BRYAN, GARNIER & CO

25th June 2019

GALAPAGOS

BUY

Fair Value	**EUR140 (+24%)**
Share price	EUR112.70
Bloomberg / Reuters	GLPG BB/GLPG.BR

Healthcare | **Biotech**

(MANTA) With or Without You

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13-week data from MANTA likely to be required by the FDA. While Gilead strengthened its case with the FINCHes trials and has been increasingly vocal on the overall risk-benefit profile of filgotinib, the FDA's upfront request for testicular toxicity data makes it unlikely that it will forego the results of the MANTA study.

Our base case scenario, which reflects the use of a PRV, implies a balanced risk profile (-8%/+4%) on the outcome of the pre-BLA meeting. Beyond the impact on our valuation, MANTA has been a hangover for the share price. As such, the mere validation of our base case scenario should provide significant relief for the shares. Moreover, we would expect a filing in Europe in Q3 2019.

MANTA unlikely to show testicular toxicity. The design of the MANTA trial set a low bar for the trial to succeed in our view. Based on observations from previous trials and the literature on JAKs, we see no evidence that filgotinib could trigger safety concerns for human testis. If there is an impact, the possible mention of testicular toxicity in the label should not lead to a black box warning.

As commercial strategies unfold, we see filgotinib as a clear winner. Filgotinib should be the only JAK to benefit from two doses, which physicians prefer in practice. It also addresses the safety shortcomings of other players in the space.

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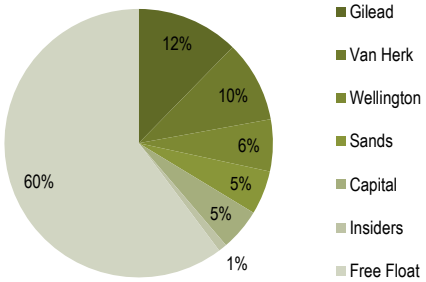
Share price	**EUR112.70**
Market Cap.	**EUR6,155m**
EPS 3Y CAGR	**NM**

Shareholders



Income Statement (EURm)	2016	2017	2018	2019e	2020e	2021e
Revenues	152	156	318	113	189	171
Change (%)	150%	3%	104%	-64%	68%	-10%
Adjusted EBITDA	-	-	-	-	-	-
EBIT	-11	-90	-45	-182	-108	-75
Change (%)	-87%	681%	-50%	306%	-41%	-30%
Financial results	66	-26	18	4	3	3
Pre-Tax profits	54	-116	-29	-178	-105	-73
Exceptionals	-	-	-	-	-	-
Tax	0	0	0	0	0	0
Profits from associates	-	-	-	-	-	-
Minority interests	-	-	-	-	-	-
Net profit	54	-116	-29	-178	-105	-73
Restated net profit	54	-116	-29	-178	-105	-73
Change (%)	-	-314,2%	-74,7%	-507,6%	-41,1%	-30,4%
Cash Flow Statement (EURm)						
Operating cash flows	5	-69	-12	-175	-101	-69
Change in working capital	-269	314	55	28	-150	14
Capex, net	-4	-5	-10	-10	-10	-10
Financial investments, net	396	353	288	0	0	0
Dividends	0	0	0	0	0	0
Other	-	-	-	-	-	-
Net debt	-970	-1,148	-1,287	-939	-816	-711
Free Cash flow	-	-	-	-	-	-
Balance Sheet (EURm)						
Tangible fixed assets	15	17	23	28	34	39
Intangibles assets	1	2	4	6	8	10
Cash & equivalents	973	1,151	1,291	943	821	716
current assets	34	46	38	38	38	38
Other assets	60	69	84	84	84	84
Total assets	1,083	1,286	1,439	1,100	984	887
L & ST Debt	107	175	224	72	72	67
Others liabilities	217	99	2	-11	-21	-40
Shareholders' funds	759	1,012	1,214	1,038	933	861
Total Liabilities	1,083	1,286	1,439	1,100	984	887
Capital employed						
Financial Ratios						
Operating margin	-7,6%	-57,6%	-14,1%	-161,1%	-56,8%	-44,1%
Tax rate	-	-	-	-	-	-
Net margin	35,6%	-74,2%	-9,2%	-157,5%	-55,3%	-42,6%
ROE (after tax)						
ROCE (after tax)						
Gearing						
Pay out ratio	0,0%	0,0%	0.0%	0.0%	0.0%	0.0%
Number of shares, diluted	36	47	50	54	54	54
Data per Share (USD)						
EPS	1,14	-2,33	-0.56	-3.41	-2.01	-1.40
Restated EPS	1,14	-2,33	-0.56	-3.41	-2.01	-1.40
% change	-	(304%)	(76%)	(508%)	(41%)	(30%)
BVPS	-	-	-	-	-	-
Operating cash flows	0,11	-1,39	-0.23	-3.36	-1.94	-1.32
FCF						
Net dividend	0,00	0,00	0.00	0.00	0.00	0.00

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

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EXECUTIVE SUMMARY

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13-week data from MANTA likely to be required by the FDA. While Gilead strengthened its case with the FINCHes trials and has been increasingly vocal on the overall risk-benefit profile of filgotinib, the FDA's upfront request for testicular toxicity data makes it unlikely that it will forego the results of the MANTA study.

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Gilead est sur le point de rencontrer la FDA pour discuter des données des études FINCH et du timing de la soumission du filgotinib. Les conclusions de ce meeting seront communiquées très prochainement.

Nous pensons que la FDA va réclamer les données à 13 semaines de l'étude MANTA. Les résultats des études FINCH ont conforté la position de force de Gilead en amont de son meeting de pré-soumission avec la FDA. Néanmoins, la demande préalable de la FDA pour des données de toxicité testiculaire rend peu probable selon nous qu'elle se passera des données de l'étude MANTA avant de se prononcer sur l'approbation du filgotinib.

Notre scenario de base représente un profil de risque équilibré (-8%/+4%) sur les conclusions du meeting avec la FDA. Au-delà de l'impact sur la valorisation, l'incertitude relative à la nécessité de cette étude pour la soumission du dossier à impacté le cours de l'action. La validation de notre scénario de base permettrait une réappréciation du cours. D'autre part, la soumission du dossier en Europe au T3 2019 représente un catalyseur.

Faible probabilité que l'étude MANTA démontre une toxicité testiculaire. Les objectifs bas fixés par l'étude renforcent son potentiel succès. Notre revue des précédentes études de ce type et de la littérature scientifique n'apporte pas de preuve sur la toxicité du produit à des doses utilisées chez l'humain. Si cela devait être le cas, le pire scénario entrainerait la mention de ces effets dans le label (pas de « black box warning »).

Alors que les stratégies commerciales vont se préciser, nous voyons filgotinib bien positionné. Ce dernier devrait être le seul de sa classe commercialisé à deux doses, une proposition favorisée par les médecins et bénéficie d'un profil de sécurité d'emploi nettement supérieur aux produits concurrents.

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Part 1: MANTA: burning questions

When should we expect the results?

13 weeks data by year-end 2019

Following observations of testicular toxicity in preclinical studies, the FDA requested that the testicular safety of filgotinib be evaluated in men. Two trials with observational safety endpoints at 13 weeks are now ongoing: MANTA and MANTA-RAy.

One of the key hurdle of the MANTA trial, initiated in July 2017 and aiming at recruiting c.250 patients suffering from ulcerative colitis (UC) was its recruitment pace. Several studies ongoing in UC (filgotinib SELECTION trial, SHP647, etrolizumab, mirikizumab) with less restrictive criteria made it hard for GILD/GLPG to recruit in the US and in Europe. Recently however, the recruitment was eased by the opening of several centres in Eastern Europe (Ukraine, Russia) and APAC (India), now representing more than half of the 135 active centres and expected to recruit around two-thirds of patients. Our understanding is that it took time for these centres to comply with the FDA's requirements (e.g. central reading). We are expecting the results by YE19.

In April, Gilead initiated the MANTA-RAy trial, which has the same objectives as the MANTA trial while broadening the recruitment to patients suffering from rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS) and non-radiographical axial spondyloarthritis (nr-aSpA). Broadening the inclusion criteria to other diseases is another way of reducing recruitment hurdles in the MANTA trial.

Fig. 1: MANTA trial : opened centres and expected distribution of patients (BGe)

Sources: clinicaltrial.gov; clinicaltrialsregister.eu; ctri.nic.in; Bryan, Garnier & Co ests.

While Gilead indicated that the results of the MANTA trial will not be required to file with the EMA in Q3 2019, it is still unclear however whether they will be needed to file with the FDA. We would expect Gilead to update on the US filing timeline once it has met the FDA in coming weeks in the context of a pre-BLA meeting.

Will MANTA be needed for FDA filing?

MANTA 13 weeks data will be needed

While the FDA's stance on the requirement for testicular toxicity studies to be submitted alongside the filing has long been flexible and obliging, it was hardened in October 2018 with the issuance of industry guidelines for the evaluation of testicular toxicity during drug development.

Although non-binding, these guidelines recommend conducting a dedicated safety study ahead of or in parallel to the phase III trial, especially if the drug does not belong to a class with known effects on the testes but for which an effect has been seen in preclinical models, which is the case of the JAK class. Note also that the FDA's guidelines also recommend a testicular safety trial should be conducted in subjects representing the population for whom the drug is intended. This might also be a reason that prompted Gilead to initiate the MANTA-Ray trial in May 2019 in our view.

Considering the FDA's upfront requested for MANTA, we doubt that the regulatory agency will forego the results of the study before ruling on the application for approval. However, Gilead's position has strengthened ahead of its pre-BLA meeting with the FDA following the readout of the FINCHes trials showing the best-in-class profile of filgotinib.

Recent comments from Gilead's CEO at a conference in early June highlighted the confidence of the management in the overall risk-benefit profile of filgotinib.

- *"In US, […] it will be the first time we'll be dialoguing with the FDA in the near term to talk about the totality of the data set. So the entirety of the safety profile associated with the efficacy that we're seeing across different doses and different treatment paradigms and we will [Gilead] come back to you [The Street] in the second half of this year with the outcome of those discussions, but we remain optimistic and confident about the path forward also in the US".*

- *"I think with any medicine and any discussion with the regulator, you have to look at the benefit risk profile in totality. And I think in my experience that's the way, the FDA has always looked at medicines and products and so we need to have that discussion. But yes, I do think one needs to look at the total benefit of that product and put certain early preclinical signals into context".*

In all, we believe that the best-in-class profile of filgotinib should ease discussions with the FDA during the pre-BLA meeting and ultimately enable the filing of filgotinib with 13-week data from the MANTA trial at hand. 24-week data is to be submitted post approval.

What is the review timeline?

Use of a voucher should not be ruled out
Balanced risk-reward on upcoming communication

Our base case scenario in which only 13-week data from the MANTA trial (readout late 2019) is needed for filing implies that the submission of filgotinib in RA should be finalised by early 2020.

Considering the opportunity that there is for filgotinib in this space, asserted by the changes in competitive landscape discussed in Part.2, we now believe that it would make sense for Gilead to use a voucher and cut the review timeline from 10-12 months down to 6-9 months. The use of a voucher would require Gilead and the FDA to agree on a timeline ahead of the beginning of the submission process. This would allow Gilead to include the 13-week findings from MANTA in the registration file. If the FDA requires the full dataset from MANTA, which should be available in H2 2020 (BGe), using a voucher may no longer make sense.

Fig. 2: Filgotinib filling and approval timelines scenarii

	Worst Case	Base Case	Blue Sky
MANTA required?	24 week data	13 week data	Not required
Filing completion	late 2020/early 2021	early 2020	H2 2019
Voucher	No	Yes	Yes
Review timeline	10-12 months	6-9 months	6-9 months
Approval	late 2021	H2 2020	mid-2020
Impact on BGe Valuation	**-8%**	**n/a**	**+4%**

Sources: Bryan, Garnier & Co ests.

The table above suggests a relatively balanced risk-reward on the outcome of the upcoming pre-BLA meeting. Beyond the impact on our valuation, MANTA has been a hangover for the share price recently (trading range EUR100-112). As such, validating the base case scenario would not impact our valuation but should offer significant relief to the shares in our view.

While this note discusses the registration file, the FDA review process and the timeline to get filgotinib approved in the US, the European opportunity should not be dismissed. We are expecting the filing with the EMA in Q3 2019 to be a strong catalyst.

Will we see testicular toxicity?

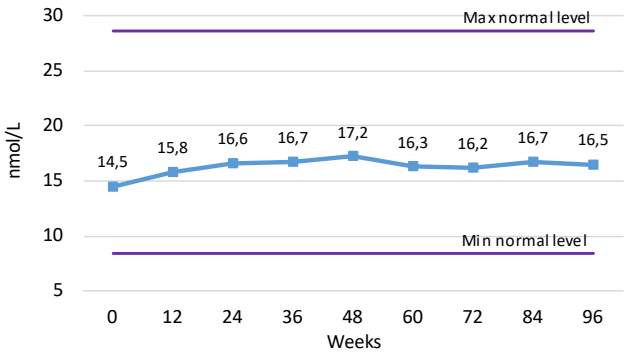
Hard to predict, yet unlikely in our view

The MANTA and MANTA-Ray trials are designed to assess the statistical difference vs placebo for patients with a ≥50% decrease in sperm count compared with the baseline and powered for 20-30% non-inferiority margin. We see the latter as wide, thereby increasing the likelihood of success of the MANTA trial. In preclinical models (rats and dogs), a sperm count decrease was observed at levels slightly higher than the 200mgBID dose used in the FINCHes studies. As per the MANTA consent form, while sperm counts in preclinical models reversed at these doses, they remained low overall and did not return to normal. At the dose equivalent to the 200mg daily human dose they were no effects seen in the testes of rats and dogs.

- It is worth mentioning that performance of animal testing in predicting spermatotoxicity is quite poor. Indeed, among the 235 FDA-approved drugs that were reported to be spermatotoxic in animals, only 26% had negative effects in humans. This could be explained by the high sensitivity of some clinical models, dogs especially, to spermatotoxicants and/or by sperm concentration, which may vary by as much as 39% in individuals (*Mangelsdorf I. et al, 2002*).

- Although there is no correlation between low testosterone and sperm count, the low impact of filgotinib in phase II and in the FINCH-2 trial on testosterone levels suggests a low impact on spermatogenesis.

Fig. 3: Total testosterone (measured in males recruited in DARWIN studies)



Sources: Galapagos.

- While FDA-approved drug labels indicated that several anti-inflammatory drugs have affect spermatogenesis, this is not supported by peer-reviewed literature and we could not find studies on the impact of hitting JAK-1 on sperm count decrease. Note that tofacitinib (JAK 1 and 3 inhibitor) has no effect on male fertility, sperm motility or concentration at exposure levels approximately 133 and 67 times the recommended doses of 5mgBID and 10mgBID respectively.

- We would not expect the results from the MANTA trial to be impacted by sulfasalazine use (oral frontline medication in IBD and other inflammatory diseases). Exclusion criteria in the MANTA and MANTA-Ray trial specifies that sulfasalazine (oral frontline medication in IBD and other inflammatory diseases) is not permitted for 26 weeks (two spermatogenic cycles) before and during the trial. Sulfasalazine is known for having an impact on sperm count, albeit reversible.

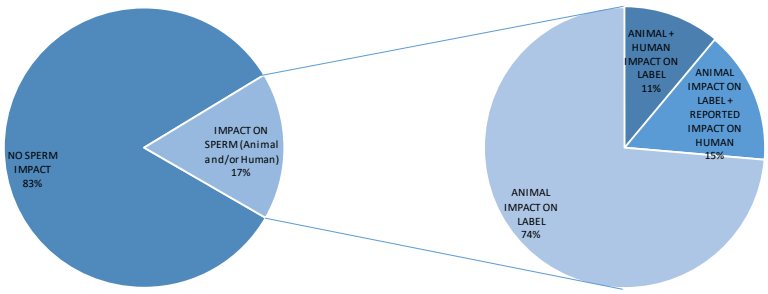
The design of the MANTA trial set a low bar for the trial to succeed in our view. Based on observations from previous trials and literature on JAKs, we see very limited if no evidence on the impact of JAK on spermatogenesis, especially at levels in humans that would trigger safety concerns. Beyond broadening the body of clinical evidence that could potentially be required by the FDA, we believe the launch of the MANTA-Ray trial with a similar design to that of MANTA is a sign of confidence from Gilead on the testicular toxicity profile of filgotinib.

What impact on the label from potential testicular toxicity?

Mention on label without black box warning

Literature shows that only 26% of single-active ingredient FDA-approved drugs with a known impact on sperm in animals have shown an impact on testis in human and only 11% have this impact reported in their label.

Fig. 4: : Single-active ingredient FDA-approved drugs, clinically prescribed.



Sources: J Assist Reprod Genet. 2018 Feb; 35(2).

Only a few products for which there is a good level of evidence of an impact on spermatogenesis and sperm parameters have guidelines related to these issues. If the results of the MANTA study show that filgotinib has an effect on spermatogenesis, not only it is unclear whether the FDA will update the label accordingly, but it is also very unlikely that this will prompt a black box warning in our view.

To our knowledge, two black box warnings have been issued by the FDA for drugs having shown an impact on spermatogenesis, Tracleer (bosentan) and Volibris/Leitaris (ambrisentan), indicated in PAH and approved in 2001 and 2007 respectively. Following the submission of bosentan's testicular toxicity data to the FDA in 2009, its label was updated with a warning for decreased sperm count. Bosentan decreased sperm count by at least 50% in 25% of patients at 3 and 6 months. Based on bosentan data, ambrisentan's label (same endothelin receptor antagonist class), was updated in 2011.

Moreover, we would not expect physicians and patients to be particularly sensitive to the potential testicular toxicity profile of filgotinib which has yet to be proven. Indeed, first-line treatments in inflammatory and IBD diseases such as 5-ASA, IL-6 and TNFα are known for impairing fertility.

If MANTA shows testicular toxicity, we would expect it to be mentioned in the drug label upon approval. However, we do not anticipate a black box warning. In all, this is not likely to hold back sales and trigger reluctance in prescribing and using the product among physicians and patients respectively.

Part 2: All bets on filgotinib as commercial strategies will unfold

Xeljanz' recent safety setback

In a post-marketing trial of Pfizer's Xeljanz (tofacitinib) carried out in RA patients, a higher rate of pulmonary embolism was reported by a DSMB for the 10mg dose. This prompted a switch of all patients in the high dose group to the 5mg dose. We believe that this setback is likely to affect the roll-out of Xeljanz in ulcerative colitis as both doses (5mg and 10mg) have been approved in this indication.

Olumiant seven-year safety data unlikely to move the needle

Seven year safety data for LLY's baricitinib at the 4mg - high-dose - presented at EULAR (#THU0078) went down well. While baricitinib is already approved at the 2mg dose this new data from the 4mg dose might prompt LLY to re-file it with the FDA.

However, we note that the seven-year data shows an imbalance on DVT/PE events (0% placebo vs 1.3% baricitinib 4mg) and do not believe that they will help to alleviate the FDA's concerns on the safety profile of baricitinib. We see its use still constrained to the last line.

If this is not the case, using a voucher for filgotinib in RA could help Gilead to be the first JAK to reach the RA market with two doses or to be approved more or less within the same timeframe as baricitinib 4mg dose.

Upadacitinib may lack a second dose and a superiority claim

ABBV's upadacitinib 15mg dose has been filed with the FDA. Upadacitinib benefits from a priority review and should be approved around August 2019. This drug is the most serious competitor to filgotinib as ABBV's commercial strategy will unfold following a launch expected in late 2019.

- ABBV has a large sales force dedicated to Humira which is likely to push patients to switch to upadacitinib before the loss of exclusivity on the former in 2023.
- Upadacitinib demonstrated a superiority to adalimumab in phase III trial.

However, it is far from being a one-horse race in our view.

- **Availability of two doses is a clear advantage**. KOLs stress the importance of having two doses to better address low- and high-disease activity patients. Being able to lower the dose upon the emergence of AEs is also part of most physicians' practice. Hence, the availability of filgotinib in two doses (100mgBID and 200mgBID), which have shown a nice dose-response profile should better fit into physicians' practice.

- **Most physicians see upadacitinib and filgotinib efficacy in the same bulk part**. In clinical trials, we have seen upadacitinib yielding responder rates slightly better than filgotinib when adjusted for placebo e.g. placebo-adjusted ACR70 responder rates stood at 21% and 25% for filgotinib 200mgBID (FINCH-1 trial) and upadacitinib 15mgQD (SELECT-COMPARE) respectively. KOL feedback suggests that a <5pp difference is not seen as key in the choice for a therapy. Moreover, we note that most US prescribers are looking at absolute scores as opposed to placebo-adjusted score for KOLs. In terms of absolute ACR scores, filgotinib yielded higher results than upadacitinib with ACR20, ACR50 and ACR70 of 78%, 58% and 36% vs 67%, 54% and 35% for filgotinib 200mgBID (FINCH-1 trial) and upadacitinib 15mgQD (SELECT-COMPARE) respectively.

- **ABBV will not be able to claim upadacitinib's superiority over adalimumab**. Despite having shown a superiority to adalimumab in the SELECT-COMPARE trial, it is our understanding that a dedicated head-to-head trial would be needed to claim superiority of upadacitinib over adalimumab and have it in its label.

- **Safety profile remains the key to unlocking the JAK market in our view**. Filgotinib has a better safety profile compared with upadacitinib, notably on serious infections and herpes zoster.

Ultimately, we see filgotinib and upadacitinib as clear leaders in the RA JAK market. As US payers generally put two molecules of the same class on their lists, the safety profile of filgotinib should help Gilead to get it on US payer's lists alongside upadacitinib. Discussions with physicians and management are reassuring in terms of filgotinib's sales prospects. We reiterate our peak sales estimate of EUR6bn, of which EUR2.5bn to be streamed from the RA indication.

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For the purposes of this Report, the Bryan Garnier stock rating system is defined as follows:

Stock rating

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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.

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BUY ratings 50,6% NEUTRAL ratings 42,6% SELL ratings 6,8%

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IMPORTANT INFORMATION