Biotechnology

Galapagos N.V. ADR (GLPG)

EQUITY RESEARCH
May 21, 2020

Price: $221.27
Price Target: $192.00

Rating: Neutral

Key Statistics:

Symbol	NYSE: GLPG
52-Week Range	$112.00 - $274.03
Market Cap (M)	14,342.5
ADV (3 mo)	189,500
Shares Out (M)	64.8

Research Analysts:

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REV

FYE (Dec)	2018A	2019A	2020E
1Q	€44.8	€40.9	€90.3E
2Q	€57.0	€67.6	€113.1E
3Q	€103.2	€644.0	€165.9E
4Q	€112.8	€90.1	€191.1E
Year	€317.8	€842.6	€560.4E

EPS

FYE (Dec)	2018A	2019A	2020E
1Q	€(0.53)	€(0.89)	€(1.46)E
2Q	€(0.62)	€(0.86)	€(1.57)E
3Q	€0.26	€5.83	€(1.47)E
4Q	€0.33	€(1.48)	€(1.61)E
Year	€(0.56)	€2.60	€(6.12)E

Note: EPS and revenues in euros.

Company Update

Ph3 Supportive of UC Approval and Uptake, but Efficacy Underwhelms High Expectations

Investment Summary. We reiterate our Neutral and $192 PT. GILD (Young, OW) and GLPG's filgotinib UC Ph3 data were announced post-close yesterday (5/20) and met their primary endpoint at the higher 200mg dose. In terms of the magnitude of efficacy, we find the results somewhat underwhelming relative to our (high) expectations. However, we view these data as supportive of approval, and we think filgotinib's safety profile continues to look materially better relative to Xeljanz, which should support meaningful switching and uptake commercially over Xeljanz. Longer term, the efficacy and safety comparison to other late stage assets such as the oral S1P1 class could affect the ultimate size of the filgotinib commercial opportunity in UC, but we see a high demand for oral and new agents in the UC space.

KOL CALL TODAY at 12pm ET: Discussion of filgotinib Ph3 UC data and implications for the UC landscape with Suneeta Krishnareddy, MD. Please register in advance for the (audio-only) Zoom call here.

- **We think filgotinib efficacy looks more similar to, than different from, Xeljanz based on the top line, but we still think filgotinib will be preferred to Xeljanz due to improved safety.** We note filgotinib's 100mg dose did not meet the primary endpoint at the induction phase, as we think had been expected. At the induction phase, at the 200mg dose, biologic naive patients had a placebo adjusted clinical remission rate of 16% versus 10-14% with tofacitinib; in biologic experienced patients, it was 7% vs. 7-9% with filgotinib vs. tofactinib. In the maintenance phase, filgotinib had a 26% placebo adjusted clinical remission rate at week-58 versus 23% (5mg BID) and 29% (10mg BID) from tofacitinib at week-52, although we note 10mg dosing levels are cautioned against in the Xeljanz label. We also note the limitations of cross-trial comparisons such as the differences (although we think relatively minor) in the definitions of clinical remission and patient populations between the studies.
- **We think filgotinib's dose level (same as in RA Ph3) held back its efficacy in this study. We note JAK upadacitinib's Ph3 UC is studying dose levels up to 3x higher than approved RA dose.** Both Xeljanz (tofacitinib) and upadacitinib studied 2-3x higher dose levels in UC than RA, whereas filgotinib did not increase its dose level in UC vs. its RA trials. We note that upadacitinib (Rinvoq) is approved in RA in only the 15mg dose, but our understanding of the Ph3 program is that the 45mg dose level is the dose level of focus. In Ph2b in UC, upadacitinib showed stronger efficacy at 45mg vs. 15mg and 30mg. We think the 5/20 filgotinib data look competitive with the 15-30mg ph2b upadacitinib efficacy, although the 45mg upadacitinib efficacy might drive higher efficacy vs. filgotinib's 200mg. However, we think the safety profile of upadacitinib, particularly at the higher dose levels, will be a key question long-term, and we believe the filgotinib safety profile will pan out to compare favorably.
- **Detailed safety will be a key question for the full filgotinib data, but the release notes no imbalances in infections or thrombotic events.** The release notes that the rates of serious infections and thrombotic events were "comparable" across active and placebo in both induction and maintenance. We see this as a key encouraging data point that is particularly favorable relative to Xeljanz, which had elevated rates of both at the 52-week maintenance timepoint. However, we suspect that investors and physicians may still want to see more details given the JAK class historical safety issues and class black box warning on thrombosis. Although we think that filgotinib

The Disclosure Section may be found on pages 4 - 5.

has a best-in-class safety profile among the JAK inhibitors, we think a commercial consideration is whether this is enough to get gastroenterologists comfortable (they tend to be more cautious on safety vs. rheumatologists from our checks).

- **Many late stage competitors on the horizon, including oral ozanimod, is a consideration for filgotinib commercial outlook in UC. These data could narrow filgotinib's efficacy margin over the S1P1 class versus our previous expectations.** We do not expect ABBV's (NC) upadacitinib to be approved in UC until 2022, at the earliest, by our estimates, which we think is a key near-term advantage for filgotinib in UC. However, we expect Ph3 data near term (guided for 3Q20) from oral S1P1, BMY's (NC) ozanimod. We generally think the JAK class efficacy from both tofacitinib and filgotinib is likely to look better vs. ozanimod in biologic experienced patients, which is our focus for the JAK opportunity. However, the lack of an elevated risk of thrombotic events associated with the S1P1 class may lead some physicians to be more comfortable prescribing S1P1s as an oral option if JAK safety is perceived as a class effect.

Valuation

We use a probability-adjusted DCF to value Galapagos shares. We assign a discount rate of 10% and a terminal growth rate of 0%, in line with peers of similar size and R&D capacity.

Risks

Key risks include greater-than-expected competition for GLPG's lead asset filgotinib and/or an unexpected clinical or regulatory setback. Key risks specific to filgotinib include:

-- Lack of efficacy in Phase 3 trials such as ulcerative colitis, Crohn's or psoriatic arthritis.

-- Greater-than-expected competition commercially, either from additional JAK inhibitors, novel biologics, or biosimilar entrants.

-- Testicular toxicity (only seen pre-clinically) is seen clinically with filgotinib.

Success in OA, IPF, or Toledo would be upside to our estimates.

Company Description

Galapagos is a clinical-stage biotechnology company. The company's lead asset, filgotinib, is partnered with Gilead (OW, covered by A. Young) and is in development for a variety of diseases in the inflammation and immunology (I&I) space, such as rheumatoid arthritis, ulcerative colitis, and Crohn's, among many others. Other programs in development include the wholly owned idiopathic pulmonary disease (IPF) franchise, which has entered Phase 3.

Disclosures Appendix

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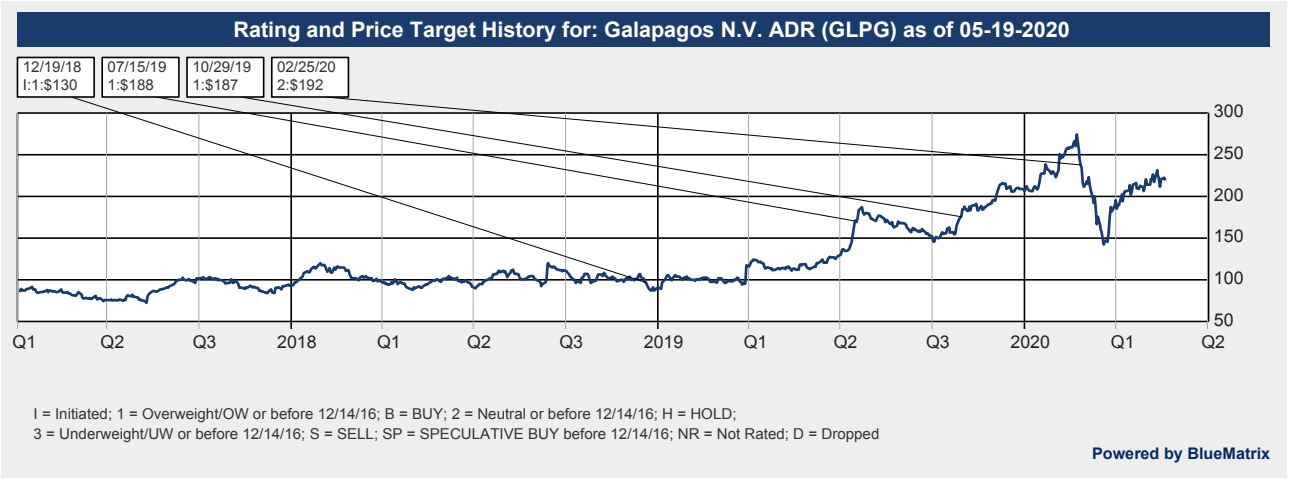

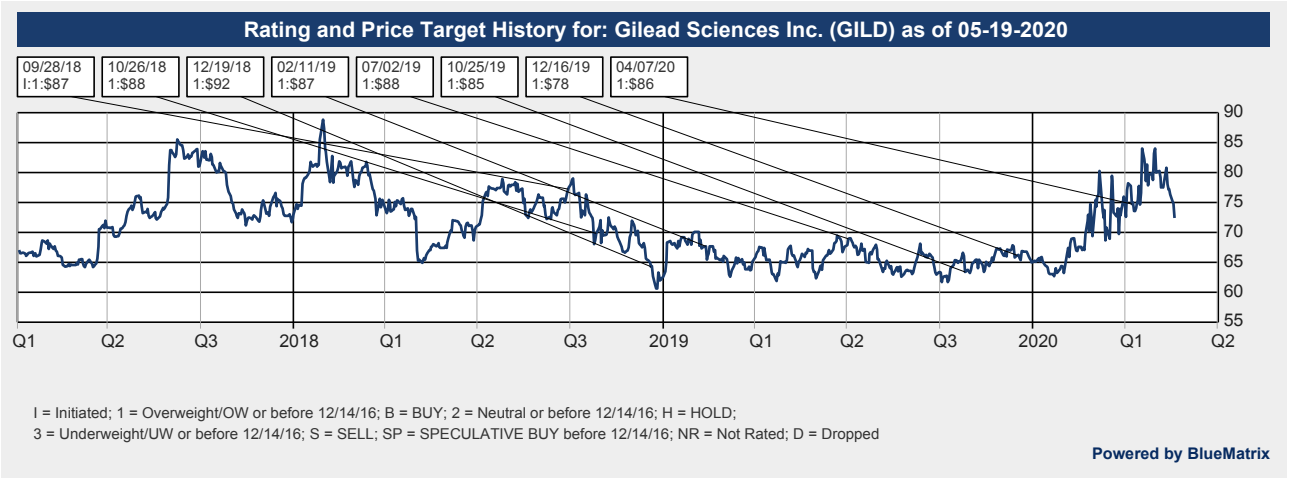

Distribution of Ratings/Investment Banking Services (IB) as of 05/21/20

Cantor

			IB Serv./Past 12 Mos.	
Rating	**Count**	**Percent**	**Count**	**Percent**
BUY [1/B]	**161**	**80.90**	**98**	**60.87**
HOLD [2]	**36**	**18.09**	**5**	**13.89**
SELL [SL/3]	**2**	**1.01**	**0**	**0.00**

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