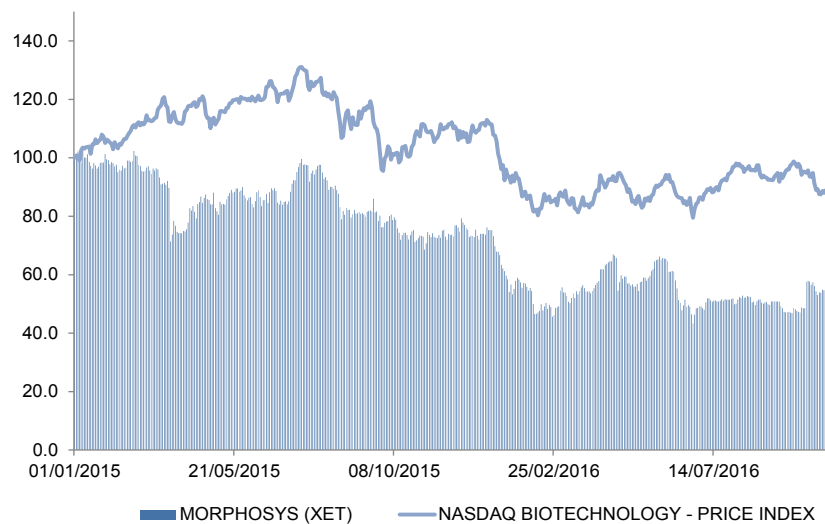
MOR shares have underperformed peers despite the recent positive news flow

We see current share price levels as an attractive entry point. Admittedly, MOR has outperformed its peers since early October (+15% vs -2% for the NBI) thanks to some strong catalysts involving its anti-IL23p19, guselkumab (positive Phase III for in plaque psoriasis followed by a filing for approval by Janssen, promising Phase II data in psoriatic arthritis). However, the overall performance since our initiation has not been that sparkling notwithstanding relatively positive news flow as a whole (-1% vs +8%).

Most of the negative news flow we anticipated is now behind us. As noted in our initiation report, we were quite cautious about the outcome of LLY's Phase III evaluating solanezumab in mid dementia due to Alzheimer's disease. And unfortunately, the results have proven us to be right, the amyloid thesis once again being called into question with this repeated failure... But the good news is that we had accorded no value to this development, and we think most of the consensus retained a fairly low PoS. So the overall perception of the equity story is probably unchanged.

Going forward, we believe the stock will continue to benefit from numerous catalysts in the coming months, and especially towards June:

Fig. 1: MOR shares vs Nasdaq Biotech (YTD)



Source: Thomson Reuters; Bryan, Garnier & Co. ests

Multiple catalysts ahead

- **We expect some follow-up data for MOR208 during the upcoming ASH meeting.** But we'll be paying particular attention to the updated depth and duration of responses in DLBCL knowing that 1/the patients involved are heavily pre-treated and most of them are rituximab-refractory (69%); 2/ ORR stood at 36% at the last update (and we hope some of the partial responses have since deepened). Going forward, we understand that the first data from the L-MIND (combo with lenalidomide in R/R DLCBL) will probably be presented at the 2017 ASCO Congress.

Please see the section headed "Important information" on the back page of this report.

- **Anetumab ravtansine (anti-mesothelin ADC)'s potential to arise during next ASCO meeting.** The market currently underestimates the potential expansion of the compound in other solid tumours like pancreatic and ovarian cancers... And we believe some preliminary/interim data are likely to be presented in H1 2017 (most probably at the next ASCO congress)
- **Utomilumab (CD137 agonist) also to shine at ASCO?** The whole therapeutic class has probably benefitted from the recently-presented data for BMS's urelumab in relapsed/refractory melanoma. But we need more data specifically for MOR/PFE's utomilumab before eventually incorporating sales perspectives in this indication, or any other tumour type... And that might the case at the upcoming ASCO meeting in our view (or at the SITC at the latest).
- **Bimagrumab to be revived?** Some mid-stage data involving bimagrumab (anti-actRIIB) are expected next year in two very different indications: hip fracture surgery, and sarcopenia. We are quite cautious about the potential outcomes, particularly regarding the latter. But following the recent failure in sporadic inclusion body myositis, and due to a lack of early-data, we understand that most analysts accord little value to these developments... Meaning they could be considered (here again) as virtually free call options.

Fig. 2: MOR – Next company-specific key catalysts

Compound	Target	Clinical stage	Indication
H2 16			
Guselkumab	IL23p19	Phase III	Plaque psoriasis (VOYAGE 2 study)
Guselkumab	IL23p19	Phase III	Plaque psoriasis (NAVIGATE study)
Guselkumab	IL23p19	Phase II	Psoriatic arthritis
MOR208	CD19	Phase II	Chronic Lymphocytic Leukemia (CLL)
MOR208	CD19	Phase II	Non Hodgkin Lymphoma (NHL)
MOR202	CD38	Phase II	Multiple Myeloma (ASH 2016)
2017			
Anetumab ravtansine	Mesothelin	Phase II	Mesothelioma (MPM)
Bimagrumab	ActRIIb	Phase II	Hip fracture surgery
Bimagrumab	ActRIIb	Phase II	Sarcopenia (dose ranging)
MOR103	GM-CSF	Phase II	Rheumatoid Arthritis
MOR103	GM-CSF	Phase II	Rheumatoid Arthritis
MOR103	GM-CSF	Phase II	Osteoarthritis
MOR208	CD19	Phase II	DLBCL (+ lenalidomide)
MOR202	CD38	Phase II	Multiple Myeloma
Utomilumab	4-1BB/CD137	Phase I/II	Solid tumours
BAY-1093884	TFPI	Phase I/II	Bleeding disorders

Source: Morphosys; Bryan, Garnier & Co. ests

1.2. We are sticking with our FV of EUR65 (upside: c.40%)

We are sticking with our FV of EUR 65. Note, however, that 1/ we still give no value to utomilumab despite the recent positive read-across from BMS's urelumab in pre-treated patients with advanced melanoma (at least pending further data); 2/ similarly, we haven't included the different developments for anetumab ravtansine beyond mesothelioma. But here again, we have adopted a cautious stance, awaiting some preliminary results before eventually including them in our FV.

Fig. 3: BG valuation

Drug candidates	Target	Indications	Stage	Peak sales (EURBn)	NPV (EURm)	PoS (%)	r-NPV (EURm)	Per share (EUR)
Unpartnered programs								
MOR208	CD19	DLBCL	Phase 2	0.6	540	35%	189	7
MOR202	CD38	Multiple myeloma	Phase 2	0.0	0	0%	0	0
MOR209	PSMA/CD3	Prostate cancer	Phase 1	0.8	1,000	20%	200	7
Partnered programs								
Guselkumab (JNJ)	IL23p19	Plaque psoriasis	Phase 3	1.6	548	80%	439	15
Guselkumab (JNJ)	IL23p19	Pustular psoriasis	Phase 3	0.6	175	60%	105	4
Guselkumab (JNJ)	IL23p19	Psoriatic arthritis	Phase 2	0.7	186	60%	112	4
Bimagrumab (NVS)	ActRIIB	sIBM & others	Phase 3	0.0	0	0%	0	0
Gantenerumab (ROG)	Amyloid-β	Mild Alzheimer's disease	Phase 3	0.0	0	0%	0	0
MOR103 (GSK)	GM-CSF	Rheumatoid arthritis	Phase 2	0.7	658	35%	230	8
Anetumab (BAY)	Mesothelin	Mesothelioma	Phase 2/3	0.6	207	60%	124	4
PF-05082566 (PFE)	4-1BB	Cancers	Phase 1	0.0	0	20%	0	0
Others	Diverse	Diverse	Phase 2	na	314	35%	110	4
= Enterprise Value					3,629	42%	1,509	52
(+) Net cash					382	100%	382	13
= Equity Value					4,011	47%	1,891	65

Source: Bryan, Garnier & Co ests.

1.3. An even more attractive risk-reward currently

A FV of EUR73 on a best-case scenario pointing to upside of c.80%

The stock has lost c.1% since our initiation... And yet the risk-reward is even more attractive currently as 1/ the downside has been significantly reduced thanks to the positive Phase III results of guselkumab in plaque psoriasis, followed by the submission of a BLA by Janssen; 2/ there is significant upside potential to our current base case valuation of EUR67 (implying an upside of c.50%)... Moreover, our FV could be increased by +EUR6 should (i) guselkumab be approved for the treatment of plaque psoriasis with a similar label to Cosentyx's (+EUR4), and (ii) positive Phase I data be published for anetumab in a range of selected solid tumours (+EUR2).

Note also that our FV could be further revised up by the addition of early-stage products (e.g. utomilumab) or high-risk candidates that we have deliberately overlooked (e.g. gantenerumab and bimagrumab). Additional upside could stem from the inking of a collaboration agreement involving MOR202... but we see this as highly unlikely in the short-term.

2. What should we expect from the upcoming ASH meeting?

2.1. MOR202: nothing special to expect

We do not expect a major update regarding MOR202

Obviously, most of the street will be looking at MOR202 (anti-CD38)'s Phase II data in multiple myeloma... But **we believe the data won't differ significantly from those presented at the 2016 annual meeting of the German Austrian and Swiss Societies for Haematology and Medical Oncology.**

Note that MOR202 is currently being tested in combination with different therapies in heavily pre-treated patients (median of four prior lines). So far, the responses obtained in combo with immunomodulatory molecules (i.e. lenalidomide or pomalidomide) are very competitive with those seen with daratumumab. But as the number of evaluable patients is still very low, we would caution against a potential variability in the forthcoming figures, particularly since 1/ some cohorts involve lower doses of MOR202 (4 and 8 mg/kg, whereas the optimal dose is 16 mg/kg), 2/ three responses were unconfirmed... So we'll be paying greater attention to the more mature data next year.

Fig. 4: MOR202 – Phase I/IIa data in heavily pre-treated myeloma patients

Response rate	MOR202 + Dex	MOR202 + Pom/Dex	MOR202 + Len/Dex
Evaluable patients	17	4	9
Disease control rate (DCR)	16 (94%)	3 (75%)	8 (89%)
Overall response rate (ORR)	5 (29%)	3 (75%)	7 (78%)
Complete response rate (CR)	0 (0%)	2 (50%)	0 (0%)
Partial response (PR) and Very Good Partial Response (VGPR)	5 (29%)	1 (25%)	7 (78%)

Source: Company Data; Bryan, Garnier & Co ests.

A licensing deal is increasingly unlikely in our view

We nonetheless remain cautious about the potential of this candidate, and even think a licensing deal is increasingly unlikely. Again, MOR202 is a candidate with very decent data in our view... but we continue to see its third entrant status, in a context where “dara” expands at an unprecedented pace, as a major obstacle in potential licensing negotiations. And as time goes on, GEN's compound will increasingly benefit from 1/ JNJ's strike force coupled with the broadening of its label in myeloma; 2/ the inking of further collaboration agreements, the most recent being with Amgen; and 3/ the clinical progress of its subcutaneous form, knowing that a Phase III is set to be initiated in 2017.

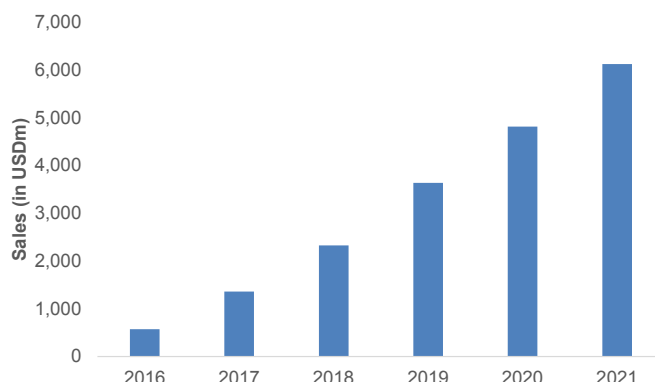
So by the time MOR202 is eventually approved (2020e – but that would assume a partner is found before the initiation of the Phase III), we expect “dara” to have become an USD5Bn blockbuster with both SC and IV forms available. And as the SC might reduce both infusion time and infusion-related reactions, we believe MOR202 will struggle to grab a significant part of the market.

Furthermore, keep in mind that 1/ SAN is sprinting for second place with isatuximab (which we consider to be its biggest asset in oncology); 2/ a Phase III trial is likely to be initiated soon.

Fortunately the downside is limited

Having said that, **most analysts have accorded no or little value to this product candidate since the termination of the collaboration agreement with CELG... So we see little downside here.**

Fig. 5: GEN/JNJ's daratumumab sales ramp-up (2015-2021e)



Source: Bryan, Garnier & Co. ests

2.2. MOR208: deepening or lasting responses in DLBCL?

Our focus will be oriented more towards MOR208 as a single-agent in NHL, and especially DLBCL (diffuse large B cell lymphomas) as this is the subtype where the compound appears to be the most competitive (see our initiation report for further details). As MOR208 is one of these un-partnered candidates, the obvious key question is: can they lead a partnering agreement?

Back at ASCO, the ORR in the DLBCL cohort stood at 36% (of which 6% are CR) while the median duration of response was c.20 months; which admittedly was very much in line with the data presented at the end of last year). Some initial partial responses might have deepened over time and even turned into complete ones in the past few months, so we will be paying particular attention to this.

Fig. 6: MOR208 – Responses in DLBCL and iNHL

	DLBCL (12 mg/kg)	iNHL (12 mg/kg)
Evaluable patients	35	45
Disease control rate (DCR)	14 (40%)	33 (73%)
Overall response rate (ORR)	9 (36%)	13 (33%)
Complete response (CR)	2 (6%)	5 (11%)
Partial response (PR)	7 (30%)	8 (18%)
Stable disease (SD)	5 (14%)	20 (44%)

Source: Company Data; Bryan, Garnier & Co ests.

We also acknowledge that data in CLL are to be presented, including some in ibrutinib-resistant patients, but we still think the competitive landscape has become a bit too challenging with ROG's venetoclax and AZN's acalabrutinib (see our initiation report for further details). We thus do not expect anything game-changing here.

3. Another look at utomilumab

BMS's CD137 agonist yielded encouraging efficacy and safety data

Among the numerous presentations made at the SITC congress, lirilumab (anti-KIR)'s data in head & neck cancer obviously got our attention. But the data involving BMS's urelumab (CD137 agonist) with nivolumab (PD-1 inhibitor) in 46 pre-treated advanced melanoma were also eye-catching with 1/ strong responses irrespectively of PD-L1 expression (50% of objective response rate in patients with $\geq 1\%$ PD-L1 expression at baseline, and 47% in PD-L1-negatives), 2/ more surprisingly, the cocktail was fairly well-tolerated with 17% Grade III adverse events in the overall study (n=138).

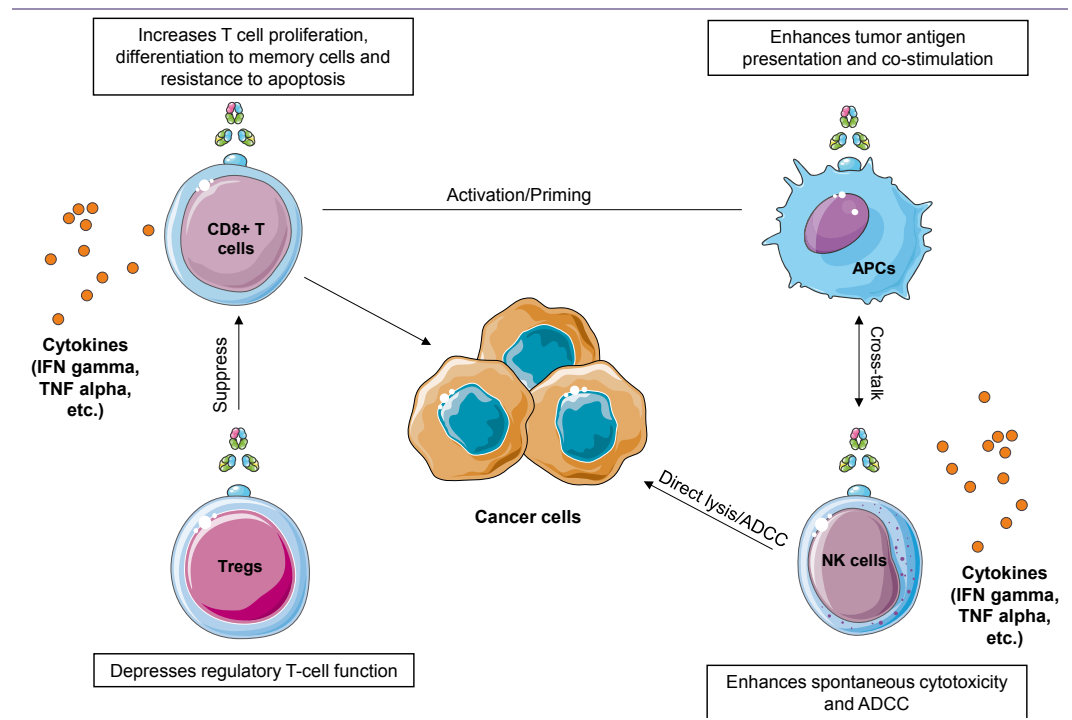
Such trends need to be confirmed in a larger randomized/controlled study, but we see them as highly encouraging and believe they will put the spotlight on the whole therapeutic class - including MOR/PFE's utomilumab. We still give no value to the latter in our SOTP... but we may change our mind if Pfizer publishes clinical data confirming the efficacy/safety profile of the compound in combination with avelumab (anti-PD-L1).

3.1. BMS's urelumab generated some very competitive data in melanoma

Response rates in relapsed/refractory patients are close to those from other combos as a first-line option

We see this preliminary efficacy dataset as very competitive... as an ORR of c.50% in pre-treated patients irrespectively of their PD-L1 status 1/ is close to the results from combinations though used as first-line options (e.g. nivo/ipi, pembro/epacadostat), and 2/ compares very favourably with PD-1/PD-L1 blockers as single agents in a R/R setting (see Fig. 8 for further details).

Fig. 7: Mechanism of action of an anti-4-1BB/CD137



Source: Adapted from Yonezawa et al, 2015; Bryan, Garnier & Co. ests.

Admittedly, we lack details about the duration/depth of responses, as well as the baseline characteristics of the recruited patients. But the data tend to confirm our view that CD137 agonists' mechanism of action synergizes well with anti-PD-1 given their ability to 1/ stimulate the activation

and the proliferation of several inflammatory cells (e.g. NK, dendritic, CD8+ T cells)... which by the way might lead to an upregulation of PD-L1 (among others); and 2/ potentially downregulate CD137-expressing Tregs (but this aspect still needs to be clarified).

Fig. 8: Response rate of I-O agents in melanoma

Candidate 1	Candidate 2	Indication	ORR	Source
Nivolumab (PD-1)	Ipilimumab (CTLA-4)	1L melanoma	57.6%	CHECKMATE-067 (Larkin <i>et al</i> , 2015)
Pembrolizumab (PD-1)	Epacadostat (IDO1)	1L melanoma	58.0%	ECHO-202 (Gangadhar <i>et al</i> , 2016)
Pembrolizumab (PD-1)	TVEC	1L melanoma	57.1% (irRC)	MASTERKEY-265 (Long <i>et al</i> , 2016)
Ipilimumab (CTLA-4)	TVEC	1L melanoma	50% (irRC)	(Puzanov <i>et al</i> , 2015)
Nivolumab (PD-1)	∅	2/3L melanoma	32%	(Weber <i>et al</i> , 2014)

Source: Company Data; Bryan, Garnier & Co ests.

A surprisingly good tolerability profile

We were (very) positively surprised by the quite low incidence of Grade III/IV induced by the combination (17%, knowing that the BMS press release provided no specific details about the melanoma population).

4-1BB/CD137 is expressed on a myriad of immune cell types, thus making it a dual-edged sword as its stimulation can theoretically lead to a strong anti-tumour response at the cost of off-target immune side effects. Among others, we saw two factors urging cautiousness: 1/ CD137 signalling is known to be implicated in the pathogenesis of several conditions, including atherosclerosis, lung inflammation, etc.; 2/ in clinical settings, the use of agonist antibodies induced severe adverse events like defects in immune homeostasis (e.g. neutropenia, thrombocytopenia), as well as moderate to severe liver inflammation. Furthermore, a previous BMS Phase II study evaluating single-agent urelumab (up to 5.0 mg/kg every 3 weeks) in relapsed/refractory advanced melanoma was terminated due to a high incidence of Grade IV hepatitis.

Thus, **it would appear that a more conservative dosing for “ure” might reduce these risks while improving the response to PD-1/PD-L1 blockers** (but again, this remains to be confirmed with larger studies over a longer period).

3.2. Can't wait for 2017 ASCO!

Let's wait for further data at the 2017 ASCO congress before including the compound in our FV

We nonetheless stick to our cautious stance and continue to exclude utomilumab from our FV. The BMS data tend to confirm our view that 4-1BB/CD137 is indeed an attractive I-O target. But bear in mind the fact that “ure” and “uto” are very different in their constructs (the first being an IgG4 antibody while the second is an IgG2 with the ability to block the ligand binding to the receptor); and so far, we cannot say which one may yield the best efficacy/safety data.

Having said that, we will probably come around once further clinical data are published (be it in melanoma, or in another tumour type)... And hopefully some are likely to be presented at the next ASCO meeting in early June 2017.

4. Guselkumab: the first MOR candidate to reach the market

Guselkumab was one of the main pillars of our equity story on our initiation of coverage of MOR, and will remain so thanks to the recently strong dataset presented by Janssen. Now that the compound has been filed for approval in its primary indication (plaque psoriasis), we believe the risk-reward is much more attractive knowing that the stock is trading at a similar level than back when we initiated coverage.

Obviously, we now have to wait for FDA approval (BG: H2 17), but we think guselkumab's addressable market is much broader than simply plaque psoriasis and psoriatic arthritis. There is absolutely no certainty here, but we would not be surprised were JNJ to initiate more studies to test this candidate in gastrointestinal indications.

4.1. Blockbuster potential in plaque psoriasis

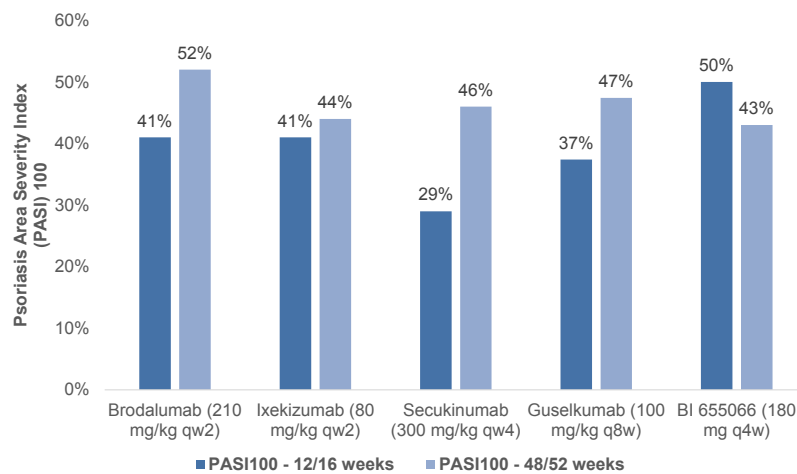
- **A competitive clinical package, and more patient-friendly administration**

The publication of positive Phase III results (VOYAGE 1) obviously de-risked our base-case scenario, especially since it showed that guselkumab could be 1/ as safe and potent as an anti-IL17 like NVS's Cosentyx; and 2/ administered much less frequently (every two months vs once-a-month). As importantly, Janssen's press release related to the BLA submission stated that the regulatory dossier included data from the two other late-stage trials (VOYAGE 2, NAVIGATE); meaning they are presumably positive, and probably in line with what we have previously seen.

FDA approval still needs to be obtained and, given the timing of the filing for approval, we believe the answer is likely to be given at the end of 2017 (no priority review was requested).

As potent and safe as recently approved anti-IL17s

Fig. 9: Guselkumab vs rivals – PASI 100 endpoint



Guselkumab: PASI 100 at week-16 and week-48 (vs 12 and 52 for the other compounds)

Source: Company data; Bryan, Garnier & Co. ests

Fig. 10: Guselkumab vs adalimumab – Safety profile – VOYAGE 1

	Placebo (n=174)	Guselkumab (n=329)	Adalimumab (n=333)
≥1 AE	49.4%	51.7%	51.1%
≥1 SAE	1.7%	2.4%	1.8%
Discontinued to ≥1 AE	1.1%	1.2%	0.9%
Infections	25.3%	25.8%	25.5%
Infections treated with antibiotics	7.5%	6.1%	7.2%
Serious infections	0.0%	0.0%	0.6%
MACE	0.0%	0.3%	0.3%
Non-melanoma skin cancer (NMSC)	0.0%	0.3%	0.0%
Malignancy other than NMSC	0.0%	0.0%	0.0%
≥1 Injection site reaction (ISR)	0.0%	2.4%	7.5%
Total number of injections	0	975	3,262
Injections with ISR	0.0%	1.1%	1.6%

Source: Company data; Bryan, Garnier & Co. ests

■ **We are sticking with our previous sales estimates**

We reiterate our EUR1.5Bn peak sales estimate regarding guselkumab (an anti-IL23p19) for the treatment of plaque psoriasis, as well as our recently increased 80% PoS.

Fig. 11: Guselkumab in plaque psoriasis - BG estimates

	2018	2019	2020	2021	2022	2023	2024	2025	2026
Psoriasis - Annual prevalence	21	21	21	21	22	22	22	22	22
- USA	6.5	6.6	6.6	6.7	6.8	6.8	6.9	7.0	7.0
- Europe	9.2	9.3	9.4	9.5	9.6	9.6	9.7	9.8	9.9
- ROW	5.1	5.2	5.2	5.3	5.3	5.4	5.4	5.5	5.5
% Plaque Psoriasis	80%								
% Moderate to severe disease	30%								
% Treated with biologics	20%								
Pricing per patient - US (USD)	35,000								
Pricing per patient - Europe & ROW (EUR)	20,000								
Guselkumab - Market shares - US (%)	1.0%	1.5%	2.5%	3.5%	4.0%	4.5%	5.0%	5.5%	6.0%
Guselkumab - Market shares - Europe (%)	0.5%	1.5%	2.5%	3.5%	4.0%	4.5%	5.0%	5.5%	6.0%
Guselkumab - Market shares - ROW (%)	0.0%	0.5%	1.5%	2.5%	3.5%	4.0%	5.0%	5.5%	6.0%
Guselkumab - Sales (EURm)	143	308	552	801	958	1,091	1,254	1,393	1,535
% var y-o-y	n/s	115.4%	79.1%	45.1%	19.5%	14.0%	15%	11%	10%

Source: Bryan, Garnier & Co ests

- **We are sticking with our cautious assumption of an annual cost net of rebates of USD35,000** (knowing that the list prices for JNJ's Stelara and NVS's Cosentyx currently stand at c. USD45,000) due to the pricing environment we foresee. Firstly, we believe that pharmacy benefit managers (PBM) are likely to ask for more discounts, especially since a range of alternatives are being introduced for the treatment of

plaque psoriasis and other auto-immune diseases (TNF- α inhibitors, anti-IL17s, and soon anti-IL23s)... Secondly, Novartis is likely to adopt an aggressive rebate policy to protect its hard-acquired position (“Hopefully in the time between now and then, we will have established a patient community. We will then fight with them (Amgen and Lilly) for market share, even if there’s pricing pressure” David Epstein, NVS’s former head of Pharma).

- **We also leave unchanged our market penetration** estimates (6% by 2026, knowing that we assume a fixed 20% rate of patients treated with biologics).

4.2. Psoriatic arthritis: another string to its bow

Psoriatic arthritis: here again, guselkumab looks as potent as IL17s

A few days ago, Janssen presented some very positive Phase II data involving guselkumab for the treatment of psoriatic arthritis (n=149 patients). Efficacy-wise, both ACR and PASI endpoints look very competitive with those seen with NVS’s Cosentyx (Mease *et al*, 2015; Mcinnes *et al*, 2014) with respectively 58% and 40% of ACR 20 and PASI 100 responders.

Obviously, further data are needed to confirm the potential of the compound in this novel indication, but these preliminary data are quite encouraging in our view. Fortunately, a Phase III program is very likely to be initiated next year... potentially leading to a second approval in 2019 or 2020 depending on the recruitment speed (and assuming the primary endpoint is based on a 24-week analysis).

Fig. 12: Guselkumab – Phase IIa data in psoriatic arthritis (Week 24)

Efficacy endpoints	Placebo	Guselkumab	p-value
ACR 20	18.4%	58.0%	p<0.001
ACR 50	10.2%	34.0%	p=0.002
ACR 70	2.0%	14.0%	p=0.023 (post-hoc)
PASI 75	12.5%	78.6%	p<0.001
PASI 90	6.3%	66.3%	p<0.001
PASI 100	6.3%	39.8%	p<0.001

Source: Company Data; Bryan, Garnier & Co ests.

Fig. 13: Ustekinumab – Phase III data in psoriatic arthritis (Week 24)

Efficacy endpoints	Placebo	Ustekinumab		
		300 mg	150 mg	75 mg
ACR 20	15.3%	54%*	51.0%*	29.3%****
- TNF-intolerant patients or with inadequate response	14.3%	45.5%****	29.7%	14.7%
- TNF-naïve patients	15.9%	58.2%****	63.5%****	36.9% ****
ACR 50	7.1%	35%***	35.0%	18.2%
ACR 70	1.0%	20.0%**	21.0%**	6.1%
PASI 75	16.3%	63.4%*	48.3%***	16.3%
PASI 90	9.3%	48.8%**	32.8%***	9.3%
* p<0.0001				
** p<0.001				
*** p<0.01				
**** p<0.01				

Source: Company Data; Bryan, Garnier & Co ests.

4.3. A potential extension to gastrointestinal diseases?

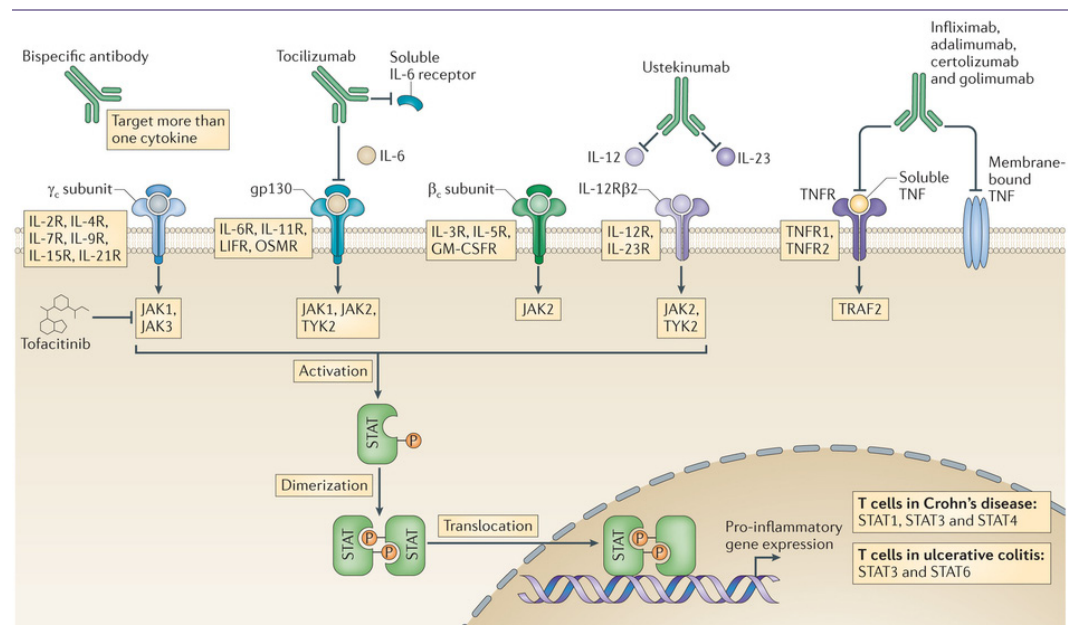
Ulcerative colitis and Crohn's disease as potential new indications?

We adopt a cautious stance here given the current competitive landscape

There is a chance that we and the street might be underestimating the potential of guselkumab in other auto-immune indications, and more precisely in gastrointestinal indications. An increasing number of pharma companies are developing their own IL23 antibodies, or have acquired rights through licensing deals. Interestingly, the focus is not restricted to plaque psoriasis and other dermatology-related indications. Lilly, for example, has initiated a Phase I/II trial to evaluate its IL23 candidate for the treatment of ulcerative colitis as well as Crohn's disease.

That said, we would advocate "cautious optimism" pending some efficacy data from the JNJ/MOR, LLY or AZN/AGN/AMGN compounds. Ulcerative colitis and Crohn's disease are two indications in which JAK inhibitors are being developed, and so far clinical packages are quite promising (Sandborn *et al*, 2012)... We would thus not be surprised to see these oral molecules grabbing a significant share of the pie, should the next clinical readout confirm their efficacy and safety profiles.

Fig. 14: Cytokines involved in inflammatory bowel disease (IBD)



Nature Reviews | Immunology

Source: Nature Reviews; Bryan, Garnier & Co. ests

5. Anetumab: ex-mesothelioma markets are significant free call options

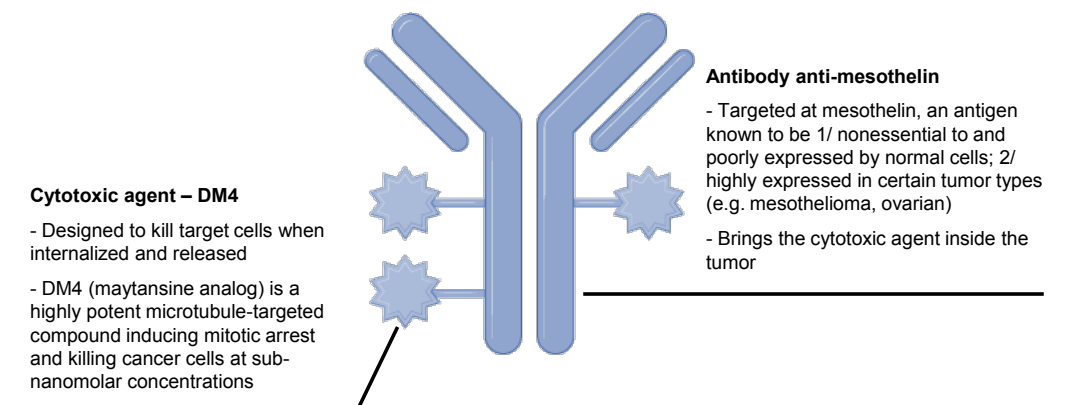
5.1. BAY sees a multi-billion blockbuster opportunity

BAY foresees peak sales of more than USD2.0n for anetumab

We have already reviewed Anetumab ravtansine, MOR/BAY's antibody drug conjugate directed against mesothelin, in our initiation report. Having said that, we only retained its first indication, i.e. mesothelioma, whereas its potential addressable market could be much larger than that... And that's probably why **BAY stated during its recent Investor Day that this compound could reach peak sales of more than USD2.0bn**. And yet, the stock has not really reacted to this statement.

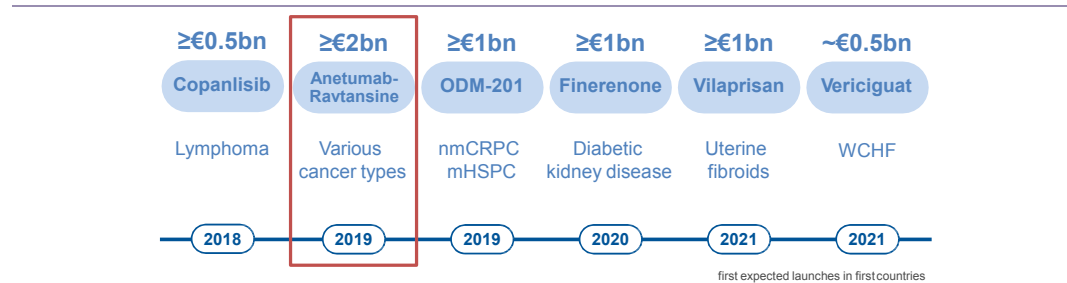
Admittedly, we lack hard numbers to really appreciate the true potential of this candidate... Still, 1/ the consensus seems to give very little value to this project, and 2/ we understand that some preliminary data will be presented in key medical congresses in the coming months. So we wanted to highlight the few elements we deem of importance; i.e. in which indications the compound has the best chances of success? Is the standard of care likely to change in the near future? Does it fit in this potentially changing landscape?

Fig. 15: Anetumab ravtansine – Mechanism of action



Source: Bryan, Garnier & Co. ests

Fig. 16: Bayer – Potential sales from pipeline products



Source: Bayer Meet the Management (2016)

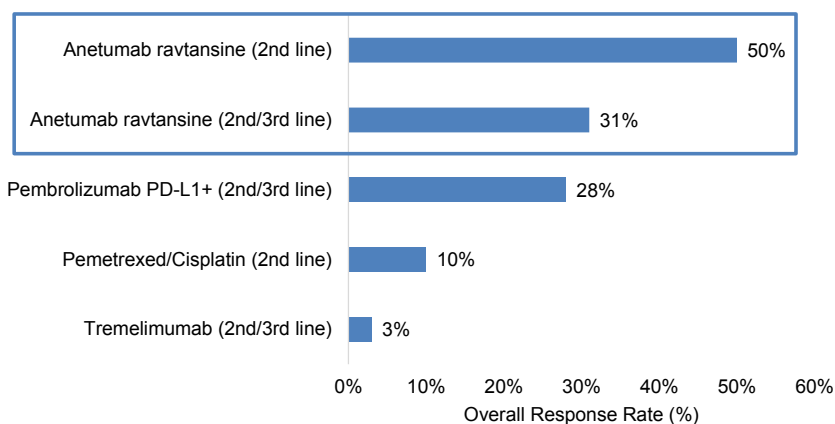
5.2. Strong preliminary dataset in mesothelioma

Before dealing with the other potential indications to be addressed with this compound, we would like to reiterate our positive bias on its development in mesothelioma. So far, our positive stance is based

Please see the section headed "Important information" on the back page of this report.

on data from a small Phase I (n = 16 patients). As always, comparing distinct trials is always tricky and could be misleading... but the response rates generated by anetumab in mesothelioma compare very favourably with I-O agents like MSD's Keytruda (see Fig. 17).

Fig. 17: Drug candidates in mesothelioma – ORRs



Source: Bryan, Garnier & Co. ests.

Fig. 18: Anetumab ravtansine – BG sales estimates (2019-2026e)

	2019	2020	2021	2022	2023	2024	2025	2026
Mesothelioma incidence	26,273	26,535	26,801	27,069	27,339	27,613	27,889	28,168
- USA	8,758	8,845	8,934	9,023	9,113	9,204	9,296	9,389
- Europe	10,303	10,406	10,510	10,615	10,721	10,829	10,937	11,046
- ROW	7,212	7,284	7,357	7,431	7,505	7,580	7,656	7,732
% Refractory/Relapse	60%							
% Advanced or metastatic	85%							
Pricing per patient - US (USD)	120,000							
Pricing per patient - Europe & ROW (EUR)	90,000							
Market shares - US (%)	5%	15%	25%	35%	40%	40%	40%	40%
Market shares - Europe (%)	0%	5%	15%	25%	35%	40%	40%	40%
Market shares - ROW (%)	0%	2%	7%	15%	20%	35%	40%	40%
Anetumab Ravtansine - Sales (EURm)	29	117	242	380	480	562	585	591
% var y-o-y		310%	106%	57%	26%	17%	4%	1%

Source: Bryan, Garnier & Co ests.

5.3. A solid rationale in other solid tumours... But let's wait for the data

5.3.1. A wide range of possibilities

Mesothelin: a tumour-associated antigen highly expressed by numerous solid malignancies

Mesothelin or MSLN is known to be **highly-expressed by a number of solid tumours** (virtually all pancreatic adenocarcinomas, and approximately 70% of ovarian cancers and 50% of lung adenocarcinomas).

Admittedly, MSLN is also present on normal mesothelial cells, but 1/ such expression is said to be relatively low; 2/ the biologic function of this antigen seems to be nonessential in normal tissues (Bera *et al*, 2000)... Thus ensuring a relatively favourable safety profile, and this has so far been reflected in the different clinical trials (Villena-Vargas *et al*, 2012).

Fig. 19: Mesothelin – Frequency and distribution pattern in solid malignancies

Indication	Level of expression	Total incidence (WW)
Oesophageal cancer	35-40%	480,000
Breast cancer	25-30%	1,400,000
Gastric cancer	50-55%	980,000
Pancreatic cancer	80-85%	280,000
Colon cancer	40-45%	1,200,000
Lung cancer	60-65%	1,600,000
Mesothelioma	85-90%	< 100,000
Ovarian cancer	60-65%	225,000

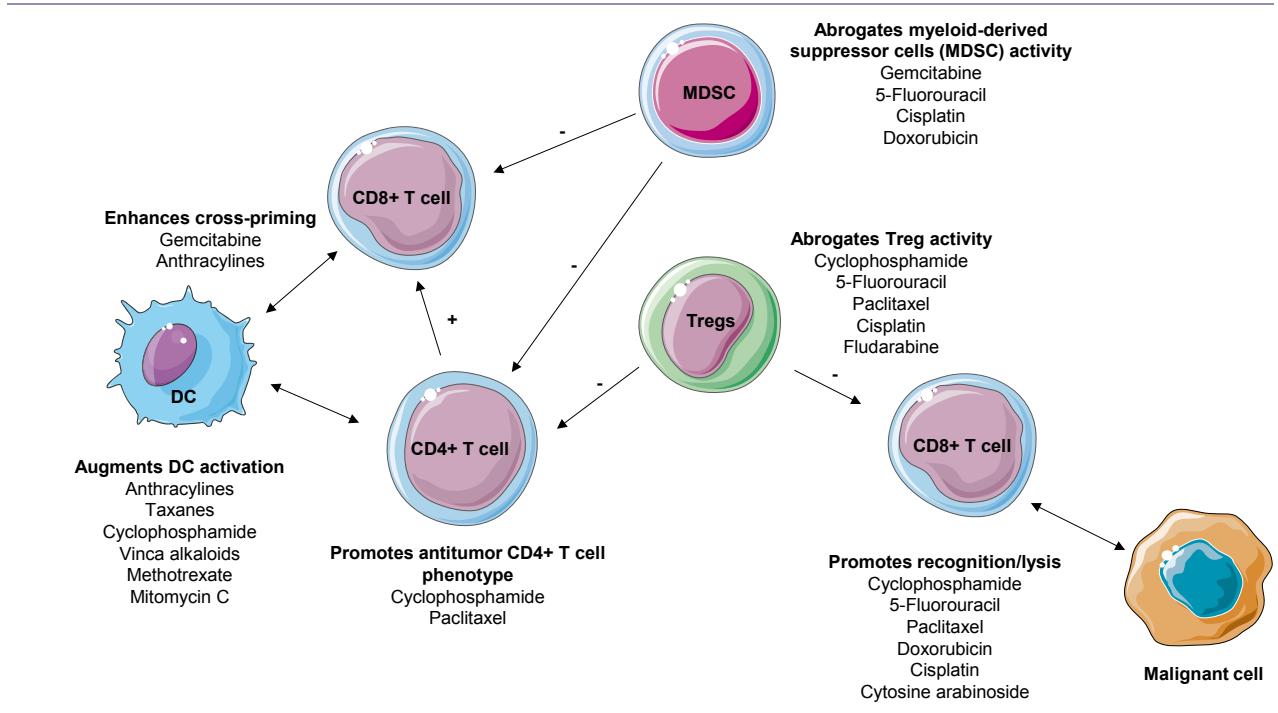
Source: Morello *et al*, 2016; Bryan, Garnier & Co. *ests*

Lung cancer: quite crowded with many I-O developments

Seven early/mid-stage trials are currently ongoing to evaluate the potential of anetumab in mesothelioma as well as in a range of solid tumours, and notably lung, ovarian and pancreatic adenocarcinomas. The current lack of clinical data naturally lean towards a cautious stance, but the therapeutic landscape is another factor to take into account.

We see lung cancer as an increasingly crowded market where both novel immunotherapies and so-called targeted therapies have significantly improved patient outcomes over the past few years. So the bar is rather high in our view. Having said that, note that DM-based ADCs might pretty well synergise with immunotherapies due to their potential ability to augment host immunity, and more precisely, though a better dendritic cell maturation (Muller *et al*, 2015; Martin *et al*, 2014). Plus, it remains to be determined if maytansinoids also enhance the immunogenic characteristics of cancer cells (similarly to the mechanisms induced by anthracyclines and oxaliplatin).

Fig. 20: How chemotherapies modulate tumour immunity



Source: Adapted from Emens et al. 2015, Bryan, Garnier & Co. ests.

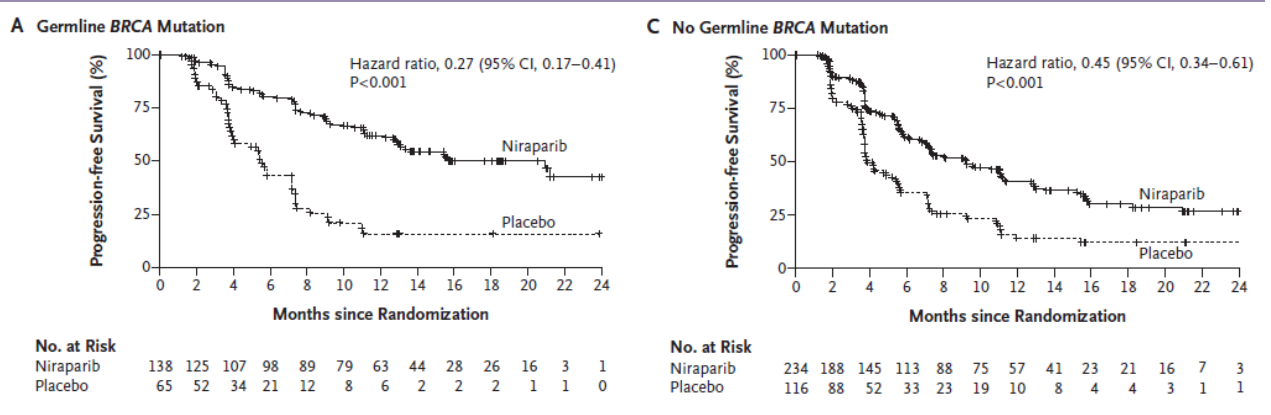
5.3.2. PARP inhibitors set the bar high in ovarian cancer

The story is a bit different regarding ovarian cancers as the competitive landscape is not so crowded... However, candidates like PARP inhibitors have set the bar high in our view, while others like IPH's monalizumab display a very promising mechanism of action.

PARP inhibitors are seen as strong competitors given the outstanding improvement in median PFS they generated 1/ in highly refractory/relapsed patients, and 2/ sometimes irrespectively of their BRCA status (although their mechanisms of action have primarily suggested they would much less potent in BRCA-positives), as seen with Tesaro's niraparib... although these oral molecules tend to be slightly less impressive in platinum-resistant patients (Fong *et al*, 2010).

So far, PARP inhibitors are mostly tested as single-agents in the maintenance setting. But we believe an increasing number of trials evaluating them with I-O and in germline BRCA-mutated carriers as their tumours are characterized by 1/ a higher mutational load, 2/ increased CD3+ and CD8+ tumor-infiltrated lymphocytes, and 3/ high levels of PD-L1 (Mittica *et al*, 2016). Plus, checkpoint blockers appear to be effective as monotherapies in ovarian cancer... As MRK's avelumab for instance induced c.17% responses in heavily pre-treated patients (median of four prior lines - Disis *et al*, 2016).

Fig. 21: Tesaro’s niraparib – Maintenance therapy in recurrent, platinum-sensitive ovarian cancer

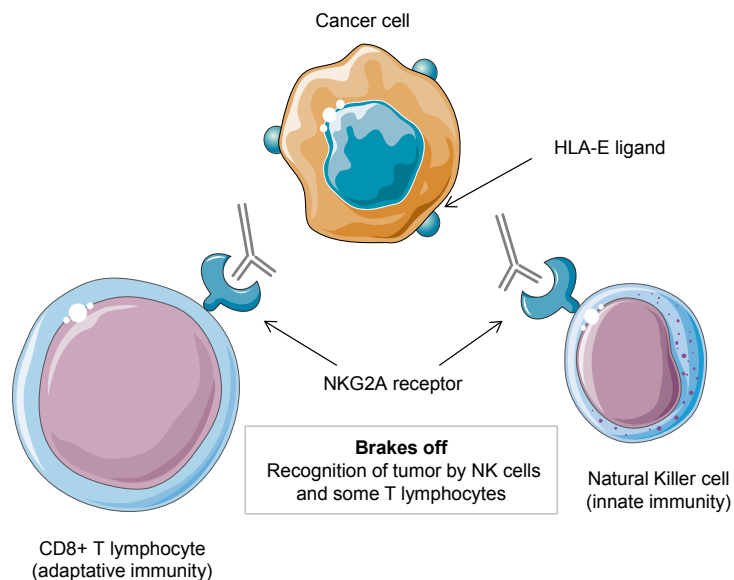


Source: Mirza et al, 2016; Bryan, Garnier & Co. ests

Apart from that, we also view Innate Pharma’s monalizumab as a promising candidate, particularly since recent data from another IPH candidate (lirilumab) confirmed that the addition of an immune checkpoint inhibitor targeting NK cells to a PD-1 agent could bring further efficacy with little additive toxicity.

Lirilumab and monalizumab are distinct molecules, as the first one binds with KIR while the other one targets NKG2A, and recently unveiled data involved another tumour type (HNSCC in this case). But “mona”’s mechanism is much more appealing in our view as 1/ NKG2A’s ligand (HLA-E) might act as a predictive marker, and potentially a more reliable one than PD-L1 (its potential overexpression being more diffuse and stable); 2/ its action probably comprises NK cells, as well as some T infiltrated lymphocytes. Last but not least, we see the development rationale as particularly appealing in this indication...with HLA-E being significantly expressed, whereas the tumor microenvironment includes numerous CD8+ TILs (and their anti-tumor capacity is probably restricted by the NKG2A receptors on their surface (Gooden et al, 2011)).

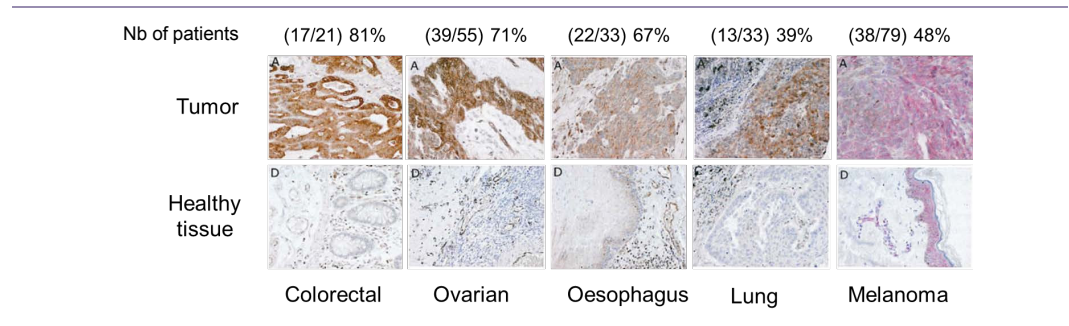
Fig. 22: Monalizumab – Mechanism of action



Source: Innate Pharma; Bryan, Garnier & Co. ests.

Please see the section headed “Important information” on the back page of this report.

Fig. 23: HLA-E : a potential marker of response to therapy in a wide range of tumors



Source: Innate Pharma

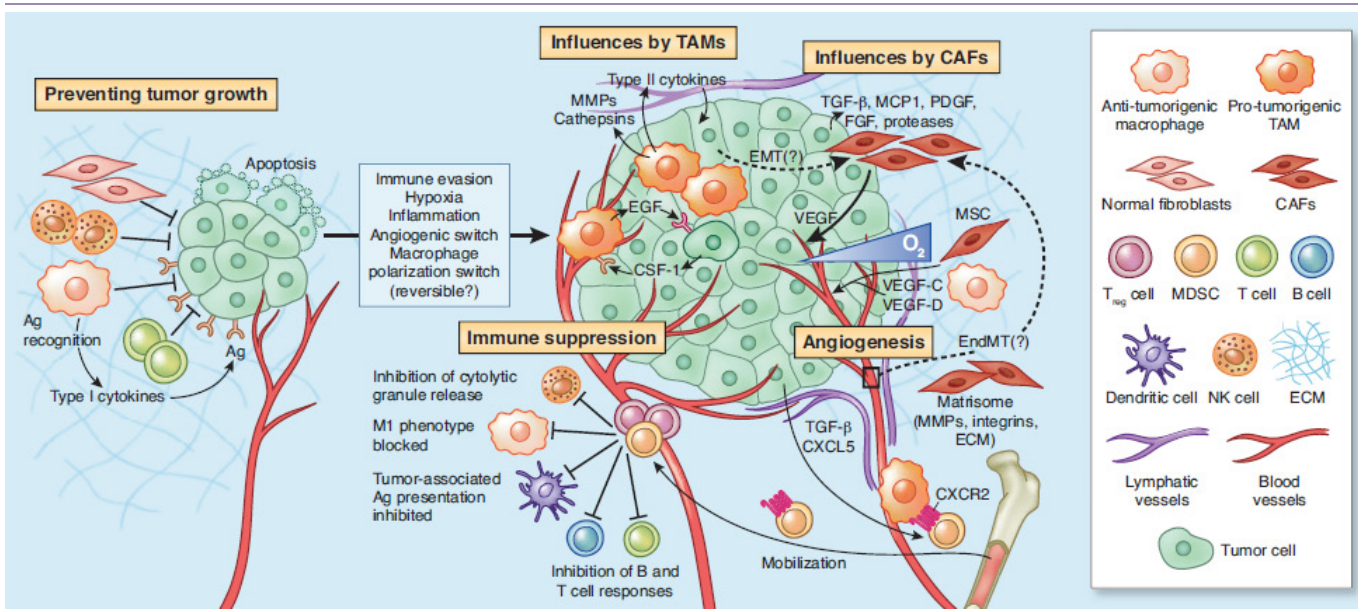
5.3.3. Pancreatic cancer: the most challenging indication

The microenvironment of pancreatic adenocarcinomas makes it challenging for both I-O and more traditional agents

Pancreatic cancer clearly is the most challenging indication in our view, particularly due to its microenvironment (TME)... so we would put relatively low expectations on this development. Both complex and in constant evolution, this TME is not only key in cancer growth/metastasis, but also serves a physical barrier to drug delivery. Many compounds have thus failed to bring a therapeutic benefit because of this; and unfortunately current lead I-O agents did not fare much better (Royal *et al*, 2010; Brahmer *et al*, 2012).

- Immune cells roughly make up for c.50% of the tumour mass, and immunosuppressive ones (e.g. Tregs, MDSCs) are predominant, which probably explain the fairly low presence of tumour-infiltrating cytotoxic lymphocytes.
- Pancreatic cancer is also characterized by the profusion of non-cellular components including proteinases, hyaluronic acid, collagen, collagen, etc. And such abundance is said to distort the normal architecture of pancreatic tissues, and induce an abnormal configuration of blood and lymphatic vessels impeding the delivery of drugs to cancer cells.
- So far, mostly non I-O agents have managed to improve patient outcomes with the disease. One of them is Celgene's Abraxane, which basically is a paclitaxel-loaded nanoparticle bound to human albumin (which by the way has the potential to be combined with a checkpoint blocker given its (hypothetical) ability to deplete certain elements within the tumour stroma).

Fig. 24: The tumour microenvironment (TME)



Source: Quail et al, 2013

Appendix

Fig. 25: Morphosys – Development pipeline (as of October 2016)

Program	Partner	Target	Indication	Clinical stage
Guselkumab	JNJ	IL23p19	Psoriasis	Phase III
Gantenerumab	Roche	Amyloid-β	Alzheimer's disease	Phase III
Anetumab Ravtansine	Bayer	Mesothelin (ADC)	Solid tumors	Phase II
BHQ880	Novartis	DKK-1	Multiple Myeloma	Phase II
BI-836455	BI	IGF-1	Solid tumors	Phase II
Bimagrumab	Novartis	ActRIIb	Musculoskeletal diseases	Phase II
BPS804	Mereo/Novartis	Sclerostin	Brittle bone syndrome	Phase II
CNTO3157	JNJ	TLR3?	Inflammation	Phase II
CNTO6785	JNJ	Nd	Inflammation	Phase II
MOR103	GSK	GM-CSF	Inflammation	Phase II
MOR202		CD38	Multiple Myeloma	Phase II
MOR208		CD19	Blood cancers (CLL, NHL)	Phase II
Elgemtumab (LJM716)	Novartis	HER3	Cancer	Phase II
Tarextumab (OMP-59R5)	Oncomed	Notch 2	Solid tumors	Phase II
Tesidolumab (LGF316)	Novartis	C5	Eye diseases	Phase II
Utomilumab (PF-05082566)	Pfizer	4-1BB	Solid tumors	Phase II
VAY736	Novartis	BAFF-R	Inflammation	Phase II
MOR209	Emergent	PSMA/CD3	Prostate cancer	Phase I
BAY1093884	Bayer	TFPI	Hemophilia	Phase I
MOR106	Galapagos	IL-17c	Atopic dermatitis	Phase I
NOV-7	Novartis	Nd	Eye diseases	Phase I
NOV-8	Novartis	Nd	Inflammation	Phase I
NOV-9	Novartis	Nd	Diabetic eye diseases	Phase I
NOV-10	Novartis	Nd	Cancer	Phase I
NOV-11	Novartis	Nd	Blood disorders	Phase I
NOV-11	Novartis	Nd	Prevention of thrombosis	Phase I
Vantictumab	Oncomed	Fzd7	Solid tumors	Phase I
MOR107		AT2-R	Fibrosis	Preclinic
Immuno-oncology program	Merck KGaA	Nd	Cancer	Preclinic
Immuno-oncology program	Immatics	Nd	Cancer	Preclinic
6 MOR programs			Various	Preclinic

Source: Company Data; Bryan, Garnier & Co ests.

Price Chart and Rating History

Morphosys



Ratings

Date	Ratings	Price
13/06/16	BUY	EUR44.347

Target Price

Date	Target price
18/11/16	EUR65
03/10/16	EUR64
13/06/16	EUR62

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NEUTRAL	Opinion recommending not to trade in a stock short-term, neither as a BUYER or a SELLER, due to a specific set of factors. This view is intended to be temporary. It may reflect different situations, but in particular those where a fair value shows no significant potential or where an upcoming binary event constitutes a high-risk that is difficult to quantify. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.
SELL	Negative opinion for a stock where we expect an unfavourable performance in absolute terms over a period of 6 months from the publication of a recommendation. This opinion is based not only on the FV (the potential downside based on valuation), but also takes into account a number of elements that could include a SWOT analysis, momentum, technical aspects or the sector backdrop. Every subsequent published update on the stock will feature an introduction outlining the key reasons behind the opinion.

Distribution of stock ratings

BUY ratings 55.1%

NEUTRAL ratings 33.5%

SELL ratings 11.4%

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