GALAPAGOS NV (GLPG-NASDAQ)

Biotechnology

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COMPANY BRIEF

SELECTION Outcome Looks Comparable to JAK Peer Group

On Wednesday after market-close, the top-line results of the SELECTION study for filgotinib in the treatment of ulcerative colitis (UC) were released. The initial read-out of the study seems to support approval of the 200mg dose for induction therapy and possibly 100mg and 200mg dosages for maintenance therapy. Based upon our recent discussion with a UC key opinion leader, it seems unlikely that the results of SELECTION would change their view that filgotinib and the other JAK agents would mostly be used as salvage line therapy. We make no change to our model forecasts, which project filgotinib sales of ~$431m within UC during 2027E. Below we highlight key points from the top-line results that will warrant more discussion with the full dataset. For fuller results of the OCTAVE studies (tofacitinib) please see our SELECTION Preview Note (Link to Note).

Top-line induction remission rates seem similar to tofacitinib and upadacitinib: The OCTAVE induction studies of tofactinib reported 10-13% placebo (PBO) adjusted remission rates by week 8 and the U-ACHIEVE study of upadactinib (15mg dose) reported a ~10% PBO adjusted remission rate by week 8. The SELECTION study reported the 10 week data for filgotinib 200mg split between *biologic naïve* and *experienced* UC patients, with the *naïve* patients performing better with a 11% PBO spread versus 7% for *experienced*. Given that the OCTAVE studies had a ~50% mix of experienced patients, the SELECTION study probably comes in slightly lower on an integrated basis. The 100mg filgotinib results for week 10 were not reported directly, but were noted to not be statistically different than the control arm. **Mucosal healing along with endoscopic remission will be important data points for the full dataset, but we would be surprised if filgotinib outperforms its peer JAK drugs based upon the topline dataset.**

Low dose filgotinib hit the maintenance endpoint but still likely underperformed tofactinib 5mg: OCTAVE-Sustain reported a 23% PBO adjusted remission rate at week 52 for tofacitinib 5mg and a 30% rate for the 10mg dosage. The 100mg filgotinib dose was stat sig at week 58 relative to PBO, but the spread was 10%. The 200mg dose performed better with a 26% PBO spread that seems more comparable to tofacitinib. **Sustained remission rates and sustained mucosal healing from the full SELECTION dataset will be very important for clinical utilization relative to peer JAK drugs.**

The description of the filgotinib safety profile seemed fine but the numbers will matter: The actual infection rates relative to PBO will be scrutinized on the full presentation of SELECTION, and the language of "low rates of venous thrombosis and pulmonary embolism" will be a focus of conversation with investors despite the rates being "balanced" across treatment groups. **Given that the upadacitinib label carries what seems to be a class black boxed warning for *infections, malignancy and thrombosis*, we would be surprised if there would be a difference with filgotinib.**

Market Perform 3

Suitability	High Risk/Speculation

MARKET DATA

Current Price (May-20-20)	$221.27
Market Cap (mln)	$14,343
Current Net Debt (mln)	$(6,282)
Enterprise Value (mln)	$8,061
Shares Outstanding (mln)	64.8
30-Day Avg. Daily Value (mln)	$17.1
Dividend	$0.00
Dividend Yield	0.0%
52-Week Range	$112.00 - $274.03

KEY FINANCIAL METRICS

	1Q	2Q	3Q	4Q
EBITDA (mln) ($, Dec FY)				
2019A	(53)	(44)	491	(23)
2020E	(45) A	(112)	(111)	(105)
2021E	(90)	(90)	(90)	(97)
2022E	(54)	(54)	(54)	(59)

	2019A	2020E	2021E	2022E
EBITDA (mln) ($, Dec FY)	370	(373)	(367)	(222)
GAAP EPS ($, Dec FY)	2.49	(5.85)	(5.67)	(3.43)
Revenue (mln) ($, Dec FY)	896	240	301	585

Source: Thomson One, Raymond James & Associates. Quarterly figures may not add to full year due to rounding.

Figure 1 - Efficacy Analysis

Induction Efficacy	SELECTION		OCTAVE Induction 1	OCTAVE Induction 2	U-ACHIEVE Spread vs Placebo			
	Biologic-naïve (200mg) vs Placebo Spread (n=659)	Biologic-experienced (200mg) vs Placebo Spread (n=689)	Tofacitinib 10 mg (n=476) vs Placebo (n=122) Spread	Tofacitinib 10 mg (n=429) vs Placebo (n=122) Spread	Upadacitinib 7.5 mg QD (n=47)	Upadacitinib 15 mg QD (n=49)	Upadacitinib 30 mg QD (n=52)	Upadacitinib 45 mg QD (n=56)
Mayo Score								
Primary: remission at wk 8, %	-	-	10.3%	13.0%	8.5%	10.0%	13.5%	19.6%
p value	-	-	0.0007	<0.001		<0.05		<0.01
Filgo Primary: remission at Week 10, %	10.8%	7.3%	-	-	-	-	-	-
p value	0.0157	0.0103	-	-	-	-	-	-

Maintenance Efficacy	SELECTION* (n=558)		OCTAVE-SUSTAIN	
	Biologic-naïve + Biologic-experienced (200mg) vs Placebo Spread	Biologic-naïve + Biologic-experienced (100mg) vs Placebo Spread	Tofacitinib 5 mg (n=198) vs Placebo (n=198) Spread	Tofacitinib 10 mg (n=194) vs Placebo (n=198) Spread
Mayo Score				
Tofa Primary: remission at Week 52, %	-	-	23.2%	29.5%
p value	-	-	<0.001	
Filgo Primary: remission at Week 58, %	26.0%	10.3%	-	-
p value	<0.0001	0.042	-	-

* Those achieving clinical response/remission after 10 weeks of treatment

Source: Raymond James Research

COMPANY DESCRIPTION

Galapagos NV is a clinical-stage biotechnology company that is researching and developing novel small molecules to treat indications such as rheumatoid arthritis and inflammation. It was founded in 1999, and is headquartered in Mechelen, Belgium. Its diverse pipeline consists of multiple programs that are in Phases 1-3, and also has preclinical developments. Its most advanced program is filgotinib, a selective JAK1 inhibitor, which is targeting multiple indications including rheumatoid arthritis, ulcerative colitis, and Crohn's disease. Besides filgotinib, Galapagos has four current primary areas of interest: IPF, atopic dermatitis, OA, and inflammation fibrosis.

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Market Perform (Hold)	42%	40%	13%	17%
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** Columns may not add to 100% due to rounding.*

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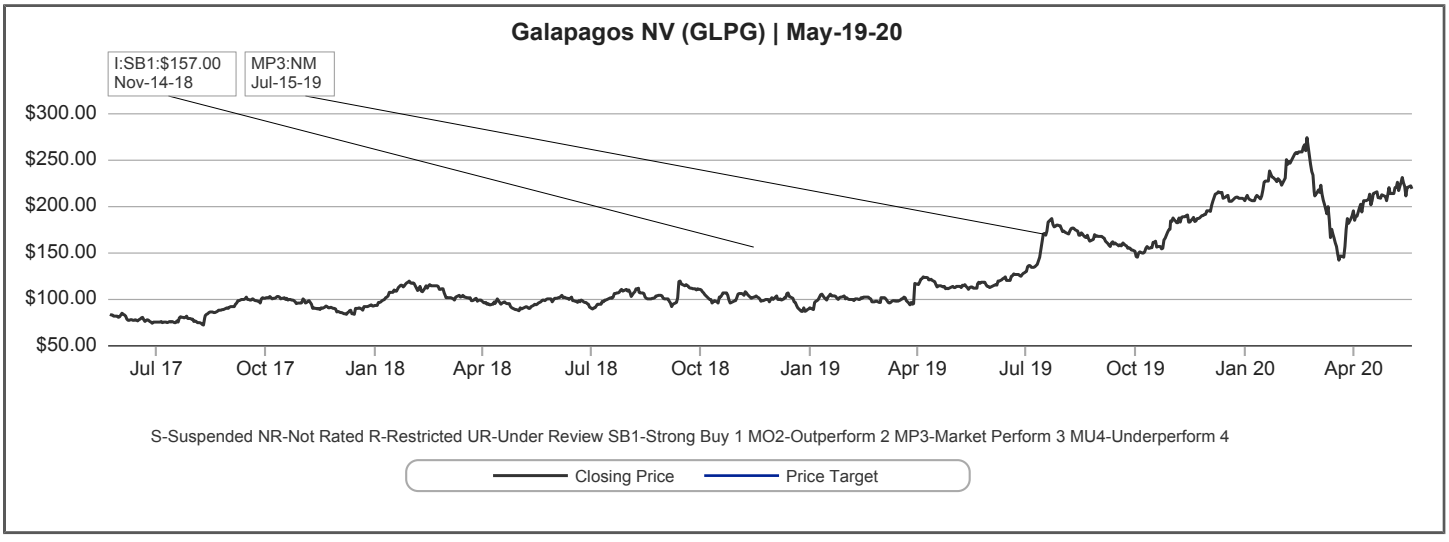

Valuation Methodology

Galapagos NV
We value based on 5 year forward EV/sales.

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Galapagos NV
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Stronger data from competitors to filgotinib could reduce our optimism for the program, along with our current commercial sales estimates.
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