### Gilead Sciences

# Phase III Filgotinib UC Data Coming - Yes Other Stuff Besides Coronavirus Too

March 29, 2020

#### Key Takeaway

GILD will report out Phase III UC data for filgotinib in Q2 and positive data could drive investor sentiment and consensus sales higher across the Street. GILD is ahead of ABBV in UC so this is an area of pot'l differentiation against competitors. We describe expectations and compare the landscape of UC data (chart inside this report). With a 3.5% yield and minimal impact from coronavirus, GILD remains a favored large cap biotech in this tough environment.

Big Picture: GILD remains a defensive positioning stock particularly in this macro environment. We appreciate short-term trading has been mostly dictated around market volatility risk-on/off and expectations on remdesivir for COVID-19 data starting in April (recently confirmed by CEO this weekend in an open letter to the public). Fundamentally however, we still like GILD for the improving story, starting more M&A (\$5B FTSV deal was a good start), and it's still cheap. We think Phase III UC data for filgotinib (\$1-2B + pot'l GILD sales here in \$6B+ UC market) would be a nice catalyst in Q2 and further improve sentiment around the franchise as an area of differentiation to ABBV.

Phase III UC data is due in Q2: Generally speaking, we think pbo-adjusted remission rates of 10-15% at Week 10 (induction period) and 20-25% at Week 58 (maintenance) would make filgotinib "competitive" with other UC drugs, including Humira, Entyvio, and other JAKs (ABBV Rinvoq in Phase III and PFE Xeljanz). While we expect investors to make cross-trial comparisons, we caution comparing directly to other UC datasets is imprecise due to differing baseline characteristics such as proportion of biologic naive/experienced and slightly different endpoints of the Mayo score. However – recent commentary from GILD suggests positive confidence around results and good activity in both biologic naive and experienced. \*\*See Exhibit 1 for UC dataset comparison table\*\*

PDUFA in RA is August 2020: Two other approval debates in RA: (1) Will they get a Black Box? Expectations are already yes given ABBV FDA approval correspondence letter suggesting the agency was likely to give a class label Black Box to the class due to the uncertainty of degree of bleeding difference between various JAKs (GILD traded down on that), (2) Will filgotinib get the 200mg "high dose" approved in RA? GILD has not commented on any Adcom panel and ABBV did not have a panel. However, it is technically possible filgotinib only gets initial approval in RA for the lower 100mg dose and not the higher 200mg dose. High dose has slightly better efficacy so we'd like to see 200mg approved. GILD says interim MANTA safety data looking at 200mg will be shared with the FDA during the RA review but note the study was recently halted due to the COVID-19 situation. In any case, it's reasonable to approve 200mg particularly if the MANTA interim look is OK but FDA is a conservative bunch (though we did note Ozanimod in MS has no first dose monitoring which was nice to see in MS last week). Also, even if not, we point out ABBV was only approved at the low dose in RA as well so it would not be a totally critical issue.

### **COMPANY UPDATE**

# USA | Biotechnology RATING BUY PRICE \$72.85^ MARKET CAP \$92.8B PRICE TARGET (PT) \$89.00 UPSIDE SCENARIO PT \$98.00 DOWNSIDE SCENARIO PT \$60.00

^Prior trading day's closing price unless otherwise noted.

FY Dec				
USD	2018A	2019A	2020E	2021E
EPS	6.68	6.64	6.28	6.47
FY P/E	10.9x	11.0x	11.6x	11.3x

EPS calculation accounts for stock-comp (starting in Q1:20)

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Please see analyst certifications, important disclosure information, and information regarding the status of non-US analysts on pages 13 to 19 of this report.

# **GILEAD SCIENCES (GILD)**

Estimates										
	2018A	2019A	2020E	2021E						
Rev. (MM)	22,127.0	22,449.0	22,269.0	22,624.3						
Previous										
Consensus EPS	-	-	7.07	6.91						
Previous										
EPS		•	•							
Q1	1.48	1.76	1.57	-						
Previous										
Q2	1.91	1.82	1.63	-						
Previous										
Q3	1.84	1.75	1.57	-						
Previous										
Q4	1.44	1.30	1.51	-						
Previous										
FY Dec	6.68	6.64	6.28	6.47						
Previous										

Valuation										
	2018A	2019A	2020E	2021E						
P/Rev	4.2x	4.1x	4.2x	4.1x						
FY P/E	10.9x	11.0x	11.6x	11.3x						
EPS calculation accounts fo	r stock-comp (starting in Q1:20)									

Market Data	
52-Week Range:	\$85.97 - \$60.89
Total Entprs. Value	\$91.7B
Avg. Daily Value MM (USD)	1,979.33
Float (%)	98.7%

Financial Summary	
Long-Term Debt (MM)	\$24,750.0
Cash & ST Invest. (MM)	\$25,840.0

### The Long View

### Scenarios

#### **Base Case**

- Our \$89 PT is based on our view that GILD remains a cheap and low-expectation story that is getting better and can achieve even a 13x multiple on 2020 earnings which is still below pharma and big biotech peers.
- Our analysis suggests a durable HIV business along with a manageable/more predictable HCV business
- Importantly, GILD does more M&A, including string-ofpearls type bolt-ons and continues to build its mid/latestage pipeline to improve 2020-2022 visibility

#### **Upside Scenario**

- Our \$98 upside scenario price is based on applying a 15-16x multiple to our 2020 non-GAAP EPS estimate, or our DCF of base business and pipeline products
- Our upside target is based on a durable HIV business that remains flattish instead of declining post 2019-2020
- We could see multiple expansion if there is near-term stabilization and/or growth in the Hep C franchise or upside positive data readouts from pipeline programs in NASH, inflammation and oncology
- The Yescarta launch goes better than expected in 2020

### **Downside Scenario**

- Our \$60 downside scenario is based on applying a 9x multiple to our 2020 non-GAAP EPS estimate
- Viread will face generics in the EU that could take more share than expected
- GSK could take increasing market share in HIV based on dolutegravir-based two-drug regimens
- HCV franchise is likely to face pricing pressures from ABBV, MRK, and JNJ with new effective HCV regimens
- The Yescarta launch could disappoint in 2020

#### Investment Thesis / Where We Differ

- We believe GILD will continue to do more M&A (potentially in the gene therapy/ gene-editing space)
- We believe GILD's HIV franchise could be durable against potential GSK competition and generics
- We believe the HCV business has increased visibility and will become more manageable (volume stabilization)

#### Catalysts

March/April: Preliminary data from remdesivir in SARS-CoV2

Q2:20: Topline data from Phase IIb/III in UC (SELECTION)

Aug 19, 2020: Potential approval of filgotinib

**H2:20:** Data from pivotal Phase III study in 2nd line DLBCL (ZUMA-7)

# Filgotinib For Ulcerative Colitis (UC)

For the Upcoming Phase III UC Data in Q2:20, We Expect To See Placebo-Adjusted "Remission" Rates of (1) 10-15% at Week 10 and (2) 20-25% at Week 58

Generally speaking, we think placebo-adjusted remission rates of 10-15% at Week 10 (induction period) and 20-25% at Week 58 (maintenance) would make filgotinib competitive with currently approved drugs, including TNF-alphas (Humira and Simponi), integrin inhibitors (Entyvio), and other JAKs (Rinvoq in Phase III and Xeljanz approved).

While we certainly expect investors to make cross-trial comparisons, we caution that comparing filgotinib directly to other UC datasets could be challenging (and somewhat imprecise), due to: (1) differing baseline patient characteristics such that the proportion of biologic-exposed patients enrolled in this filgotinib study could be significantly greater, (making it more challenging for filgotinib to demonstrate comparable efficacy), and (2) differing efficacy timepoints and clinical endpoints. For instance, GLPG is using a Modified mayo score (vs traditional Mayo score) so the baseline severity could differ, and filgotinib's co-primary endpoints are assessed at slightly later timepoints.

- During GILD's Q4:19 EPS call in early Feb 2020, management noted it still expects to see efficacy in the treatment-experienced subgroup akin to what other Phase III UC trials have previously shown: "But, in terms of expectations of response, I think if you look at this population, as you know, they cycle through a variety of medications. And while the response rate, when they cycle to the next medication, isn't usually as robust as a naïve patient, there are good there's good evidence that going from let's say Entyvio to a TNF inhibitor or vice versa, you have -- you still have a good proportion of patients who respond in that. So, I think our expectations are fairly realistic about what the response -- that we'll have responders in there to filgotinib."
- GLPG's definition of 'clinical remission': The SELECTION trial's definition of 'clinical remission' utilizes the modified Mayo score called "EBS" (entails 5-9 points for inclusion), rather than the more traditional Phase III Mayo score endpoint (6-12 points for inclusion).

Compared to PFE's Xeljanz (approved oral JAK inhibitor), our base assumption is for filgotinib to show (1) comparable efficacy and (2) a more favorable safety profile (e.g. lesser DVT/PE instances). Also, while we do not fully expect to see a clear efficacy separation between the 100/200mg doses as the US sites can only administer the 200mg dose to treatment-experienced patients (or "harder to treat" patients), it still wouldn't surprise us to see a dose-response given the higher dose did demonstrate slightly better efficacy in the separate Phase III rheumatoid arthritis (RA) studies.

- We expect to see an overall 10-15% pbo-adj remission rate at the 10-week mark (induction period). For relative context, remission rates for other Phase III studies that enrolled a mix of biologic-naive and biologic-experienced patients were:
- (1) 7-9% for ABBV's Humira at Week 8 (22% of patients were TNF refractory or TNF-IR),
- (2) 12% for Takeda's Entyvio at Week 6 (39% were TNF-IR),
- (3) 12% for JNJ's Stelara at Week 8 (51% were biologic-IR, and 17% were dual refractory to TNF/integrin blockers),
- (4) 10-13% for PFE's Xeljanz at Week 8 (50%+ were TNF-IR);

### **EQUITY RESEARCH**

Gilead Sciences, Inc. (GILD)



(5) Notably, ABBV's Rinvoq (JAK1) showed a higher 15-20% placebo-adjusted remission
rate, although the results were based on a smaller Phase IIb study so this could moderate
when they complete their Phase III.

# Gilead Sciences, Inc. (GILD)

# Jefferies

**UC Efficacy Comparison Table** 

		Marakaniamar		Balanani	%Prior Biologic				Respon	se Rates	S					Rei	mission Ra	ates			
Company*	Drug	Mechanism of Action (MOA)	Status	Relevant Trial Data	Exposure <sup>1</sup>	Arm	Wk	Induce <sup>2</sup>	vs Pbo	Wk	Sustain <sup>3</sup>	vs Pbo	Wk	Induce <sup>2</sup>	vs Pbo	Wk	Maintain 4	vs Pbo	Wk	Sustain <sup>3</sup>	vs. Pbo
Janssen (JNJ)	Remicade (Infliximab)	TNFα	Approved (2005)	Phase III	N/M	5mg/kg	8	65-69% 29-37%	32-36%	8,30,54	39% 14%	25%	8	34-39% 6-15%	24-28%	54	35% 17%	18%	8,30,54	20% 7%	13%
AbbVie (ABBV)	Humira	ΤΝΕα	Approved	Phase III	~22% (TNF-IR)	placebo 160/80mg	8	42-50%	7-15%	8, 52	24%	12%	8	17-19%	7-9%	54	17%	9%	8, 52	9%	4%
	(Adalimumab) Simponi		(2012) Approved		, ,	Placebo		35% 51%			12% 50%			9% 18%			9% 34%			4% 28%	
Janssen (JNJ)	(Golimumab)	ΤΝΓα	(2013)	Phase III	0%	200/100mg Placebo	6	30%	21%	30,54	31%	19%	6	6%	11%	54	22%	12%	30, 54	16%	12%
Takeda/ Millennium	Entyvio (vedolizumab)	Integrin inhibitor (IRA)	Approved (2014)	Phase III	~39% (TNF-IR)	300mg	6	47% 26%	22%	6, 52	57% 24%	33%	6	17% 5%	12%	52	42% 16%	26%	6, 52	21% 9%	12%
Pfizer (PFE)	Xeljanz	JAK 1,2,3	Approved	Phase III	~52% (TNF-IR)	Placebo 10mg/5mg	8	55-60%	26-27%	8,32,60	52%	32%	8	17-19%	10-13%	52	34%	23%	0,24,52	46%	36%
` '	(Tofacitnib)	JAN 1,2,3	(2018)			Placebo		29-33%			20%			4-8%			11%			10%	
Jonhson (JNJ)	Stelara (ustekinumab)	IL-12/IL-23	Approved (2019)	Phase III	~51% (Bio-IR) ~17% (TNF/IRA-IR)	6mg/kg, 90mg Placebo	8	58% 31%	27%	8, 52	74% 48%	26%	8	19% 7%	12%	52	45% 26%	19%	8, 52	66% 36%	30%
AbbVie (ABBV)**	Rinvoq (Upadacitinib)	JAK1	In clinic	Phase IIb	~74% (Bio-IR)	15-45mg	8	44-50% 13%	31-37%	-	-	-	8	14-20% 0%	14-20%	-	-	-	-	-	-
Roche	etrolizumab	Integrin inhibitor	In clinic	Phase II	~61% (TNF-IR)	Placebo 100-300mg	10	31-33%	2-4%	-	-	-	10	10-21%	10-21%	-	-	-	-	-	-
		(IRA)				placebo		29%			-			0%			-			-	

#### \* For all trials (except Rinvoq):

(1) Clinical response: Mayo score reduction by ≥30% and ≥3 points, plus decrease in rectal bleeding subscore of ≥1 or a rectal bleeding subscore of ≤1 point

(2) Clinical remission: Mayo score of ≤2 points, plus no individual subscore >1 point

#### \*\* For ABBV Rinvoq:

(1) Clinical response: (per Adapted Mayo Score) is defined as a decrease from baseline in the Adapted Mayo score >2 points and >30% from baseline, plus a decrease in RBS >1 or an absolute RBS <1.

(2) Clinical remission: (Adapted Mayo Score [MBS)=0, and endoscopic subscore (ES)<1. rectal bleeding subscore (RBS)=0, and endoscopic subscore (ES)<1.

<sup>1</sup>TNF-IR: TNF-Inadequate Responder; Bio-IR: Biologic-Inadequate Responder; IRA-IR: Inadequate Responder to Integrin Receptor Antagonist

<sup>2</sup> Induce: Induction phase - "initial" dosing period, with response/remission rates evaluated at Weeks 6-10 (e.g. end of study portion)

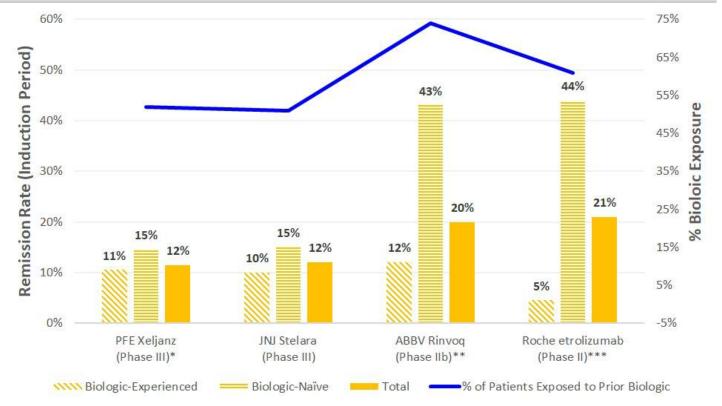
<sup>3</sup> Sustain: % of patients with sustained responses/remissions at further timepoints (e.g. at Weeks 8, 30, 52)

<sup>4</sup> Maintain: Maintenance phase - % of patients who maintain responses/remissions at end of study period (e.g. at Week 52)

Source: Jefferies estimates, Company reports

- We are hopeful the treatment-experienced patient subgroup can show a fairly similar short-term remission rate to that of the treatment-naive subgroup. We note PFE Xeljanz and JNJ Stelara have shown that their respective JAK and IL-12/IL-23 inhibitors achieve a remission rate that appears mostly irrespective to prior treatment (e.g. 10-11% for biologic-experienced vs 15% for biologic-naive patients).
- Separately, we expect to see a 20-25% pbo-adj remission rate at Year 1 (maintenance period). Again, remission rates seen by comparable Phase III studies range between 10-20% for TNFs and 15-25% for others, including PFE's Xeljanz (JAK). Even though ABBV's Rinvoq and Roche's etrolizumab have shown a stark efficacy difference between their patient subgroups, we would attribute their findings to a relatively small Phase II study so this is difficult to interpret (see chart below).
- Our general expectations for the other efficacy parameters: (1) A consistent 20-30% response rate throughout the entire study would be comparable, in our view, (2) for endoscopic remission, the comparable data points are sparse but a 10-25% remission rate during the initial 10-week period would appear comparable to PFE's Xeljanz and ABBV's Rinvoq (both of which are JAK inhibitors).

Exhibit 1 - Comparing the Placebo-Adjusted Remission Rates for Various UC drugs (During the Initial Induction Period), Broken out by Treatment-Naïve and Treatment-Experienced Patients



\*Averaged across trials; \*\*45mg dose only, used different clinical remission definition; \*\*\*100mg dose only Source: Company reports, Jefferies estimates



# Data Should Also Confirm Filgotinib's Differentiated Safety Profile...

Even though a handful of companies including GILD/GLPG are developing or already commercializing oral drugs that target the "JAK signaling" pathway, we believe filgotinib has more JAK1 selectivity (than on JAK2/3) than any other JAK inhibitor which could improve safety. Other JAK inhibitors have shown to produce a range of side effects, including higher bleeding rates, abnormalities in LDL, cholesterol, red blood cell counts, etc. In fact, the FDA issued a black box warning for LLY Xeljanz's unapproved 10mg BID dose back in July 2019 - a few months after the agency concluded the higher dose increased the risk of blood clots and death.

• We continue to expect Phase III filgotinib UC data to show a favorable safety profile versus other JAKs, such as: (1) a very low incidence of deep venous thrombosis (DVT) and pulmonary embolisms (PE), (2) low infection rates, (3) increased hemoglobin (Hb) levels, (4) prevention of fatty plaque formation in the arteries, and (5) increased lipid fractions, including HDL.

However -- whether the agency still puts a Black Box on the filgotinib label remains an unanswered question given the conservative nature of the agency and typical practice for "class labeling" by FDA. In addition, commentary in the ABBV FDA approval correspondence letter suggested the FDA was likely to give a class label Black Box to all drugs in the class given the uncertainty of degree of difference between the various drugs.

- It is also possible that this year GILD's filgotinib only gets approval in RA for the lower 100mg dose in the US and not the higher 200mg dose.
- While the EMA did not have major concerns about the 200mg dose and allowed this to be tested in clinical trials for RA, the FDA has had concerns about this dose and has been requiring an ongoing Phase II "male reproductive toxicity" study to determine if the 200mg dose has adverse male reproductive effects (may include lower sperm count or other factors). Because the clinical efficacy is slightly better for 200mg over 100mg in RA but not significantly different and because the male tox study may not yet be finished by the time of FDA approval it's reasonable the FDA might only approve the lower 100mg dose in the US. The EU may approve the 200mg dose however.

### Current Status of Filgotinib for Rheumatoid Arthritis (RA)

Filgotinib is a highly-selective oral JAK1 inhibitor currently under regulatory review in the US, Europe, and Japan for rheumatoid arthritis (RA). We expect regulatory approvals for all three regions in H2:20.

- (1) In the US, GILD used a priority review voucher during its NDA filing on Dec 19, 2019, implying an FDA decision around Aug 19, 2020. Interestingly, the co did not formally press release the acceptance of the NDA but has acknowledged it was accepted with Priority Review.
- (2) In the EU, GILD submitted the MAA around mid-2019 (EMA validated the filing in Aug 2019), so we estimate a CHMP recommendation and approval decision sometime around Q3:20.
- (3) In Japan, GILD submitted the JNDA in Q3:19, meaning that a PDUFA decision is expected in H2:20.



 To date, GLPG has generated compelling Phase II/III data in RA, as well as positive Phase II datasets in psoriatic arthritis (PsA), ankylosing spondylitis (AS), and Crohn's disease (CD).

# Timing of Phase III UC Data in Q2:20 Should Be Unaffected by the Coronavirus Situation

The Coronavirus pandemic has slightly delayed filgotinib's ongoing clinical programs, but the important Phase III ulcerative colitis (UC) data remains on track for Q2:20. Filgotinib is currently in three Phase III studies for Ulcerative Colitis (UC), Crohn's disease (CD), and psoriatic arthritis (PsA). In March 2020, GLPG paused patient enrollment for the Phase III CD (DIVERSITY) and PsA (PENGUIN) studies, due to the Covid-19 pandemic. The CD program was originally expected to complete enrollment in H2:20 (suggesting topline data in H2:21 or early 2022), while PENGUIN began enrolling patients in Q4:19. Fortunately, the Phase III ulcerative colitis program (SELECTION) remains unaffected and is on track to report data in Q2:20.

 In addition to CD and PsA, the company halted enrollment in filgotinib's other clinical studies, including: (1) a Phase II uveitis trial, (2) the MANTA/MANTA-RAy trials (male toxicity studies), and (3) a Phase III ankylosing spondylitis study, which is now expected to start later in 2020 (vs prior guidance of H1:20).

**Exhibit 2 - Selected Filgotinib Studies** 

Area	Program	Phase	Status
Rheumatoid Arthritis (RA)	FINCH	Filing	Regulatory Review (US, EU, Japan)
Ulcertative Colitis (UC)	SELECTION	Phase III	Data in Q2:20
Crohn's Disease (CD)*	DIVERSITY	Phase III	Complete enrollment in H2:20
Psoriatic Arthritis (PsA)*	PENGUIN	Phase III	Enrolling
Ankylosing Spondylitis (AS)*	-	Phase III	Starting Phase III in 2020
Safety (Male Toxicity)*	MANTA/MANTA-RAy	Phase II	Complete enrollment in H2:20
Small bowel Crohn's	DIVERGENCE1	Phase II	Ongoing (enrollment completed)
Uveitis*	HUMBOLDT	Phase II	Enrolling
Fistulizing Crohn's	DIVERGENCE2	Phase II	Enrolling
Sjogren's	-	Phase II	Data in 2019
Cutaneous Lupus (CLE)	-	Phase II	Data in 2019
Lupus nephropathy	-	Phase II	No longer enrolling

<sup>\*</sup> Enrollment paused due to Coronavirus

Source: Company reports, Jefferies estimates

Compared to currently approved biologic agents such as TNFs (e.g. Humira, Remicade), filgotinib is administered orally, targets JAK1 specifically, and has a rapid onset, sustained response with potential for monotherapy use. For RA, UC and CD, the current standard-of-care includes biologics consisting of mostly TNF therapies. However, since biologics require injections and often lose their efficacy over time, there remains a considerable unmet need in terms of efficacy, safety and convenience of use.

As a JAK1 inhibitor, filgotinib prevents the overstimulation of JAK1 proteins (located inside immune cells), which in turn reduces inflammation and curbs the instances of abdominal pain, diarrhea and bloody stools.

# MANTA (Male Toxicity) Safety Study Remains Paramount - We Expect Further Updates in 2020

The recent Coronavirus pandemic has forced GLPG to halt patient enrollment in many of filgotinib's ongoing clinical studies, including the MANTA/MANTA-RAy male toxicity trials. Over the past few years, the FDA became concerned with the 200mg high-dose as

preclinical data in rats and dogs suggested filgotinib could potentially cause testicular toxicity (low sperm count), after which GLPG excluded males from the 200mg cohort in the Phase II RA study (DARWIN).

- The FDA's concerns led GLPG to start the dedicated Phase II male toxicity safety trial in UC and CD patients (MANTA). Later in 2019, GLPG initiated a second safety study called MANTA-RAy that leverages a more relaxed inclusion criterion (e.g. by enrolling patients with rheumatic diseases such as RA, PsA, AS) to accelerate recruitment.
- It remains unclear when GILD/GLPG will share the topline MANTA data, given GILD expects patient recruitment to finish in "H2:20". We initially assumed the partners would unblind the data in 2020 to support the RA filing (PDUFA expected in Aug 2020), but GLPG has recently said MANTA is not required for approval, and that the company would share the data in an unblinded manner.
- While the Phase II RA dataset (DARWIN) and the subsequent Phase III data (FINCH) ultimately confirmed no meaningful changes in male hormone levels even at the 200mg high dose studied in FINCH, US males in the Phase III UC study (SELECTION) can only receive the higher dose if they have failed (1) at least one anti-TNF (e.g. Humira/Remicade), and/or (2) vedolizumab (Entyvio), which is an integrin receptor antagonist.

## Rationale of Pursuing Filgotinib in Ulcerative Colitis (UC)

In 2016, positive Phase II filgotinib data in Crohn's disease (FITZROY) prompted GILD to start two Phase III studies in Crohn's disease (CD) as well as ulcerative colitis (UC). Since CD and UC are both inflammatory bowel diseases (IBDs) and are somewhat similar in nature, UC represented a natural extension for filgotinib. Whereas CD affects the gastrointestinal (GI) tract broadly, UC causes inflammation of only the colon and rectum.

 In short, the Phase II FITZROY data (n=174) showed that 47% of Crohn's patients achieved the 10-week primary endpoint of clinical remission, compared to 23% for placebo (or a 24% stat-sig difference).

We believe IBD affects ~2M patients in the US and Europe (of which 0.5M are treated with biologics), representing a \$9B+ market. Specifically, we think UC affects over 1.2M+ patients, representing a \$5B+ market. While anti-TNF biologics are widely used, only ~33% of UC patients achieve long-term remission, and many of them become unresponsive to treatment over time.

### Phase III UC Trial Design (SELECTION)

In Dec 2016, GILD initiated the placebo-controlled Phase IIb/III study (SELECTION) to evaluate 100mg and 200mg once-daily filgotinib doses in moderate/severe UC patients, including both biologic-naive and biologic-experienced patients. The study completed screening in 2019 and has enrolled 1,350+ patients who reside in the US, Europe, Latin America, Canada and Asia. Topline data is expected in Q2:20, with the primary endpoint being % remission (based on Mayo score components).

- 4 of 5 patients receive filgotinib for 10 weeks during the initial induction phase. Patients who respond favorably during this period move on to the maintenance phase.
- 2 of 3 patients receive filgotinib for another 48 weeks during the maintenance phase.
- Patients whose symptoms get worse after 10 weeks in the induction phase can receive filgotinib in a separate long-term extension study.

Interim futility analysis completed in 2018: In May 2018, the independent Data Monitoring Committee (DMC) conducted a planned interim futility analysis of SELECTION after 350 UC patients completed the induction period in the Phase IIb portion of the study. The DMC recommended GLPG/GILD to move into Phase III and evaluate the 100mg and 200mg daily doses against placebo.

### Design of the III SELECTION study:

- Patients: 3551 adult UC patients who are biologic-naive and biologic-experienced.
   Treatment-experienced patients must have at least 1 prior inadequate response to a corticosteroid, immunomodulator, TNF-antagonist, or Entyvio (the prior treatment regimen depends on country treatment guidelines).
- Inclusion criteria: Moderate/Severe UC diagnosis of at least 6 months, with a minimum disease extent of 15cm from the anal verge.
- **Exclusion criteria:** Presence of Crohn's disease, indeterminate colitis, ischemic colitis, fulminant colitis, ulcerative proctitis, or toxic mega-colon.
- Doses: 100mg and 200mg vs placebo (once-daily)
- Specific dosing restriction for US patients: US males can only receive the higher 200mg dose if they have failed (1) at least one anti-TNF (e.g. Humira/Remicade), and/or (2) vedolizumab (Entyvio), which is an integrin receptor antagonist.
- Duration: 10 weeks for the induction phase, plus 48 weeks for the maintenance phase
- Co-Primary Endpoints: Remission at Week 10 (induction) and Week 58 (maintenance), based on components of the Mayo Clinical Score (MCS)
- Secondary Endpoints: Endoscopic remission, histologic remission, safety
- Extension Phase: Patients who do not meet the response/remission criteria at Week 10
  have the option to enter a long-term extension (LTE) study.
- Primary Completion Date: April 2020
- Clinicaltrials.gov Identifier: NCT02914522

# **GLPG/GILD Collaboration Details**

### Galapagos Collaboration

Dec 2015 (Filgotinib): GILD partnered with GLPG to develop and commercialize filgotinib for inflammatory indications, paying GLPG \$725M upfront including a \$300M fee and \$425M equity stake. In addition, GLPG is entitled to (1) development and regulatory milestones of up to \$755M (\$110M of which has been paid to GLPG, as of Dec 2019), (2) sales milestones of up to \$600M, and (3) ex-EU royalties in the 20-30% range, except for certain EU co-commercialization territories where profits are shared equally (e.g. UK, Germany, France, Italy, Spain, Belgium, Netherlands and Luxemberg).

- GILD has a worldwide sublicensable license for filgotinib.
- GILD is primarily responsible for the development and regulatory approval of filgotinib, whereas GLPG has agreed to co-fund 20% of development costs through regulatory approval.

July 2019 (Significant Expanded partnership deal): In the revised collaboration, GILD now gets access to a portfolio beyond filgotinib, including multiple clinical compounds, 20 preclinical programs and a drug discovery platform: (1) GILD paid \$4B upfront and acquired a \$1.1B equity investment, increasing its stake from 12% to 22% (paid at a 20% premium) which could be increased towards 30%. (2) GILD receives USA (ex-EU) rights to Phase III

'1690 for IPF, an option (\$250M opt-in) on '1972 in OA after the Phase IIb data, and an option (\$150M ex-EU option rights) to all of GLPG's other programs post Phase II data. (3) Meanwhile, GLPG agrees to co-commercialize filgotinib in certain EU countries with a 50/50 profit-share, and is entitled to \$1.3B in milestones and 20-30% in royalties for ex-EU countries. For assets outside of filgotinib, GLPG is entitled to royalties in 20-24% range, (4) agreement also includes a 10-year standstill.

In Q4:19, GILD exercised a warrant and purchased 2.6M shares of GLPG for \$586M. GILD now owns 16.7M of GLPG shares and holds a ~25.8% stake (up from 22%).

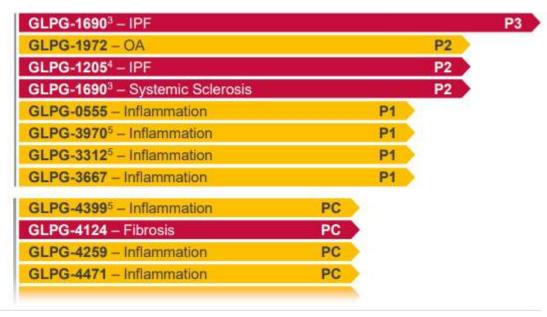
### Eisai Collaboration for Filgotinib

**Dec 2019 (Eisai to co-promote filgotinib in Japan)**: GILD handles manufacturing and marketing approval of filgotinib in Japan, while Eisai is responsible for product distribution in Japan in RA and other potential future indications, including UC, Crohn's and Psoriatic Arthritis.

Exhibit 3 - Optionable Partnered Programs Outside of Filgotinib (GILD/GLPG Collaboration)

8 clinical programs<sup>1,2</sup>

>20 pre-clinical



Source: Company reports

programs<sup>2</sup>

March 29, 2020

# Gilead Sciences, Inc. (GILD)

# **Jefferies**

Exhibit 4 - GILD Income Statement

Fiscal Year (Ending in December)	FY17	1Q18	2Q18	3Q18	4Q18	FY18	1Q19	2Q19	3Q19	4Q19	FY19	1Q20E	2Q20E	3Q20E	4Q20E	FY20E	FY21E
(\$ figures in MM, except per share)		Mar-18	Jun-18	Sep-18	Dec-18		Mar-19	Jun-19	Sep-19	Dec-19		Mar-20	Jun-20	Sep-20	Dec-20		
Non-GAAP Income Statement				<u> </u>					<u> </u>								
HCV Sales	\$9,137.0	\$1,048.0	\$1,000.0	\$902.0	\$738.0	\$3,688.0	\$790.0	\$842.0	\$674.0	\$630.0	\$2,936.0	\$624.0	\$618.0	\$607.0	\$596.0	\$2,445.0	\$2,274.6
Harvoni	4,370.0	350.0	331.0	311.0	232.0	1,224.0	225.0	193.0	124.0	101.0	643.0	105.0	100.0	90.0	85.0	380.0	323.0
Sovaldi	964.0	55.0	60.0	11.0	(24.0)	102.0	11.0	81.0	(29.0)	8.0	71.0	3.0	3.0	3.0	3.0	12.0	12.0
Epclusa (SOF / VEL)	3,510.0	536.0	500.0	477.0	453.0	1,966.0	491.0	493.0	516.0	465.0	1,965.0	460.0	460.0	460.0	455.0	1,835.0	1,729.0
Vosevi (SOF/VEL/VOX)	293.0	107.0	109.0	103.0	77.0	396.0	63.0	75.0	63.0	56.0	257.0	56.0	55.0	54.0	53.0	218.0	210.6
HIV Sales	\$14,003.0	\$3,247.0	\$3,665.0	\$3,727.0	\$4,065.0	\$14,704.0	\$3,618.0	\$4,041.0	\$4,202.0	\$4,577.0	\$16,438.0	\$4,216.0	\$4,378.0	\$4,440.0	\$4,487.0	\$17,521.0	\$17,799.7
Atripla (Emtriva/Viread/Sustiva)	1,806.0	314.0	349.0	258.0	285.0	1,206.0	171.0	152.0	149.0	128.0	600.0	105.0	95.0	85.0	75.0	360.0	150.0
Truvada (Emtriva/Viread)	3,134.0	652.0	765.0	757.0	823.0	2,997.0	606.0	718.0	721.0	768.0	2,813.0	522.0	370.0	318.0	216.0	1,426.0	704.0
Complera (Rilpivirine/Emtriva/Viread)	966.0	190.0	199.0	139.0	125.0	653.0	115.0	123.0	93.0	75.0	406.0	60.0	50.0	40.0	30.0	180.0	100.0
Stribild (Elvitegravir/Cobicistat/Emtriva/Viread)	1,053.0	174.0	187.0	146.0	137.0	644.0	96.0	108.0	94.0	71.0	369.0	50.0	45.0	40.0	35.0	170.0	100.0
Viread (TDF)	1,046.0	97.0	-	-	-	97.0	-	-	-	-	-	-	-	-	-	-	-
Genvoya (Elvitegravir/Cobicistat/Emtriva/TAF)	3,674.0	1,082.0	1,160.0	1,176.0	1,206.0	4,624.0	1,015.0	980.0	978.0	958.0	3,931.0	935.0	950.0	930.0	910.0	3,725.0	3,482.7
Descovy (Emtriva/TAF)	1,218.0	361.0	403.0	406.0	411.0	1,581.0	342.0	358.0	363.0	437.0	1,500.0	555.0	715.0	775.0	835.0	2,880.0	3,059.0
Odefsey (Rilpivirine/Emtriva/TAF)	1,106.0	342.0	385.0	423.0	448.0	1,598.0	397.0	387.0	436.0	435.0	1,655.0	410.0	420.0	415.0	410.0	1,655.0	1,560.0
Biktarvy (Bictegravir/F/TAF)	, -	35.0	185.0	386.0	578.0	1,184.0	793.0	1,116.0	1,259.0	1,570.0	4,738.0	1,440.0	1,590.0	1,690.0	1,825.0	6,545.0	8,000.0
HIV Other (Post Viread Generic 2018)	_	_	32.0	36.0	52.0	120.0	83.0	99.0	109.0	135.0	426.0	139.0	143.0	147.0	151.0	580.0	644.0
Other antiviral	\$196.0	\$80.0		-	-	\$80.0	-	-	-	-	-	-	-		-	-	-
Other Product Sales	\$2,326.0	\$626.0	\$875.0	\$826.0	\$878.0	\$3,205.0	\$792.0	\$724.0	\$640.0	\$589.0	\$2,745.0	\$512.0	\$487.0	\$474.0	\$490.0	\$1,963.0	\$2,200.0
Axi-Cel (KTE-C19)	7.0	40.0	68.0	75.0	81.0	264.0	96.0	120.0	118.0	122.0	456.0	140.0	150.0	160.0	170.0	620.0	780.0
Filgotinib (RA)	-	-	-	-	-	-	-	-	-	-	-	-	-	5.0	13.0	18.0	190.0
Zydelig (iNHL/CLL)	149.0	33.0	39.0	20.0	41.0	133.0	27.0	26.0	26.0	24.0	103.0	22.0	20.0	18.0	16.0	76.0	50.0
AmBisome (ex-US)	366.0	107.0	103.0	102.0	108.0	420.0	93.0	105.0	99.0	110.0	407.0	65.0	55.0	35.0	30.0	185.0	80.0
Letairis	887.0	204.0	244.0	241.0	254.0	943.0	197.0	204.0	121.0	96.0	618.0	45.0	20.0	10.0	5.0	80.0	80.0
Ranexa	717.0	195.0	208.0	178.0	177.0	758.0	155.0	19.0	31.0	11.0	216.0	5.0	2.0	1.0	1.0	9.0	1
	/1/.0	195.0	76.0	87.0		263.0	101.0	116.0	134.0	137.0			160.0	170.0			820.0
Vemlidy	-	-	76.0 82.0	70.0	100.0 58.0		72.0	75.0	57.0	39.0	488.0	150.0		25.0	180.0	660.0 115.0	820.0
Viread (TDF)	200.0	47.0				210.0	_				243.0	35.0	30.0		25.0		
Other (excludes Sovaldi)	200.0	47.0	55.0	53.0	59.0	214.0	51.0	59.0	54.0	50.0	214.0	50.0	50.0	50.0	50.0	200.0 \$21.929.0	200.0
Product Sales (Antiviral Franchise + Other Products)	\$25,662.0	\$5,001.0	\$5,540.0	\$5,455.0	\$5,681.0	\$21,677.0	\$5,200.0	\$5,607.0	\$5,516.0	\$5,796.0	\$22,119.0	\$5,352.0	\$5,483.0	\$5,521.0	\$5,573.0	. ,	\$22,274.3
Royalty, contract and other revenues	445.0	87.0	108.0	141.0	114.0	450.0	81.0	78.0	88.0	83.0	330.0	85.0	85.0	85.0	85.0	340.0	350.0
Total Revenues	\$26,107.0	\$5,088.0	\$5,648.0	\$5,596.0	\$5,795.0	\$22,127.0	\$5,281.0	\$5,685.0	\$5,604.0	\$5,879.0	\$22,449.0	\$5,437.0	\$5,568.0	\$5,606.0	\$5,658.0	\$22,269.0	\$22,624.3
Cost of Sales	3,422.0	687.0	875.0	771.0	1,257.0	3,590.0	660.0	714.0	759.0	1,406.0	3,539.0	670.3	697.4	757.3	792.2	2,917.2	2,917.9
Operating Expenses	\$6,654.0	\$1,698.0	\$1,761.0	\$1,696.0	\$1,971.0	\$7,126.0	\$1,833.0	\$1,931.0	\$1,921.0	\$2,161.0	\$7,846.0	\$2,130.2	\$2,129.4	\$2,220.4	\$2,351.3	\$8,831.3	\$8,954.3
Research and Development (R&D)	3,291.0	814.0	921.0	844.0	939.0	3,518.0	871.0	916.0	954.0	1,029.0	3,770.0	1,038.4	1,012.6	1,041.2	1,133.9	4,226.0	4,276.7
Sales, General and Administrative (SG&A)	3,363.0	884.0	840.0	852.0	1,032.0	3,608.0	962.0	1,015.0	967.0	1,132.0	4,076.0	1,091.9	1,116.8	1,179.2	1,217.5	4,605.3	4,677.6
Total Costs and Expenses	10,076.0	2,385.0	2,636.0	2,467.0	3,228.0	10,716.0	2,493.0	2,645.0	2,680.0	3,567.0	11,385.0	2,800.5	2,826.7	2,977.7	3,143.6	11,748.5	11,872.2
Operating Income (EBIT)	\$16,031.0	\$2,703.0	\$3,012.0	\$3,129.0	\$2,567.0	\$11,411.0	\$2,788.0	\$3,040.0	\$2,924.0	\$2,312.0	\$11,064.0	\$2,636.5	\$2,741.3	\$2,628.3	\$2,514.4	\$10,520.5	\$10,752.1
Operating Margin	61.4%	53.1%	53.3%	55.9%	44.3%	51.6%	52.8%	53.5%	52.2%	39.3%	49.3%	48.5%	49.2%	46.9%	44.4%	47.2%	47.5%
Total Other Income	(577.0)	(165.0)	(130.0)	(127.0)	(94.0)	(516.0)	(84.0)	(77.0)	(86.0)	(121.0)	(368.0)	(112.5)	(123.5)	(118.2)	(112.9)	(467.0)	(463.4)
Pre-tax income	15,454.0	2,538.0	2,882.0	3,002.0	2,473.0	10,895.0	2,704.0	2,963.0	2,838.0	2,191.0	10,696.0	2,523.9	2,617.8	2,510.1	2,401.6	10,053.4	10,288.7
Provision for taxes	3,784.0	579.0	376.0	597.0	600.0	2,152.0	453.0	637.0	617.0	545.0	2,252.0	530.0	549.7	527.1	504.3	2,111.2	2,160.6
Effective Tax Rate (non-GAAP)	24.5%	22.8%	13.0%	19.9%	24.3%	19.8%	16.8%	21.5%	21.7%	24.9%	21.1%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%
Net loss attributable to noncontrolling interest	16.0	1.0	2.0	2.0	-	5.0	(7.0)	(5.0)	(3.0)	(7.0)	(22.0)	-	-	-	-	-	-
Net Income (non-GAAP)	\$11,654.0	\$1,958.0	\$2,504.0	\$2,403.0	\$1,873.0	\$8,738.0	\$2,258.0	\$2,331.0	\$2,224.0	\$1,653.0	\$8,466.0	\$1,993.9	\$2,068.1	\$1,983.0	\$1,897.2	\$7,942.2	\$8,128.1
EPS Basic (non-GAAP)	\$8.92	\$1.50	\$1.93	\$1.85	\$1.45	\$6.73	\$1.77	\$1.84	\$1.76	\$1.31	\$6.67	\$1.58	\$1.64	\$1.58	\$1.51	\$6.30	\$6.50
EPS Diluted (non-GAAP)	\$8.84	\$1.48	\$1.91	\$1.84	\$1.44	\$6.68	\$1.76	\$1.82	\$1.75	\$1.30	\$6.64	\$1.57	\$1.63	\$1.57	\$1.51	\$6.28	\$6.47
Shares Outstanding - Basic (non-GAAP)	1,307.0	1,307.0	1,298.0	1,296.0	1,290.0	1,297.8	1,276.0	1,270.0	1,267.0	1,266.0	1,269.8	1,265.6	1,261.6	1,257.8	1,254.1	1,259.8	1,250.8
Shares Outstanding - Diluted (non-GAAP)	1,319.0	1,320.0	1,308.0	1,307.0	1,299.0	1,308.5	1,283.4	1,277.4	1,267.4	1,273.4	1,275.4	1,271.2	1,267.3	1,263.5	1,259.8	1,265.4	1,256.6

Source: Jefferies estimates, Company reports



### **Company Description**

#### **Gilead Sciences**

Gilead is a leader in the development and marketing of anti-infective drugs, with approved products for the treatment of HIV/AIDS, Hep C, hepatitis B, liver and pulmonology diseases. Gilead is developing a pipeline of antivirals, liver disease, immunology and oncology. The company has an extensive worldwide sales and marketing infrastructure.

### Company Valuation/Risks

#### **Gilead Sciences**

Our PT is based on a pipeline-adjusted DCF and multiple of our 2020 EPS estimate. Risks: competition, pipeline disappointments, and worse-than-expected sales.

#### **Galapagos**

Our Price Target is based on a sum-of-the-parts valuation largley comprising probability-adjusted NPVs for filgotinib, GLPG1690 in IPF, GLPG1972 in osteoarthritis, and Toledo in autoimmune disorders, plus Net Cash. Risks include: (1) regulatory setbacks for filgotinib; (2) upcoming late-stage pipeline catalysts are high risk; and (3) clinical trial failures.

#### GlaxoSmithKline Plc

Valuation: Our Price Target is based on a 50:50 blend of P/E and NPV, assuming a 0% premium to the sector 2021E PE and a discount to the NPV sum-of-the-parts valuation. Risks: Dividend, Competition; M&A; Regulatory; LOEs/ litigation; FX; R&D; Manufacturing.

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### **Investment Recommendation Record**

(Article 3(1)e and Article 7 of MAR)

Recommendation Published March 29, 2020 , 17:31 ET.
Recommendation Distributed March 29, 2020 , 17:31 ET.

### **Company Specific Disclosures**

Jefferies LLC is acting as a financial advisor to Kite Pharma (KITE) on the sale of the company to Gilead Sciences (GILD).

Jefferies Group LLC makes a market in the securities or ADRs of Gilead Sciences, Inc.

Jefferies Group LLC makes a market in the securities or ADRs of Galapagos.

Jefferies Group LLC makes a market in the securities or ADRs of GlaxoSmithKline Plc.

### **Explanation of Jefferies Ratings**

Buy - Describes securities that we expect to provide a total return (price appreciation plus yield) of 15% or more within a 12-month period. Hold - Describes securities that we expect to provide a total return (price appreciation plus yield) of plus 15% or minus 10% within a 12-month period.

Underperform - Describes securities that we expect to provide a total return (price appreciation plus yield) of minus 10% or less within a 12-month period.

The expected total return (price appreciation plus yield) for Buy rated securities with an average security price consistently below \$10 is 20% or more within a 12-month period as these companies are typically more volatile than the overall stock market. For Hold rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is plus or minus 20% within a 12-month period. For Underperform rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is minus 20% or less within a 12-month period.

- NR The investment rating and price target have been temporarily suspended. Such suspensions are in compliance with applicable regulations and/or Jefferies policies.
- CS Coverage Suspended. Jefferies has suspended coverage of this company.
- NC Not covered. Jefferies does not cover this company.

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### **Jefferies Franchise Picks**

Jefferies Franchise Picks include stock selections from among the best stock ideas from our equity analysts over a 12 month period. Stock selection is based on fundamental analysis and may take into account other factors such as analyst conviction, differentiated analysis, a favorable risk/reward ratio and investment themes that Jefferies analysts are recommending. Jefferies Franchise Picks will include only Buy rated stocks and the number can vary depending on analyst recommendations for inclusion. Stocks will be added as new opportunities arise and removed when the reason for inclusion changes, the stock has met its desired return, if it is no longer rated Buy and/or if it triggers a stop loss. Stocks having 120 day volatility in the bottom quartile of S&P stocks will continue to have a 15% stop loss, and the remainder will have a 20% stop. Franchise Picks are not intended to represent a recommended portfolio of stocks and is not sector based, but we may note where we believe a Pick falls within an investment style such as growth or value.

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### Other Companies Mentioned in This Report

- · Galapagos (GLPG: \$182.14, HOLD)
- GlaxoSmithKline Plc (GSK: \$36.44, BUY)





Jefferies LLC is acting as a financial advisor to Kite Pharma (KITE) on the sale of the company to Gilead Sciences (GILD).





**Notes:** Each box in the Rating and Price Target History chart above represents actions over the past three years in which an analyst initiated on a company, made a change to a rating or price target of a company or discontinued coverage of a company.

<u>Legend:</u>

I: Initiating Coverage

D: Dropped Coverage

B: Buy

H: Hold

**UP: Underperform** 



# **Distribution of Ratings**

Distribution of Ratings											
			IB Serv./Pa	st12 Mos.	JIL Mkt Serv./Past12 Mos.						
	Count	Percent	Count	Percent	Count	Percent					
BUY	1288	54.28%	114	8.85%	12	0.93%					
HOLD	935	39.40%	34	3.64%	3	0.32%					
UNDERPERFORM	150	6.32%	1	0.67%	0	0.00%					



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