STIFEL

Galapagos NV
GLPG– NASDAQ; GLPG – NA

May 21, 2020

Biotechnology

BUY
Price $221.27 (close, 05/20/2020)

FLASH NOTE

Positive Topline Filgotinib Data in UC Suggests Likely Approval; Cross Trial Comparisons With Competitors Highly Challenging

Summary

GLPG and partner GILD announced positive topline data from P2b/3 SELECTION study with filgotinib (filgo) in UC. In the induction phase with 200mg filgo at Week 10, biologic-naïve patients achieved a 10.8% pbo-adjusted remission rate (RR; p=0.0157), while biologic-experienced patients achieved a 7.3% pbo-adjusted RR (p=0.0103). In the maintenance trial, both filgo doses achieved the primary endpoint. At Week 58, 37.2% of both biologic-naïve and biologic-experienced patients receiving filgo 200 mg achieved clinical remission vs. 11.2% for pbo (p#0.0001). For filgo 100 mg, 23.8% achieved clinical remission vs. 13.5% for pbo (p=0.0420). Safety appears in line with prior filgo studies. Although GLPG previously pointed to ABBV's Rinvoq Week 8 induction efficacy as likely best comparator (~14-20% pbo-adjusted remission), **cross trial comparisons are highly challenging due to differing baseline characteristics, pbo response rates, trial designs/endpoints)**. We expect more clarity after our call with management later this morning.

Key Points

Filgotinib 200mg achieved stat sig clinical remission vs. placebo in the induction and maintenance portions of the SELECTION trial; results and attempted competitor comparisons are tabulated in Exhibit 1. 26.1% of biologic-naïve patients treated with 200mg filgo in the induction portion of the study achieved clinical remission at Week 10, compared with 15.3% for pbo (p=0.0157) - a pbo-adjusted RR of 10.8%. Among biologic-experienced patients, 11.5% of those treated with 200 mg of filgo achieved clinical remission at Week 10, vs. 4.2% for pbo (p=0.0103) - a pbo-adjusted RR of 7.3%. Of note, filgo 100mg did not achieve statistically significant clinical remission at Week 10. As a reminder patients who achieved clinical response or remission after 10 weeks of treatment with filgo at either dose were subsequently re-randomized to their induction dose of filgo or pbo at a 2:1 ratio and treated through Week 58 (n=558). Both doses of filgo achieved the primary endpoint in this maintenance trial. At Week 58, 37.2% of biologic-naïve and biologic-experienced patients receiving filgo 200mg achieved clinical remission, vs. 11.2% for pbo (p#0.0001) - a pbo. adj. RR of 26%. For filgo 100 mg, 23.8% achieved clinical remission at Week 58 vs. 13.5% for pbo (p=0.0420) - a pbo. adj. RR of 10.3%. We are encouraged by the data, although not surprised given prior successes observed with competing JAKi (PFE's Xeljanz and ABBV's Rinvoq). However, we acknowledge the notable level of response in the placebo arms, which could skew benchmarking to other JAKi studies in UC (more on that below).

How to gauge the level success compared with others, specifically Rinvoq? We believe it's hard tell at the moment without more data. As a reminder, GLPG had previously signaled (note) that it was aiming for filgo efficacy to fall in line with what Rinvoq has shown (~15-20% placebo adjusted remission rate), but had cautioned (as do we) against cross-trial comparisons given the differences between the trials (i.e. differing baseline characteristics, pbo response rates, trial designs/endpoints). We outline major differences between studies in **Exhibit 1 and the appendix below**. Briefly, ABBV's P2b U-ACHIEVE study with Rinvoq includes an induction (15/30/45mg,QD) and maintenance phase in treatment-experienced patients. The primary endpoint includes an adapted Mayo score at 8 wks in the induction phase. PFE's P3 Octave study also included an induction portion followed by a maintenance phase in treatment experienced patients. However, the primary endpoint was remission measured at 8 wks using a total Mayo score. The placebo adjusted remission rate was ~10-13% at 8 wks in that study. By contrast, the primary endpoint in GLPG/GILD's P3 includes remission based on components of the Mayo Clinic Score at 10 wks. These differences in the endpoint measures and differences in baseline patient characteristics between the studies could account for differences in the rates of remission. In addition, placebo response rates varied greatly between the studies. We note that the filgo results are preliminary, and we expect to have more clarity after we speak with management in the morning and importantly when full data are presented or published. However, we continue believe that filgo will ultimately be approved in UC with significant revenue opportunity in UC alone - sales of Xeljanz (approved in RA, psoriatic arthritis, and UC) were $2.2B in FY19. We model filgo peak WW sales in UC of ~$4B in FY32, which is derived using just 10% penetration into the eligible UC patient population. In our view, this demonstrates a large filgo UC revenue opportunity, even if actual penetration rates prove more conservative than our current projections.

Initial safety profile consistent with prior filgo studies. Recall filgo's safety profile is considered a primary differentiator compared with other JAKi. Although we do not have a breakdown of the SAEs reported in the study, the incidence of SAEs between the treatment arms (induction and maintenance) and the placebo were comparable. ***Continued...***

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Investment Thesis

With the recent GILD partnership, GLPG is well-positioned to capitalize on its core drug discovery and development capabilities. We believe filgotinib has best-in-class safety that will prove a competitive advantage in the market and allow for meaningful penetration despite fourth to market status in RA. We think filgotinib also has significant potential in the IBD space, where oral compounds are likely to dominate the future treatment landscape. GLPG1690 has demonstrated potential in a P2, and P3 is progressing. The Toledo inflammation program remains opaque, but we are optimistic as we expect GILD examined the data in depth as part of its recent due diligence. We view GLPG as a well-funded, R&D productive, corporate partner validated, biotech player with a deep and broad pipeline and multiple significant value-creating milestones on the horizon.

Continued from above...The company reported that rates of serious infections, herpes zoster, venous thrombosis, pulmonary embolism and gastrointestinal perforation were low and comparable across treatment groups in both the induction and maintenance phases of the study. As a reminder, one of the debates around filgo is whether it will be able to avoid a black box for thromboembolic events (TE). GLPG believes that filgo's safety profile is more favorable when put up against its competitors, although Street thinks black box for filgo is likely due to Rinvoq black box that appears to be class warning. In UC, GLPG sees the MANTA and MANTA-ray testicular tox studies as important given the prevalence of UC in younger individuals (males of child bearing age) compared with RA, which tends to affect the older population. We plan to get a clearer picture regarding safety after our call with management, and will update appropriately.

Exhibit 1. Select Differences Between JAKi Studies in UC; Efficacy Data

	Filgotinib	Rinvoq	Xeljanz	TD-1473
Company	GLPG/GILD	ABBV	PFE	JNJ/ TBPH
Phase Dev	P2b	P3	Approved	P2/3
No. Patients	Induction - Biologic-naïve cohort (Cohort A; n=659), - Biologically-experienced cohort (Cohort B; n=689) Maintenance trial, n=558	N=250; inadequate response, loss of response or intolerance to corticosteroids, immunosuppressants or biologic therapies.	OCTAVE Induction 1; n=598 OCTAVE Induction 2; n=541 Patients with moderately to severely active UC despite previous conventional therapy or therapy with a TNF antagonist	N= 40; intolerant, refractory, or only partially responsive to aminosalicylates, corticosteroids, immunomodulators, or biologics.
Baseline Characteristics	Induction: • Biologic-naïve cohort (Cohort A induction trial; n=659), 52% had a baseline Mayo Clinic Score (MCS) of ≥ 9. • Biologically-experienced cohort (Cohort B induction trial; n=689), 74% had a baseline MCS of ≥ 9 • 51% were previously treated with 2 different classes of biologics (TNFα antagonists and an integrin receptor antagonist).	At baseline, 77.6% had prior use of biologics, 36% had an **Adapted Mayo Score >7,** and 79% had an endoscopic subscore of 3.	Induction: Total Mayo Score ranged from 8.9-9.1	NA
Efficacy	**Induction (10 wks)** : 200 mg dose Biologic-naïve patients: 26.1% vs. plbo: 15.3% (p=0.0157); plbo adj. **10.8%** Biologic-experienced patients: 11.5 % vs. plbo: 4.2 percent (p=0.0103); plbo adj. **7.3%**. 100 Dose: Not stat sig. (N/A) **Maintenance (58 wks)**: 200 mg dose Biologic-naïve patients: 37.2% vs. plbo: 11.2% (p=0.0001); plbo adj. **26%** Biologic-experienced patients: 37.2% vs. plbo: 11.2% (p=0.0001); plbo adj. **26%** 100 mg dose at 58wks: 23.8% vs. plbo: 13.5% (p=0.0420; plbo adj. **10.3%**	**Induction (8 wks.)**: Plb 0 % 7.5 mg: 9 % 15 mg: 14 % (P<0.05) 30 mg:14% (P<0.05) 45 mg: 20% (P<0.01)	**Induction (8 wks.)**: Octave 1: Tofacitinib 10mg BID; 18.5% vs. plbo: 8.2% (p=0.007) Octave 2: Tofacitinib 10mg BID; 16.6% vs. plbo: 3.6% (p<0.001) **Octave Sustain (Maintenance)**: Tofacitinib 10mg BID; 40.6% vs. plbo: 11.1% (p<0.001)	Plb: 11 %; TD-1473 20 mg: 20 %; TD-1473 80 mg: 20 %; TD-1473 270 mg: 55 %

Source: Biomedtracker, Company report, Stifel Research

Target Price Methodology/Risks

We arrive at our 12-month target price of $298 using a discounted cash flow (WACC 10%, terminal growth 1.5%). We probability-adjust our revenue projections for individual product candidates to reflect clinical, developmental and regulatory risks. We use a 10% WACC, which is in line with industry peers, to reflect inherent risk in biotechnology drug development. Our 1.5% terminal growth rate reflects drug patent expirations, partially offset by assumed new drug approvals to sustain steady-state CF.

Risks include: development, clinical, regulatory, manufacturing, commercial, competitive, financing, political, and volatility inherent to the sector.

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.

Full Comparison of JAKi Studies in UC

	Filgotinib	Rinvoq	Xeljanz	TD-1473
Company	GLPG/GILD	ABBV	PFE	JNJ/ TBPH
Phase Development	P2b	P3	Approved	P2/3
No. Patients	Induction - Biologic-naïve cohort (Cohort A; n=659), - Biologically-experienced cohort (Cohort B; n=689) Maintenance trial, n=558	N=250; inadequate response, loss of response or intolerance to corticosteroids, immunosuppressants or biologic therapies.	• OCTAVE Induction 1; n=598 • OCTAVE Induction 2; n=541 Patients with moderately to severely active UC despite previous conventional therapy or therapy with a TNF antagonist	N= 40; intolerant, refractory, or only partially responsive to aminosalicylates, corticosteroids, immunomodulators, or biologics.
Baseline Characteristics	Induction: • Biologic-naïve cohort (Cohort A induction trial; n=659), 52% had a baseline Mayo Clinic Score (MCS) of ≥ 9. • Biologically-experienced cohort (Cohort B induction trial; n=689), 74% had a baseline MCS of ≥ 9 • 51% were previously treated with 2 different classes of biologics (TNFα antagonists and an integrin receptor antagonist).	At baseline, 77.6% had prior use of biologics, 36% had an **Adapted Mayo Score >7,** and 79% had an endoscopic subscore of 3.	Induction: Total Mayo Score ranged from 8.9-9.1	NA
Trial design	P 2b/3, multi-center, randomized, double-blind, placebo-controlled trial of filgotinib in adult patients with moderately to severely active UC. The trial comprises 2 Induction Trials and a Maintenance Trial. The Cohort A Induction Trial enrolled biologic-naive patients; Cohort B Induction Trial enrolled biologic-experienced patients. Pts were randomized to receive filgotinib 200 mg, filgotinib 100 mg or placebo in a 2:2:1 ratio. Patients with clinical remission or response at Week 10 of induction were subsequently re-randomized to the induction dose of filgotinib or placebo in a 2:1 ratio and treated through Week 58.	P 2/3 multi-center, randomized, double-blind, placebo-controlled study of ABT-494 for Induction and Maintenance Therapy in Subjects With Moderately to Severely Active UC Adult patients with Adapted Mayo Score (Mayo score without Physician Global Assessment) of 5- 9 points and centrally-read endoscopy subscore of 2-3, were randomized to receive upadacitinib 7.5, 15, 30, 45 mg once daily (QD) or placebo for 8 weeks. Phase IIb portion of the study was to characterize the dose-response, efficacy and safety of upadacitinib compared to placebo	A 3-part P3, randomized, double-blind, placebo-controlled trials of tofacitinib in adults with UC. OCTAVE Induction 1 and 2 trials of patients with moderately to severely active UC despite previous conventional therapy or therapy with a TNF antagonist were randomly assigned to receive induction therapy with tofacitinib (10 mg twice daily) or placebo for 8 weeks. The primary end point was remission at 8 weeks. In the OCTAVE Sustain trial (maintenance) patients who had a clinical response to induction therapy were randomly assigned to receive maintenance therapy with tofacitinib (either 5 mg or 10 mg twice daily) or placebo for 52 weeks. The primary endpoint was remission at 52 weeks.	P1b, double-blind, placebo-controlled, multicenter, 40 subjects were enrolled and administered placebo (n=9), 20mg (n=10), 80mg (n=10), or 270mg (n=11) TD-1473 once daily for 28 days after meeting eligibility criteria (including Mayo rectal bleeding subscore of ≥ 1, stool frequency subscore of ≥ 1, and centrally read endoscopic subscore of ≥ 2).

	The primary endpoints: efficacy of filgotinib compared with placebo in establishing EBS clinical remission as determined by the Mayo Clinic endoscopic subscore of 0 or 1, rectal bleeding subscore of 0, and ≥ 1 point decrease in stool frequency from baseline to achieve a subscore of 0 or 1 at Week 10 and Week 58. Eligible patients who completed treatment in the SELECTION trial through Week 58 were enrolled in the ongoing SELECTION long-term extension trial to evaluate the long-term safety of filgotinib in patients with moderately to severely active UC.	in inducing clinical remission in order to identify the induction dose of upadacitinib for further evaluation in Phase III studies. The primary endpoint of the Phase IIb study was the proportion of patients who achieved clinical remission (defined as stool frequency subscore [SFS] ≤1, rectal bleeding subscore [RBS] of 0 and endoscopic subscore [ES] ≤1) at week 8. Secondary endpoints included endoscopic improvement (ES ≤1), clinical remission (per Full Mayo score ≤2 with no subscore >1) and clinical response (decrease from baseline in the Adapted Mayo score >2 points and >30 percent from baseline in the Adapted Mayo Score, plus a decrease in RBS >1 or an absolute RBS <1) at week 8.		
Efficacy	**Induction (10 wks)** : 200 mg dose Biologic-naïve patients: 26.1% vs. plbo: 15.3% (p=0.0157); plbo adj. **10.8%** Biologic-experienced patients: 11.5 % vs. plbo: 4.2 percent (p=0.0103); plbo adj. **7.3%**. 100 Dose: Not stat sig. (N/A) **Maintenance (58 wks)**: 200 mg dose Biologic-naïve patients: 37.2% vs. plbo: 11.2% (p=0.0001); plbo adj. **26%** Biologic-experienced patients: 37.2% vs. plbo: 11.2% (p=0.0001);	**Induction (8 wks.)**: Plb 0 % 7.5 mg: 9 % 15 mg: 14 % (P<0.05) 30 mg:14% (P<0.05) 45 mg: 20% (P<0.01)	**Induction (8 wks.)**: Octave 1: Tofacitinib 10mg BID; 18.5% vs. plbo: 8.2% (p=0.007) Octave 2: Tofacitinib 10mg BID; 16.6% vs. plbo: 3.6% (p<0.001) **Octave Sustain (Maintenance)**: Tofacitinib 10mg BID; 40.6% vs. plbo: 11.1% (p<0.001)	Plb: 11 %; TD-1473 20 mg: 20 %; TD-1473 80 mg: 20 %; TD-1473 270 mg: 55 %

	plbo adj. **26%** 100 mg dose at 58wks: 23.8% vs. plbo: 13.5% (p=0.0420; plbo adj. **10.3%**			
Safety	**Induction**: SAEs: 200 mg: 1.2 %; 100 mg: 4.7%; placebo: 2.9 %). **Maintenance**: SAEs: 200 mg: 4.5% vs. 0% plbo; 100 mg: 4.5% vs. 7.7% plbo. Rates of serious infections, herpes zoster, venous thrombosis, pulmonary embolism and gastrointestinal perforation were low and comparable across treatment groups in both the induction and maintenance phases of the study.	SAEs occurred in 0%/4%/6%/5% of the 7.5/15/30/45 mg upadacitinib groups, respectively, vs. 11% plbo group. Serious infections occurred in 0%/2%/0%/4% of the 7.5/15/30/45 mg upadacitinib groups, respectively, compared to 4% in the placebo group. 1 event of herpes zoster with the upadacitinib 45 mg dose 1 malignancy (malignant melanoma) with the upadacitinib 7.5 mg dose were reported. No venous thromboembolic events, major adverse cardiovascular events or deaths occurred.	In **OCTAVE Induction 1,** 23.3% and 1.3% of patients receiving tofacitinib 10 mg BID had infections and serious infections, respectively, compared to 15.6% and 0 receiving placebo. In **OCTAVE Induction 2,** 18.2% and 0.2% of patients receiving tofacitinib 10 mg BID had infections and serious infections, respectively, compared to 15.2% and 0 receiving placebo. **OCTAVE Sustain**: Serious infection rates were 1.0%, 0.5% and 1.0% across tofacitinib 5 mg BID, 10 mg BID and placebo groups, respectively. Overall infection rates were 35.9%, 39.8% and 24.2% across tofacitinib 5 mg BID, 10 mg BID and placebo groups, respectively. Cases of herpes zoster were more frequently observed with tofacitinib 10 mg BID compared to other treatment groups (1.5%, 5.1% and 0.5% across tofacitinib 5 mg BID, 10 mg BID and placebo groups, respectively). Across all studies, 5 tofacitinib-treated patients had adjudicated non-melanoma skin cancer, 5 had adjudicated cardiovascular events and there were increases in lipids with tofacitinib. There were 2 cases of malignancy in the control groups limited to 1 case of non-melanoma skin cancer and 1 case of invasive ductal breast carcinoma.	No SAEs, no serious infections, tuberculosis or other opportunistic infections, bowel perforations, or herpes zoster. Additionally, there were no meaningful changes in hepatic, renal, lipid, or hematologic laboratory parameters.

Source: Biomedtracker, Company Report, Stifel Research

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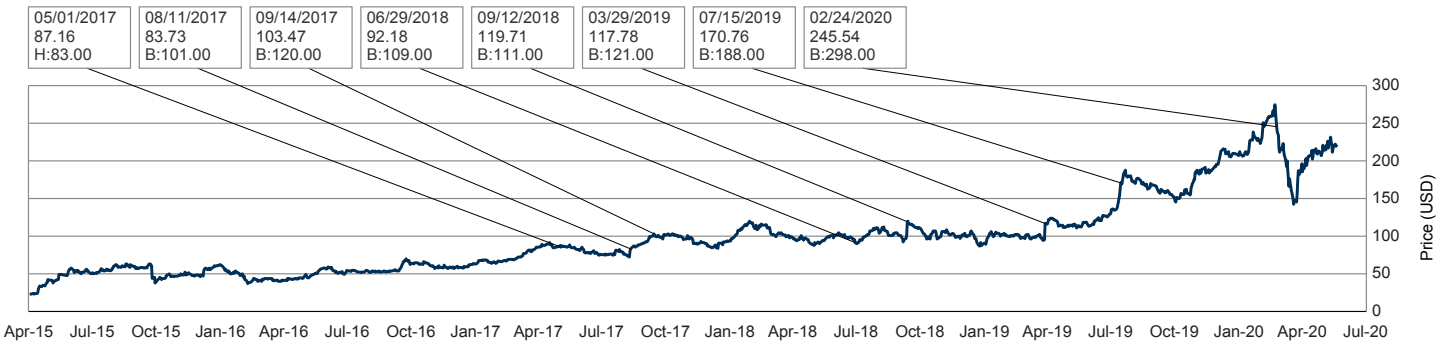
Galapagos NV (GLPG) as of May 20, 2020 (in USD)



*Represents the value(s) that changed.
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