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Galapagos NV

GLPG – NASDAQ; GLPG – NA

July 10, 2020

Biotechnology

HOLD

TRANSFER OF COVERAGE

Financial Summary

Changes	Previous	Current
Rating	Buy	Hold
Target Price	$298.00	$193.00
FY20E Revenue	€630.8	€590.0
FY21E Revenue	—	€675.0

Price (07/09/20):	$201.07
52-Week Range:	$274 - $112
Market Cap.(mm):	13,069.6
Shr.O/S-Diluted (mm):	65.0
Avg Daily Vol (3 Mo):	99,700
Dividend / Yield:	$0.00 / 0.0%
Cash (mm):	€5,781

Revenue	2019A	2020E	2021E
Q1	€40.9	€106.9A	€NE
Q2	€67.6	€100.0	€NE
Q3	€644.0	€101.0	€NE
Q4	€143.2	€282.0	€NE
FY (Dec)	€895.9A	€590.0	€675.0

EPS IFRS	2019A	2020E	2021E
Q1	(0.89)	(0.78)A	NE
Q2	(0.86)	(0.87)	NE
Q3	5.83	(0.98)	NE
Q4	(1.79)	1.54	NE
EPS IFRS	2.49A	(1.07)	(0.41)

Price Performance

Downgrading To Hold As Shares Look Fairly Valued And We Expect Limited Upside From The Pipeline In The Near Term

Summary

In conjunction with our GLPG transfer of coverage, we are downgrading shares to Hold and lowering our target price to $193. Our downgrade is predicated on: (1) an unfavorable stock setup ahead of filgotinib US/EU approval in rheumatoid arthritis (RA) as we think the chance of it receiving a meaningfully differentiated label within the JAK class is low; (2) we are cautious on GILD (NC, $74.71)/GLPG's ability to deliver filgotinib sales ahead of consensus estimates between 2020-2025 which to us seem high; and (3) while we are positive on GLPG's pipeline and its long-term prospects, we don't see any major, near-term catalysts from the pipeline that would sufficiently offset our commercial concerns. While there is a lot to like here given GLPG's meaningful cash position and robust R&D engine, we would seek a better entry point.

Key Points

The next upcoming catalyst for shares will be US/EU approvals for filgotinib in RA and whether it can gain any meaningful differentiation from the other JAKs. Since ABBV's Rinvoq received a block box warning, our base case (POS: 75%) assumes filgotinib receives a similar JAK class black box warning but that both the 100mg and the 200mg doses are approved. We think this scenario is being priced into the stock and only see modest upside on approval. Our bear case (POS: 20%) assumes a JAK class black box, approval of only the 100mg dose and potential warnings for testicular toxicity. The FDA could take a similar conservative approach as it did with LLY's (NC, $166.45) Olumiant and ABBV's Rinvoq approving only the lower dose given JAK adverse events appear to be dose dependent. In this scenario, we think shares could be down 20% as filgotinib could see less utilization than what consensus is forecasting. Lastly, our bull case (POS: 5%), which we don't think is very likely, would be if filgotinib did not receive a JAK class black box warning and both doses were approved. We think shares could be up 30-35% in this scenario.

The consensus filgotinib sales ramp looks aggressive, and we take a more conservative view. First off, we believe filgotinib is likely to be a major player in the JAK class and will generate billions in peak sales as it continues to gain approval in additional inflammatory indications. With that said, early consensus estimates look high, particularly given the fact GILD and GLPG will be competing against commercial heavyweights ABBV and PFE (NC, $33.46), with a fourth to market JAK that may or may not have a meaningfully differentiated label. Our KOL checks in RA, ulcerative colitis and Crohn's disease all spoke favorably of the JAK class but largely viewed the efficacy and safety of the four treatments as similar. Several KOLs positively highlighted ABBV's commercial strategy for Rinvoq saying it is "running the Humira playbook," securing prime formulary placement and providing solid, low-cost patient access. Based on our analysis of the previous JAK launches, we believe the filgotinib launch will be slower than Rinvoq but could be better than Olumiant and Xeljanz which we think is less optimistic than current consensus forecasts suggest.

We don't anticipate major stock moves on positive potential readouts in the 2H20. For ziritaxestat in scleroderma, we are most interested in the secondary endpoints and whether improvements on lung function (i.e. FVC) are seen which we think would translate positively for ziritaxestat's Phase 3 in IPF. Yet, its unclear if GLPG will report this data with the top line. For GLPG1972 in osteoarthritis, the novel primary endpoint being used will be informative but improvement on the traditional WOMAC score, a secondary endpoint, is more important for approval. If the trial is positive, GILD could opt-in and GLPG could receive up to a $450 million milestone.

Where could we be wrong? We could be under appreciating GILD/GLPG's ability to ramp filgotinib sales faster than consensus and its possible investors could be willing to assign more pipeline credit based on the upcoming read outs than we are.

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All relevant disclosures and certifications appear on pages 26 - 28 of this report.

Investment Thesis

Our thesis is predicated on: (1) unfavorable stock setup ahead of filgotinib US/EU approval in rheumatoid arthritis (RA) as we think the chance of it receiving a meaningfully differentiated label within the JAK class is low. (2) we are cautious on GILD (NC, $76.42)/GLPG's ability to deliver filgotinib sales ahead of consensus estimates between 2020-2025 which to us seem high; and (3) while we are positive on GLPG's pipeline and its long-term prospects, we don't see any major, near-term catalysts from the pipeline that would sufficiently offset our commercial concerns. While there is a lot to like here given GLPG's meaningful cash position and robust R&D engine, we would seek a better entry point.

Target Price Methodology/Risks

Our target price for GLPG shares is $193. This is based on a probability-weighted, risk-adjusted NPV analysis which assigns 75% odds of our base case of $196, 20% odds of our bear case $159 and 5% odds of our bull case $274. In our base case we assign $75, $4, $10, $2, $5 for filgotinib, GLPG1690, GLPG1972, Other revenue, Other pipeline, respectively. We assign $100 of value for cash.

Risks: Underperforming filgotinib consensus sales, failures from the pipeline, delays from the pipeline, competition.

Company Description

Galapagos is a clinical-stage biotechnology company specialized in the discovery and development of disease modifying, small molecule medicines with novel mechanisms of action. The pipeline includes clinical candidates focused on rheumatoid arthritis, inflammatory bowel disease, idiopathic pulmonary fibrosis, osteoarthritis, and atopic dermatitis. Lead assets include filgotinib (partnered with Gilead), GLPG1690 in IPF, and GLPG1972 in OA. Galapagos recently signed a transformational deal with Gilead that brought in significant cash and should allow for accelerated R&D. The Galapagos group, including fee-for-service subsidiary Fidelta, has approximately 460 employees, operating from its Mechelen, Belgium headquarters and facilities in The Netherlands, France and Croatia.

Our Bull And Bear Cases For Galapagos

The Bull Case: Reasons For Optimism

- Filgotinib receives FDA and EMA approval for both the 100mg and 200mg doses without a JAK class black box warning.
- Worldwide filgotinib sales outpace consensus estimates between 2020-2025.
- Ziritaxestat has clear and convincing Phase 2 proof-of-concept results in scleroderma leading investors to assign value for this program and de-risks it in idiopathic pulmonary fibrosis.
- GILD in-licenses rights to GLPG1972 for osteoarthritis after positive results on its primary and key secondary endpoints; GLPG receives $450 million in milestones.
- Results from GLPG1205 in idiopathic pulmonary fibrosis are compelling and ahead of consensus expectations.

The Bear Case: What We Worry About

- Filgotinib either: (1) gets a CRL and doesn't receive US or EU approval; or (2) only gets approved for the lower 100mg dose with a JAK class black box warning and an additional warning for testicular toxicity.
- Competitor infrastructure in the rheumatology category, notably ABBV's, may create a significant commercial challenge for filgotinib to gain share in the US and EU.
- Worldwide filgotinib sales underperform lofty consensus sales estimates between 2020-2025.
- Results from GLPG's pipeline programs over the next 12-18 months either do not provide supportive de-risking data or enough proof-of-concept to assign credit.

Source: Company Information and Stifel Research

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Our Probability-Weighted Sum-Of-The-Parts NPV Analysis Yields At $193 Target Price In Our Base Case Scenario

Stifel Commentary

Our base case assumes filgotinib generates meaningful sales across five different indications (rheumatoid arthritis [POS: 95%], ulcerative colitis [POS: 75%], Crohn's disease [POS: 55%], ankylosing spondylitis [POS: 55%] and psoriatic arthritis [POS: 55%]) with GLPG receiving economics through its deal with GILD. We assume filgotinib captures 20% share of the JAK class in the US and 15% in the EU in our base case. We only assign $20 a share in pipeline value for GLPG's key programs at this time as we view these programs as early. Our bull (POS: 5%) and bear cases (POS: 20%) are largely dictated by filgotinib's FDA label and is the basis on which we assign market share in our market model.

	Bull	Base	Bear
Un-risk adjusted Gross Filgotinib Worldwide Peak Sales – all indications (2030):	**$23 billion**	**$14 billion**	**$7 billion**
NPV of scenario ($)	**$152**	**$74**	**$37**
Assigned pipeline NPV value ($):			
Ziritaxestat – Idiopathic Pulmonary Fibrosis	**$4**	**$4**	**$4**
GLPG1972 – Osteoarthritis	**$10**	**$10**	**$10**
Other Pipeline (Ziritaxestat in SSc, GLPG1205 in IPF, Toledo, etc.)	**$6**	**$6**	**$6**
Other revenue	**$2**	**$2**	**$2**
Net Cash ($)	**$100**	**$100**	**$100**
Target Price For Each Scenario	**$274**	**$196**	**$159**
Probability of Scenario	**5%**	**75%**	**20%**
Scenario Contribution	**$14**	**$147**	**$32**
Probability-Weighted NPV Per Share		**$193**	

Source: Company Information and Stifel Research

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Key Trading Events / Clinical Development Calendar

Filgotinib
(JAK1 inhibitor for autoimmune diseases)

- **2H20 – Estimated US approval for filgotinib for rheumatoid arthritis**
- **2H20 – Estimated EU approval for filgotinib for rheumatoid arthritis**
- 2H20 – Estimated US/EU filgotinib commercial launch by GILD/GLPG
- 2H20/1H21 – Estimated NDA submission for filgotinib in ulcerative colitis

GLPG1205
(GPR84 inhibitor)

- **2H20 – Phase 2 proof-of-concept results in idiopathic pulmonary fibrosis**

Ziritaxestat
(Autotaxin inhibitor)

- **2H20 – Phase 2 proof-of-concept results in systemic sclerosis**
- 1H21 – Futility analysis for IPF Phase 3 study

GPLG1972
(ADAMTS-5)

- **2H20 – Phase 2 proof-of-concept results in osteoarthritis**
- **2H20/1H21 – GILD could in-license if results are positive**

Source: Company Information and Stifel Research

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The Key Investor Debates For GLPG Shares In The Next ~6-12 Months

1. What are the bull/bear scenarios for filgotinib's label and what are the potential implications for its commercial opportunity?

2. What will the sales ramp for filgotinib look like and will it exceed consensus expectations?

3. What are the near-term catalysts from GLPG's pipeline and how much pipeline value is currently in the stock?

Source: Company Information and Stifel Research

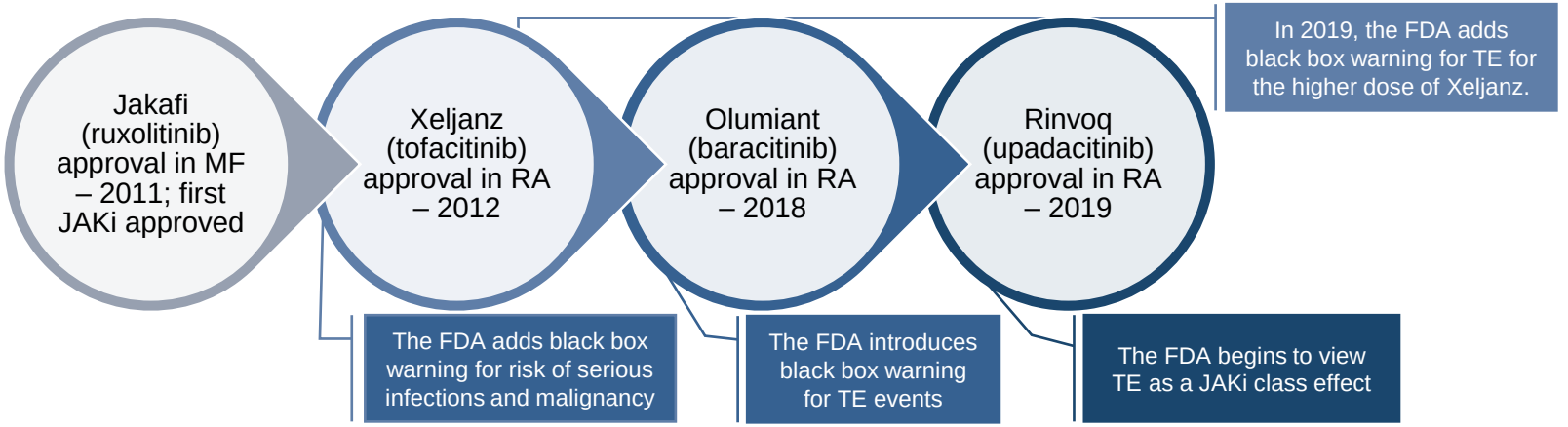
The Evolution of JAK Inhibitor Labeling, Which Includes a Black Box Warning, and What It Could Mean For Filgotinib

Multiple JAKi's Have Had Thromboembolic (TE) Adverse Events And The FDA's View On This Safety Risk Has Evolved Over Time

Stifel Commentary

JAK inhibitors have a history of TE adverse events at higher doses and the FDA's approach to this risk has changed over time – most recently demonstrated by the "class" black box applied to ABBV's upadacitinib (Rinvoq). GLPG believes filgotinib's safety profile is differentiated from competitor profiles, which could be manifested in labeling or approval of a higher dose and offer a commercial competitive advantage. In our KOL checks, physicians have noted comfort with the safety of the JAKi class is growing, and a black box warning wouldn't slow adoption, though a higher approved dose with differentiated efficacy could be a meaningful advantage. We would also note that regulators globally have taken varied approaches (i.e. the same drug can have different labeling between FDA, EMA, Japan).

JAKi Class Approval History



*Our **base case** is that both doses of filgotinib will be approved with a black box warning. We believe that in a **bull case** scenario, filgotinib is approved without a black box at both dose levels after showing a satisfactory benefit-risk profile. Our **bear case** assumes that filgotinib is approved at its lower dose with a black box warning and limited/onerous label or meaningful novel safety concerns.*

Sources: FDA label information, Company information and Stifel Research

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The Evolution In The FDA's Labeling For The JAKi Class Drives Our Base Case That Filgotinib Will Receive A Class Black Box Similar To Upadacitinib's

2012 - PFE's Xeljanz (tofacitinib)

XELJANZ® (tofacitinib) tablets, for oral use
XELJANZ® XR (tofacitinib) extended-release tablets, for oral use
Initial U.S. Approval: 2012

WARNING: SERIOUS INFECTIONS AND MALIGNANCY
See full prescribing information for complete boxed warning.

- Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving XELJANZ. (5.1)
- If a serious infection develops, interrupt XELJANZ/XELJANZ XR until the infection is controlled. (5.1)
- Prior to starting XELJANZ/XELJANZ XR, perform a test for latent tuberculosis; if it is positive, start treatment for tuberculosis prior to starting XELJANZ/XELJANZ XR. (5.1)
- Monitor all patients for active tuberculosis during treatment, even if the initial latent tuberculosis test is negative. (5.1)
- Lymphoma and other malignancies have been observed in patients treated with XELJANZ. Epstein Barr Virus-associated post-transplant lymphoproliferative disorder has been observed at an increased rate in renal transplant patients treated with XELJANZ and concomitant immunosuppressive medications. (5.2)

- PFE's tofacitinib was approved in 2012 for the treatment of RA along with a black box warning for serious infections (tuberculosis and other opportunistic infections) and malignancy (lymphoma).

2018 - LLY's Olumiant (baricitinib)

OLUMIANT (baricitinib) tablets, for oral use
Initial U.S. Approval: 2018

WARNING: SERIOUS INFECTIONS, MALIGNANCY, AND THROMBOSIS
See full prescribing information for complete boxed warning.

- Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving OLUMIANT. (5.1)
- If a serious infection develops, interrupt OLUMIANT until the infection is controlled. (5.1)
- Prior to starting OLUMIANT, perform a test for latent tuberculosis; if it is positive, start treatment for tuberculosis prior to starting OLUMIANT. (5.1)
- Monitor all patients for active tuberculosis during treatment, even if the initial latent tuberculosis test is negative. (5.1)
- Lymphoma and other malignancies have been observed in patients treated with OLUMIANT. (5.2)
- Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with OLUMIANT. Patients with symptoms of thrombosis should be evaluated promptly. (5.3)

- LLY/INCY's baracitinib was only approved at the lower 2mg dose after an FDA advisory panel voted against the safety profile of the 4mg dose due to serious venous thromboembolic events, which made it on to its label.

2019 - ABBV's Rinvoq (upadacitinib)

RINVOQ™ (upadacitinib) extended-release tablets, for oral use
Initial U.S. Approval: 2019

WARNING: SERIOUS INFECTIONS, MALIGNANCY, AND THROMBOSIS
See full prescribing information for complete boxed warning.

- Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving RINVOQ. (5.1)
- If a serious infection develops, interrupt RINVOQ until the infection is controlled. (5.1)
- Prior to starting RINVOQ, perform a test for latent tuberculosis; if it is positive, start treatment for tuberculosis prior to starting RINVOQ. (5.1)
- Monitor all patients for active tuberculosis during treatment, even if the initial latent tuberculosis test is negative. (5.1)
- Lymphoma and other malignancies have been observed in patients treated with RINVOQ. (5.2)
- Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with Janus kinase inhibitors used to treat inflammatory conditions. (5.3)

- ABBV's upadacitinib – approved for RA – received a black box warning for infections, malignancies, and thromboembolic events despite rates in both the placebo-controlled and OLE remaining consistent with the background rate in the RA population. We note the language to include "Janus kinase inhibitors" instead of Rinvoq specifically, highly suggests the FDA views this as a class effect.

Sources: FDA label information, Company information and Stifel Research

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In 2017, INCY/LLY Received A CRL For Baracitinib After The 4mg Dose Demonstrated An Increased Risk For TE Versus The 2mg Dose

LLY submits NDA for Olumiant – Jan. 2016

Olumiant receives a CRL – April 2017

The FDA concluded that the benefit-risk assessment of baracitinib 2mg and 4mg was not favorable given the potential serious risk of thrombosis, coupled with the lack of a consistent efficacy advantage of the 4mg dose over the 2mg dose.

Safety Data From The Original Submission

Table 6. Update of VTE (DVT and PE) in Baricitinib Clinical Program in RA

	BARI 4	BARI 2	Placebo
Original Submission, August 10, 2015 Data Lock			
0-16 weeks			
Number of patients	1265	403	892
Total exposure in patient years	387	123	267
Patients with thromboses, n (rate)	5* (1)	0	0
0-52 weeks			
Total exposure in patient years	1695	305	365
Patients with thromboses, n (rate)	9* (0.5)	2 (0.7)	0
> 52 weeks			
Total exposure in patient years	1301	210	NA
Patients with thromboses, n (rate)	8 (0.6)	0	
0-any duration			
Total exposure in patient years	2996	515	NA
Patients with thromboses, n (rate)	17* (0.5)	2 (0.4)	

Efficacy Data Submitted For Approval of Olumiant

Table 10. JADX: Proportion of ACR20 Responders

Week	% Responders (Responders/Total)			Odds Ratio (p-value) (95% CI)		
	BARI 4	BARI 2	Pbo	BARI 4:Pbo	BARI 2:Pbo	BARI4:BARI2
12	62 (140/227)	66 (151/229)	39 (90/228)	2.5 (<.001) (1.7, 3.7)	3.0 (<.001) (2.0, 4.4)	0.8 (.4) (0.6, 1.2)
24	65 (148/227)	61 (140/229)	42 (96/228)	2.6 (<.001) (1.8, 3.9)	2.2 (<.001) (1.5, 3.2)	1.2 (0.3) (0.8, 1.8)

Source: FDA statistical reviewer
Abbreviations: BARI=baricitinib; Pbo=placebo; CI=confidence interval

Table 11. JADW: Proportion of ACR20 Responders

Week	% Responders (Responders/Total)			Odds Ratio (p-value) (95% CI)		
	BARI 4	BARI 2	Pbo	BARI 4:Pbo	BARI 2:Pbo	BARI 4:BARI 2
12	55 (98/177)	49 (85/174)	27 (48/176)	3.4 (<.001) (2.2, 5.4)	2.7 (<.001) (1.7, 4.2)	1.3 (0.3) (0.8, 2)
24	46 (82/177)	45 (78/174)	27 (48/176)	2.4 (<.001) (1.5, 3.7)	2.3 (<.001) (1.5, 3.6)	1.0 (.9) (0.7, 1.6)

Source: FDA statistical reviewer
Abbreviations: BARI=baricitinib; Pbo=placebo; CI=confidence interval

Source: FDA Summary Review for baricitinib, Company information and Stifel Research

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The FDA Advisory Panel Ended Up Recommending Approval Of Only The Baricitinib 2mg Dose In Rheumatoid Arthritis And Not The 4mg Due To These Safety Concerns

Stifel Commentary

Although members of the advisory committee agreed the data presented by LLY for baracitinib supported efficacy at both doses, the TE signal at the 4mg dose compared to 2mg led to the recommendation to approve only the 2mg with the inclusion of a black box warning for TE. While the panel also noted uncertainty with regard to TE risk at the 2mg dose due to the limited safety database, the panel highlighted other data pointing to a dose response in terms of its safety profile, which could translate into a lower risk of SAEs of interest, such as serious infection, at lower doses.

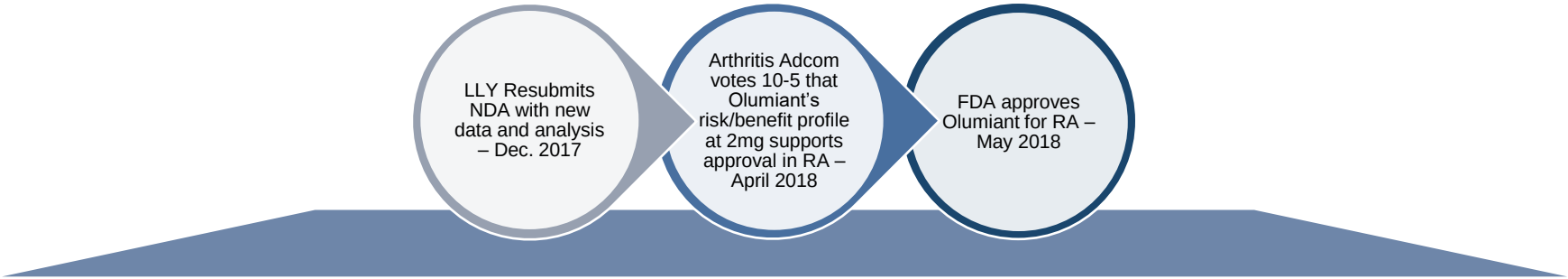

Table 1: Thromboembolic events from the baricitinib safety database update

	Exposure Weeks 0-16			Exposure of any duration	
	Placebo n (IR)	Baricitinib 2mg n (IR)	Baricitinib 4mg n (IR)	Baricitinib 2mg n (IR)	Baricitinib 4mg n (IR)
No. Patients	892	403	1265	929	2717
Patient-Years Exposure	267	123	387	1261	5820
Venous thromboembolism	0	0	5 (1.3)	5 (0.4)	34 (0.6)
Arterial thromboembolism	1 (0.4)	2 (1.6)	2 (0.5)	4 (0.3)	28 (0.5)

IR = Incidence rate per 100 patient-years
Source: FDA Briefing Document Arthritis Advisory Committee Meeting, April 23, 2018, p. 161-162; Information Request Response NDA 207924, March 19, 2018, p. 8.

Source: FDA Summary Review for baricitinib, Company information and Stifel Research

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Similarly In 2019, PFE's Tofacitinib Received A Black Box After A Post-Marketing Study Showed The Higher 10mg BID Dose Was Associated With TE and All-Cause Death

Stifel Commentary

A post-marketing study in RA evaluating tofacitinib 5mg BID and 10mg BID compared to anti-TNF therapy demonstrated an increase rate of blood clots (19/3,884 patient years in the 10mg BID arm vs. 3/3,982 patient years for anti-TNF therapy and death (45/3,884 patient in the 10mg BID arm vs. 25/3,982 patient years for anti-TNF therapy). The DSMB advised PFE to transition all patients to 5mg BID.

Boxed Warning About Increased Risk Of Thrombosis And Death With Higher Dose Of Xeljanz In RA And Ulcerative Colitis

[7-26-2019] The U.S. Food and Drug Administration has approved new warnings about an increased risk of blood clots and of death with the 10 mg twice daily dose of tofacitinib (Xeljanz, Xeljanz XR), which is used in patients with ulcerative colitis. In addition, the approved use of tofacitinib for ulcerative colitis will be limited to certain patients who are not treated effectively or who experience severe side effects with certain other medicines. We approved these changes, including adding our most prominent *Boxed Warning*, after reviewing interim data from an ongoing safety clinical trial of tofacitinib in patients with rheumatoid arthritis (RA) that examined a lower and this higher dose of the medicine.

The 10 mg twice daily dose of tofacitinib is not approved for RA or psoriatic arthritis (PsA). This dose is only approved for ulcerative colitis for initial treatment and for long-term use in limited situations. While the increased risks of blood clots and of death were seen in patients taking this dose for RA, these risks may also apply to those taking tofacitinib for ulcerative colitis.

In 2019, the FDA added a new warning for the risk of blood clots and death for the 10mg BID dose of tofacitinib.

Source: FDA label information, Company information and Stifel Research

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While Upadacitinib's Safety Was Clean, The FDA Only Approved The Lower Dose Due To Concerns About The Risk-Benefit Of Increasing JAKi Doses

- Recall, upadacitinib and filgotinib are similar in that they are both JAK1 specific and thereby should have improved safety.
- Data from five Phase 3 studies were submitted for upadacitinib's approval, which demonstrated ample evidence of efficacy for both the 15mg and 30mg doses.
- However, there was a minimal incremental benefit – in terms of efficacy – between the 15mg and 30mg doses.
- In short-term controlled studies, upadacitinib did not show higher incidence rates of venous TE compared to placebo, methotrexate, or adalimumab. However, the FDA noted that the short placebo-controlled period of the study limited definitive conclusions regarding the risks of TE event with upadacitinib.
- Long-term venous TE event data with upadacitinib did not show a dose-dependent relationship between upadacitinib treatment and venous TE.

In the upadacitinib summary review, the FDA first outlined its view of thrombosis as a JAKi class effect and determined that: "Given that two JAK inhibitor programs have identified thrombosis as a safety signal, thrombosis is now considered a class safety issue and the upadacitinib product label will include a Boxed Warning regarding VTE." In addition, the FDA concluded that the small incremental benefit of the 30mg dose does not outweigh the dose-related safety risks with the 30mg dose of upadacitinib.

Efficacy Data Of Phase 3 Studies With Upadacitinib In RA

Treatment Arm	N	Count(%)[1]	Diff (%) [95 % CI]; P-value[2]
MTX Add-on Studies[3]			
M13-542			
Placebo	169	48 (28%)	
UPA 15 mg QD	164	106 (65%)	36.2% (26.2% - 46.2%); <0.001
UPA 30 mg QD	165	93 (56%)	28.0% (17.8% - 38.1%); <0.001
M13-549			
Placebo	221	79 (36%)	
UPA 15 mg QD	221	141 (64%)	28.1% (19.1% - 37.0%); <0.001
UPA 30 mg QD	219	145 (66%)	30.5% (21.6% - 39.4%); <0.001
M14-465			
Placebo	651	237 (36%)	
UPA 15 mg QD	651	459 (71%)	34.1% (29.0% - 39.2%); <0.001
ADA 40 mg EOW	327	206 (63%)	26.6% (20.2% - 33.0%); <0.001
MTX Monotherapy Studies[3]			
M15-555			
MTX	216	89 (41%)	
UPA 15 mg QD	217	147 (68%)	26.5% (17.5% - 35.6%); <0.001
UPA 30 mg QD	215	153 (71%)	30.0% (21.0% - 38.9%); <0.001
M13-545 (ACR50)			
MTX	314	89 (28%)	
UPA 15 mg QD	317	165 (52%)	23.7% (16.3% - 31.1%); <0.001
UPA 30 mg QD	314	177 (56%)	28.0% (20.6% - 35.4%); <0.001

Long-term Data For VTEs – Pooled Data Across Controlled Long-term Periods Of The Phase 3 Studies

	MTX[a] (N=314) n/PY (n/100 PY)	ADA [b] (N=579) n/PY (n/100 PY)	All UPA 15 mg [c] (N=2630) n/PY (n/100 PY)	Any UPA 15 mg [d] (N=1213) n/PY (n/100 PY)	Any UPA 30 mg [d] (N=1204) n/PY (n/100 PY)
VTE	2/314 (0.6)	5/468 (1.1)	16/2653 (0.6)	12/1409 (0.9)	5/1362 (0.3)

Source: Genovese, M.C. et al. 2018 Jun 23;391(10139):2513-2524, Burmester, G.R. et al. 2018. Jun 23;391(10139):2503-2512, FDA Summary Review for upadacitinib and Stifel Research

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With That Said, The Safety Profile Of Both The 100mg And The 200mg Doses Of Filgotinib Look Good Compared To Other JAKs – But Will It Be Enough?

Stifel Commentary

The fact the FDA issued a black box warning for upadacitinib in RA despite demonstrating VTE events similar to the background rate in the RA population, may be a harbinger for filgotinib. Compared to its peers, filgotinib dosed between 50-200mg demonstrated lower rates of serious infection, deep vein thrombosis/pulmonary embolism events (DVT/PE), and deaths. Moreover, data from the FINCH studies (100-200mg) at 24 weeks, demonstrate low rates of both DVT and death compared to placebo/methotrexate and adalimumab, and also compares favorably to the safety data from its peers in the JAK class.

DARWIN3 Long Term Safety Data In Comparison To Peers

Event per 100 PYE	filgotinib	baricitinib	tofacitinib	upadacitinib	tocilizumab	adalimumab
	50-200 mg	2 and 4 mg QD	5 mg BID	6 and 12 mg BID	4 and 8 mg/kg	
Patient year exp.	2,203	6,637	5,278	725	14,994	23,943
Serious infection	1.2	2.9	2.4	2.3	4.5	4.6
herpes zoster	1.5	3.2	3.8	3.7	ND	ND
DVT/PE	2/2,203 0.1	31/6,754 0.5	3/1,849 0.2	5/725 0.7	ND	ND
Deaths	0.2	0.3	0.6	0.3	0.6	0.8
Malignancy excluding NMSC	0.5	-	-	-	-	-
MACE	0.1	-	-	-	-	-
Source	DARWIN3 wk156	Genovese *et al* ACR2017	Wollenhaupt ACR 2017	Genovese ACR2017	Genovese ACR 2012	Burmester 2011

FINCH Safety Data Up To Week 24

N (%)	PBO/MTX	ADA 40 mg EOW	FIL 100 mg + MTX/cDMARDs	FIL 200 mg + MTX/cDMARDs	FIL 200 mg monotherapy	FIL total
	N=1039	N=325	N=840	N=1038	N=210	N=2088
serious infection	10 (1.0)	8 (2.5)	13 (1.5)	13 (1.3)	3 (1.4)	29 (1.4)
herpes zoster	4 (0.4)	2 (0.6)	5 (0.6)	6 (0.6)	1 (0.5)	12 (0.6)
DVT/PE	3 (0.3)	0 (0)	0 (0)	1 (0.2)*	0 (0)	1 (<0.1)
deaths	2 (0.2)	0 (0)	1 (0.1)	3 (0.3)	0 (0)	4 (0.2)
malignancy excl. NMSC	4 (0.4)	1 (0.3)	1 (0.1)	0 (0)	0 (0)	1 (<0.1)
MACE	5 (0.5)	1 (0.3)	2 (0.2)	2 (0.2)	1 (0.5)	5 (0.2)

Note: FINCH 1, 2, and 3 events up to week 24
*Incident retinal vein occlusion observed in FINCH 2
FIL: filgotinib; ADA: adalimumab; MTX: methotrexate; PBO: placebo; cDMARD: conventional synthetic disease-modifying antirheumatic drug; DVT: deep vein thrombosis; PE: pulmonary embolism; NMSC: nonmelanoma skin carcinoma; MACE: major cardiovascular event

GLPG will likely highlight these data and also argue that filgotinib's specificity for JAK1 makes it distinct from others in the class which could lead to differences in label language.

Source: Company information and Stifel Research

STIFEL

Could The Risk Of Testicular Toxicity Also Make The Filgotinib Label In Rheumatoid Arthritis?

- One point of concern for investors has been the potential for language in filgotinib's label warning for a risk of testicular toxicity. This signal was picked up in pre-clinical animal models and appeared to be dose dependent. While there has been no specific cases to-date in GLPG's human clinical trials, there is still not sufficient evidence to make a call on this.
- We think this concern is especially relevant for two reasons: (1) in ulcerative colitis, patients tend to be younger compared to the older population in RA and the higher 200mg dose performed the best in the recent Phase 2 ulcerative colitis study; (2) the testicular toxicity was seen at higher doses and could be another reason for the FDA to only approve the 100mg dose of filgotinib.
- To flesh out this signal, GILD/GLPG is conducting the MANTA (ulcerative colitis) - and MANTA-RAy (in rheumatoid arthritis) studies to evaluate testicular toxicity in adult males treated with filgotinib.
- We think it is unlikely the FDA will require data from the MANTA/MANTA-RAy studies, which were expected to read out in early 2021 but have been impacted by COVID19, before approving filgotinib in RA but its technically possible. Additionally, if it is approved, it is possible the FDA could add language on filgotinib's label warning of the potential for testicular toxicity.

Stifel Commentary

We think if the FDA requires the data from the MANTA/MANTA-RAy studies resulting in a CRL for filgotinib, it could push out a filgotinib launch in RA to late 2021 or 2022 depending on the delay from COVID19 and review timelines. If it is approved with specific label language for testicular toxicity before the read out of the MANTA/MANTA-RAy studies, this could lead to less uptake in the early part of launch until the read out of the studies.

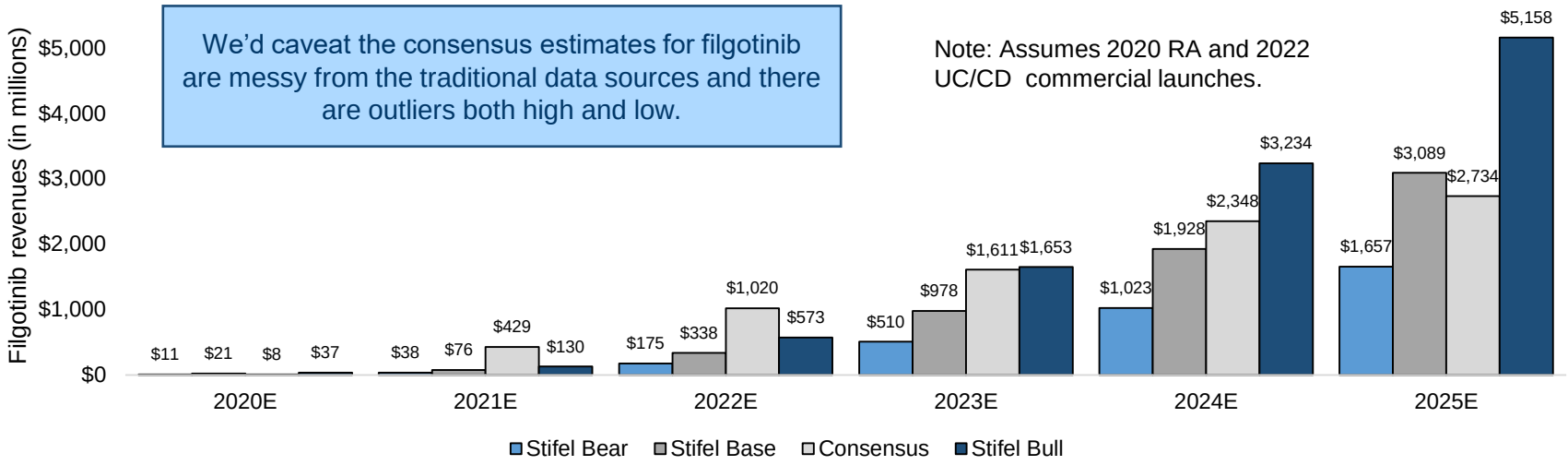
Source: Company information, clinicaltrial.gov and Stifel Research

What Will The Sales Ramp For Filgotinib Look Like And Will It Exceed Consensus Expectations?

The JAK Class Is Highly Competitive And We Think Early Consensus Estimates For Filgotinib Seem Aggressive

The market opportunity in the canonical inflammatory diseases (i.e. RA, UC, CD, PsA, and AS) is undeniably large, with patients numbering well into the millions. With that said, GLPG's main competitors, ABBV and PFE, have enormous global commercial footprints in rheumatology while GILD/GLPG's are essentially starting from scratch. We'd highlight ABBV in particular, as numerous KOLs indicate to us they are replicating their wildly successful adalimumab playbook with upadacitinib and using these synergies to their advantage.

Filgotinib US and EU RA and IBD Sales Consensus (2020-2025)



Key Takeaway

Filgotinib consensus estimates seem aggressive given our base case for its label. Based on our KOL discussions with physicians who treat RA and IBD, the prevailing view was filgotinib was not that differentiated from the other JAKs in the class and decisions on which to use is largely dictated by formulary coverage/access and is where ABBV has done a good job with adalimumab and upadacitinib.

Source: IQVIA, FactSet, VisibleAlpha and Stifel Estimates

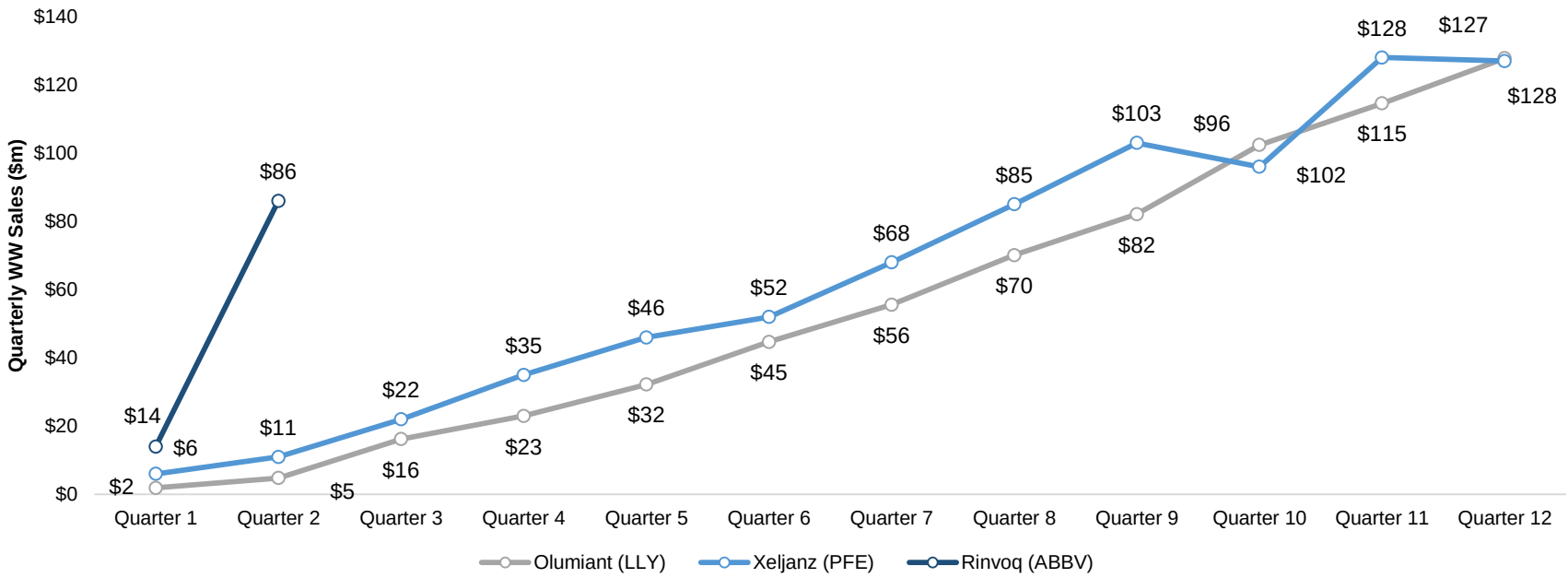
STIFEL

In Our View, The Filgotinib Launch Is Likely To Be Somewhere Between The Olumiant/Tofacitinib Launches And Upadacitinib

Stifel Commentary

We believe the quarterly sales from the launches of competing JAK programs provides a range of what filgotinib's launch could look like. KOLs spoke very highly of upadacitinib (Rinvoq) and ABBV's marketing strategy for the drug, while acknowledging PFE and LLY could've have launched their respective drugs better. Therefore, our base case assumption is the filgotinib launch is likely to be slightly better to baracitinib (Olumiant) and tofacitinib (Xeljanz), but given it is GILD/GLPG's first foray into the space, we believe the quick uptake seen with Rinvoq may be too aggressive for a filgotinib launch assumption.

Launch of JAK Competitors

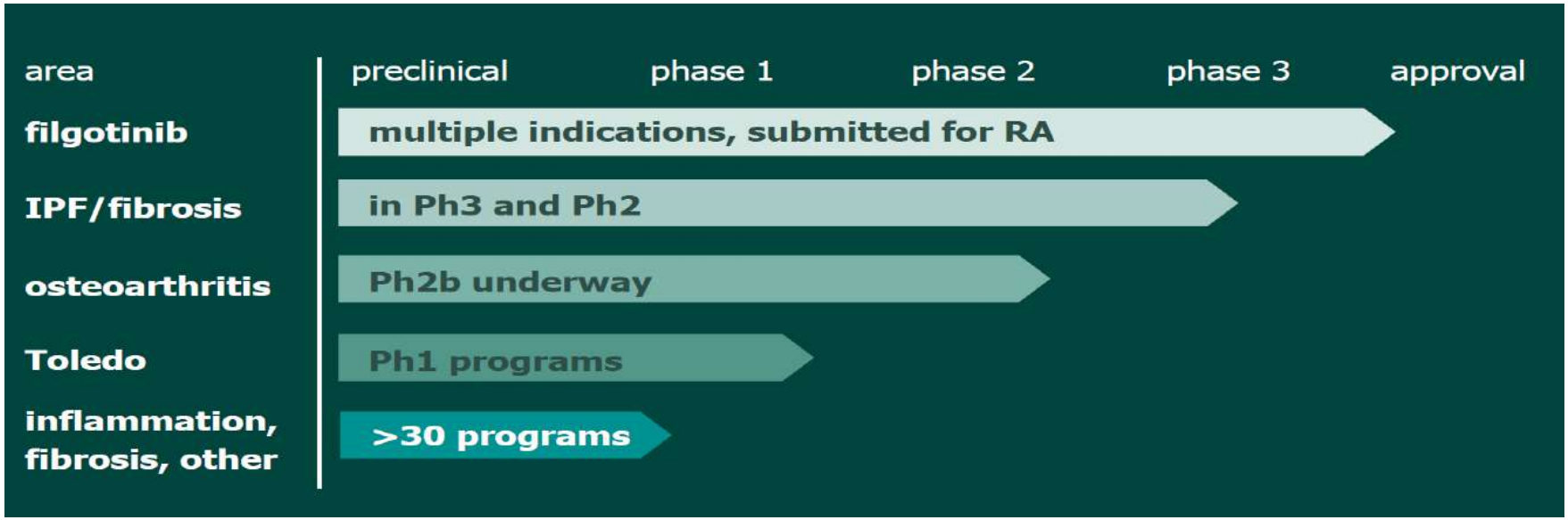


Source: Company information, FactSet and Stifel Research

STIFEL

How De-risked Is GLPG's Pipeline And How Much Value Is Priced Into The Stock?

Recall, GLPG Has Multiple Phase 2 Proof-Of-Concept Trial Read Outs In The 2H20 Across Various Indications



Stifel Commentary

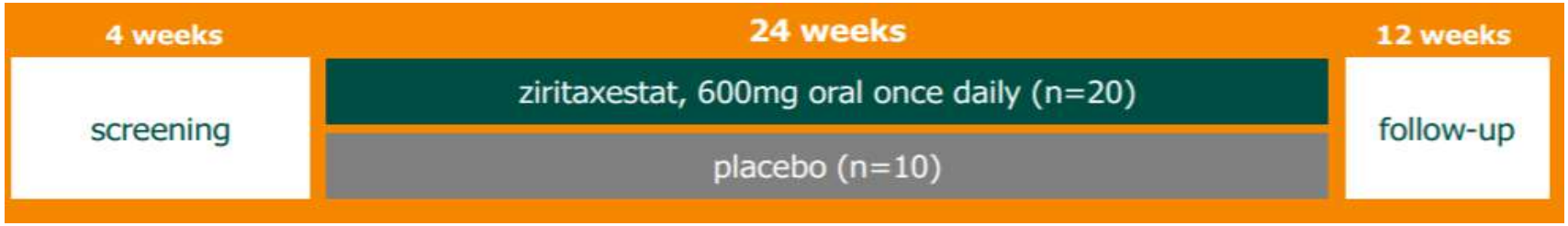
Given GLPG's strong cash position, we believe long-term it is well positioned to deliver meaningful value from its pipeline over time. We currently assign only $20 in value for GLPG's pipeline and based on our investor discussions, this seems in-line with the current sentiment that GLPG's pipeline beyond filgotinib is early with only modest value in the stock. With that said, we believe the three upcoming read outs in the 2H20 are unlikely to move the needle, and its not totally clear how de-risking these studies will be given the use of either novel endpoints in certain cases (GLPG1972 in osteoarthritis) or not so relevant endpoints (Ziritaxestat in scleroderma). So we think upside is likely limited even on positive data.

Source: Company information and Stifel Research

First Up, We Think Ziritaxestat's NOVESA Study Will Largely Be Informative Though Results On Secondary Endpoints Could Help De-Risk IPF But It Is Unclear If They Will Be Part Of The Top Line Results

- GLPG is evaluating ziritaxestat in the Phase 2 NOVESA study in scleroderma. Scleroderma is a multisystem disease characterized by prevalent vascular malfunction and progressive fibrosis of the skin and internal organs. Patients with diffuse scleroderma are more likely to experience rapid progression of skin thickening with early development of lung fibrosis and have a higher risk of renal crisis and cardiac involvement.
- The study is a randomized, double-blind, placebo-controlled, multi-center study evaluating the efficacy, safety, and tolerability of Ziritaxestat in ~30 patients with progressive diffuse scleroderma. The primary endpoint is a change in modified Rodnan skin score (mRSS) over 24 weeks. Secondary and exploratory endpoints include safety, tolerability and broad range of measures, namely: FVC, QOL, composite response index in systemic sclerosis (CRISS).

Phase 2 Study For Ziritaxestat In Scleroderma



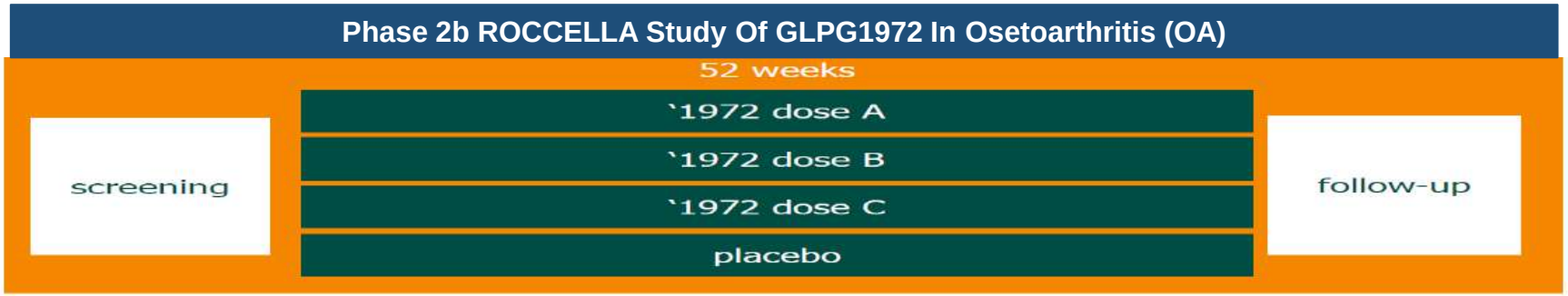
KOL Commentary

Based on our discussions with KOLs, the improvement on mRSS is not the most clinically relevant data point. While the skin thickening is a key issue in scleroderma, the poor outcomes that occur in patients are associated with lung fibrosis, renal impairment and cardiovascular issues and KOLs noted the mRSS doesn't correlate to outcomes in this disease. Thus, positive efficacy signals on FVC, a measure of lung function, is more important for the development of this therapy in scleroderma. Additionally, we think this could also de-risk ziritaxetat in IPF. With that being said, this is a small study and its not clear what GLPG will report in the top line so we think the read out is likely to have a minimal impact on valuation.

Source: Company information and Stifel Research

We View GLPG1972's Phase 2b Results In Osteoarthritis As A Potential Modest Pipeline Catalyst, Though The Novel Endpoints May Make Interpreting The Data A Challenge

- GLPG is evaluating GLPG1972 – a drug candidate targeting ADAMTS-5 – in a randomized, double-blind, placebo controlled, dose ranging study over 52-weeks in ~900 subjects. The primary endpoint is reduction of cartilage loss measured by qMRI and secondary endpoints include quantitative structural measures, global assessments and a change from baseline in western Ontario and McMaster universities osteoarthritis index (WOMAC) subscales scores for pain, function, and stiffness – a common endpoint measure used in registrational osteoarthritis trials.
- The use of MRI to assess osteoarthritis disease modification has evolved substantially, owing to its ability to visualize individual tissue pathologies, as well as the interrelationship between tissue pathologies – which has been shown to contribute to symptomatic osteoarthritis. However, this is a novel endpoint and its unclear how strong the correlation between an improvement on qMRI and WOMAC is given the limited data. We'd note its unclear if WOMAC will be reported as part of the top line results.



Stifel Commentary

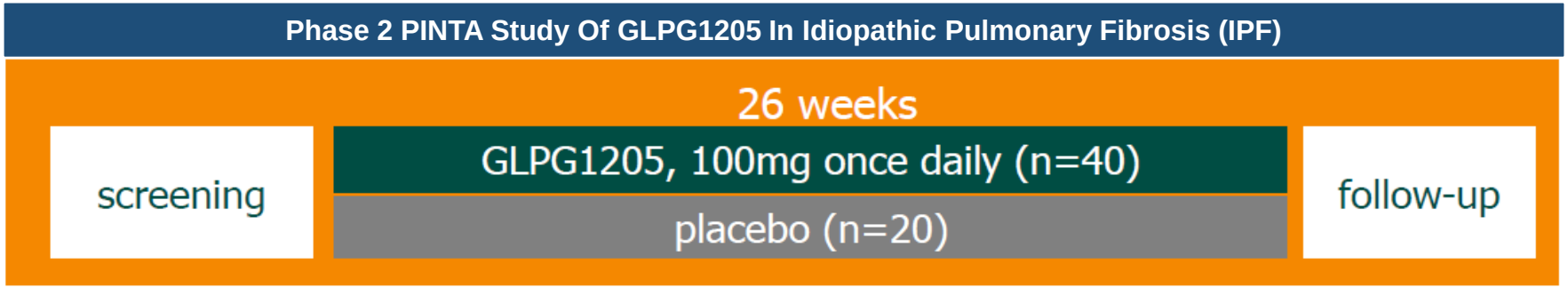
We think positive results from this study that will get investors to assign more credit would require a statistically significant result on the primary endpoint but more importantly on secondary endpoints such as the traditional WOMAC scores. Positive results could also lead to GILD opting in to this program and GLPG could receive up to $450 in milestones.

Source: Company information and Stifel Research

STIFEL

PINTA Study Results Likely To Offer Some Insight For GLPG1205 As Part Of Combo Therapy In Idiopathic Pulmonary Fibrosis

This is a randomized, double-blind, parallel group, placebo-controlled, multicenter, Phase 2 study evaluating GLPG1205 – a GPR84 antagonist – in 60 patients with IPF on top of local standard of care – nintedanib, pirfenidone, or neither. The primary endpoint is forced vital capacity (FVC) at 26 weeks, and secondary measures include safety, tolerability among other measures such as functional respiratory imaging. Data from this study are expected in 3Q20.



Stifel Commentary

We aren't sure how stock moving this data will be given the small size of the trial but we think it will be quite informative in terms of learning how GLPG1205 could be used in combination with nintedanib and pirfenidone or its performance ontop of local standard of care and how that looks compared to the aforementioned approved agents. We think a positive signal of efficacy (probably won't be statistically significant given the size of the trial) will likely be enough to continue development but we don't think investors will assign much value until a larger study is conducted.

Source: Company information and Stifel Research

Model Disclosures For GLPG

Model development process and alternative approaches: Our model is built to replicate the company's reported financial information, supplemented with market research information provided by IQVIA, Inc., its affiliated companies and consultant interviews, where pertinent and available.

Data: Company reports; Key opinion leader (KOL) consultant interviews; Peer-review articles; Market research

Model Theory: The model is built to forecast Galapagos' income, balance sheet, and cash flows, primarily driven by assumptions of WAC pricing for comparable and relevant therapies, sales volumes, royalties to GLPG and production costs. Our target price for GLPG shares is $193. This is based on a probability-weighted, risk-adjusted NPV analysis which assigns 75% odds of our base case of $196, 20% odds of our bear case $159 and 5% odds of our bull case $274. In our base case we assign $75, $4, $10, $2, $5 for filgotinib, GLPG1690, GLPG1972, Other revenue, Other pipeline, respectively. We assign $100 of value for cash.

Model Processing Steps: All user inputs in the model are indicated by a blue font color.

Qualitative Overlays and Assumptions: Forecasts for key assumptions are based in part on our expectations for 1) filgotinib's label and potential implications for its commercial opportunity; 2) filgotinib's sales ramp and its prospects for exceeding consensus expectations; 3) and the value of GLPG's pipeline.

Model Limitations: From the guidelines: "Research recommendations, models, and estimates are of course limited in their accuracy of predicting future results. Model limitations are covered based on standard disclosures contained in each published research report."

GLPG Annual P&L Summary
(figures in €m, except per share data)

	2017	2018	1Q19	2Q19	3Q19	4Q19	2019	1Q20	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E	2024E	2025E
Filgotinib EU Sales (JAKi; RA, UC, CD, AS, PsA)	-	-	-	-	-	-	-	-	-	1	3	4	16	60	177	362	635
GLPG1690 EU Sales (Autotaxin; IPF)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	10	31
Total Product Sales	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1**	**3**	**4**	**16**	**60**	**177**	**372**	**667**
Filgotinib Royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	6	162	427	853
GLPG1690 Royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11	34
GLPG1972 Royalties (OA)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	23	72
Total Royalties	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**6**	**162**	**461**	**958**
Other Revenues (upfronts, milestones, grants, etc.)	**156**	**318**	**41**	**68**	**644**	**143**	**896**	**107**	**100**	**100**	**279**	**586**	**659**	**460**	**553**	**440**	**252**
Total Revenues	**156**	**318**	**41**	**68**	**644**	**143**	**896**	**107**	**100**	**101**	**282**	**590**	**675**	**526**	**891**	**1,273**	**1,877**
% y/y growth	*3%*	*104%*	*-9%*	*19%*	*524%*	*27%*	*182%*	*161%*	*48%*	*-84%*	*97%*	*-34%*	*14%*	*-22%*	*69%*	*43%*	*47%*
COGs	-	-	-	-	-	-	-	-	-	1	3	4	2	6	18	37	67
% of sales	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*1%*	*1%*	*1%*	*0%*	*1%*	*2%*	*3%*	*4%*
Gross Income	156	318	41	68	644	143	896	107	100	100	279	586	673	520	874	1,236	1,811
% gross margin	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*100%*	*99%*	*99%*	*99%*	*100%*	*99%*	*98%*	*97%*	*96%*
G&A Expense	24	36	11	18	33	37	74	35	29	30	24	118	130	137	147	157	168
% of sales	*16%*	*11%*	*27%*	*26%*	*5%*	*26%*	*8%*	*32%*	*29%*	*30%*	*9%*	*20%*	*19%*	*26%*	*16%*	*12%*	*9%*
S&M Expense	3	4	-	-	-	-	25	-	7	8	15	30	50	90	115	127	139
% of sales	*2%*	*1%*	*0%*	*0%*	*0%*	*0%*	*3%*	*0%*	*7%*	*8%*	*5%*	*5%*	*7%*	*17%*	*13%*	*10%*	*7%*
R&D Expense	219	323	83	94	121	129	427	117	115	122	130	484	516	532	547	564	581
% of sales	*140%*	*102%*	*203%*	*140%*	*19%*	*90%*	*48%*	*109%*	*115%*	*121%*	*46%*	*82%*	*76%*	*101%*	*61%*	*44%*	*31%*
GILD Profit (Loss) Share Expense, net	-	-	-	-	-	-	-	-	-	(1)	(2)	(2)	(11)	(50)	(19)	46	150
% of sales	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*-1%*	*0%*	*-2%*	*-10%*	*-2%*	*4%*	*8%*
Operating Income	**(90)**	**(45)**	**(53)**	**(44)**	**491**	**(23)**	**370**	**(45)**	**(51)**	**(60)**	**112**	**(43)**	**(12)**	**(188)**	**84**	**343**	**773**
% operating margin	*na*	*na*	*na*	*na*	*76%*	*na*	*41%*	*na*	*na*	*na*	*40%*	*na*	*na*	*na*	*9%*	*27%*	*41%*
Total financial income (expense)	(26)	16	5	(3)	(146)	(76)	(220)	(6)	(6)	(6)	(6)	(24)	(15)	(10)	(8)	(8)	(8)
Pre-tax income	**(116)**	**(29)**	**(49)**	**(47)**	**344**	**(99)**	**150**	**(50)**	**(57)**	**(66)**	**105**	**(67)**	**(27)**	**(198)**	**76**	**335**	**765**
% pre-trax income margin	*na*	*na*	*na*	*na*	*53%*	*na*	*17%*	*na*	*na*	*na*	*37%*	*na*	*na*	*na*	*8%*	*26%*	*41%*
Tax expense (benefit)	0	0	0	0	(17)	17	0	0	-	-	-	-	-	-	-	-	-
% tax rate	*na*	*na*	*na*	*na*	*-3%*	*na*	*0%*	*na*	*na*	*na*	*0%*	*na*	*na*	*na*	*0%*	*0%*	*0%*
Net income (loss)	**(116)**	**(29)**	**(49)**	**(47)**	**361**	**(115)**	**150**	**(51)**	**(57)**	**(66)**	**105**	**(67)**	**(27)**	**(198)**	**76**	**335**	**765**
% net margin	*na*	*na*	*na*	*na*	*56%*	*na*	*17%*	*na*	*na*	*na*	*37%*	*na*	*na*	*na*	*8%*	*26%*	*41%*
IFRS EPS	**(2.34)**	**(0.56)**	**(0.89)**	**(0.86)**	**5.83**	**(1.82)**	**2.49**	**(0.78)**	**(0.87)**	**(0.98)**	**1.54**	**(1.07)**	**(0.41)**	**(2.96)**	**1.10**	**4.72**	**10.45**
% y/y growth	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*	*na*
Weighted Average Diluted Shares	49.5	52.1	54.6	54.8	62.0	63.5	60.1	64.8	65.2	66.9	68.6	63.1	65.0	67.0	69.0	71.0	73.2
% y/y growth	*5%*	*5%*	*7%*	*7%*	*14%*	*17%*	*15%*	*19%*	*19%*	*8%*	*8%*	*5%*	*3%*	*3%*	*3%*	*3%*	*3%*

Source: Company information and Stifel estimates

Important Disclosures and Certifications

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Galapagos NV (GLPG) as of July 08, 2020 (in USD)

*Represents the value(s) that changed.
Buy=B; Hold=H; Sell=S; Discontinued=D; Suspended=SU; Discontinued=D; Initiation=I

For a price chart with our ratings and target price changes for GLPG go to
http://stifel2.bluematrix.com/sellside/Disclosures.action?ticker=GLPG

Prior to July 10, 2020, a different Stifel research analyst provided research coverage of Galapagos NV and its securities. Galapagos NV's price chart for the period prior to July 10, 2020 reflects the rating and price target history of the former Stifel research analyst for such issuer and its securities.

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Stifel or an affiliate is a market maker or liquidity provider in the securities of Galapagos NV.

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BUY -We expect a total return of greater than 10% over the next 12 months with total return equal to the percentage price change plus dividend yield.

HOLD -We expect a total return between -5% and 10% over the next 12 months with total return equal to the percentage price change plus dividend yield.

SELL -We expect a total return below -5% over the next 12 months with total return equal to the percentage price change plus dividend yield.

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