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Galapagos NV GLPG.OQ GLPG US

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Competitive Landscape Updates

Quick Note

Based on recent clinical updates from GILD on GLPG assets during its 4Q earnings call as well as other updates from competitors, we are updating our 2018 potential catalysts and highlight several key competitor updates relevant to GLPG programs (**VRTX**, **ABBV**, **LLY/INCY**; see catalyst table Figs. 1 and 2). We look to the FINCH 2 data readout in 2H18, which we believe will further help differentiate against competitors with a clean safety profile and possible efficacy advance in biologic DMARD refractory RA patients. We also anticipate multiple CF combination data readouts in FY18.

- **FINCH Trials Enrolling Quickly, FINCH 2 Data in 2H18.** GILD provided updated clinical guidance on its 4Q call for GLPG's filgotinib programs. Impressively, the company now anticipates completing enrollment for FINCH 1 and FINCH 3 studies evaluating filgotinib in RA by 2Q and 3Q, respectively. Furthermore, the company guided to FINCH 2 Ph 3 data readout with filgotinib in combination with csDMARD in biologic DMARD inadequate responder RA patients in 2H18. However, the company did not guide to FINCH 3 readout in 2018, which we now anticipate in early 2019. Additionally, GILD guided to additional potential filgotinib data readouts in other indications such as UC (Ph 3 interim futility analysis, 2Q18) as well as Ph 2 in PsA and ankylosing spondylitis, expected to complete in 2Q18 and 4Q18, respectively. As a reminder, GLPG decided to opt-in to filgotinib co-promote with GILD in 8 EU countries while receiving tiered 20-30% royalties elsewhere (see previous note).
- **LLY/INCY's JAK1/2 Inhibitor Baricitinib Likely Launch in US 2H18 in Mod-Sev RA.** We believe the FDA will likely approve the baricitinib NDA in RA in mid-2018 with the resubmission highlighting DVT/PE rates in trials as in line with background RA pt rate. LLY also noted on its 4Q call that there have been no DVT/PE safety signals in its Phase 2 atopic dermatitis trials.
- **VRTX Sheds Light On Triple-Combos Path Forward Update Following FDA Interactions 1H18 – Likely to Apply to GLPG Too.** VRTX is also advancing multiple next-gen correctors ('659 and '445) into two triple-combo Phase 3s based on ongoing Ph 2 data and FDA discussions. We anticipate similar guidance will apply to GLPG/ABBV's triple program. The Ph 2 results showed mean absolute improvements ppFEV1 of 13.3% pts from baseline for VX-659 (400 mg qD) and 13.8% pts from baseline for VX-445 (200mg QD). The triple-combo regimens were generally well tolerated with low discontinuation rates and most AEs being mild to moderate. Triple-combo VX-659 + teza + iva to start 1H18, and '445 + teza + '561 to start mid-2018 following an update from ongoing Ph 2 studies in CF patients with F508del/minimal function mutation. VRTX also plans to initiate triple-combo trials in CF patients with one F508del and one second-gating or residual function mutation.

Instinet, LLC, Equity Research

7 February 2018

Rating Remains	**Buy**
Target Price Remains	USD 124.00
Closing price 6 February 2018	USD 112.13

Research analysts

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Recap of Recent GLPG Updates

CF Program Updates

- GLPG announced results from FLAMINGO and a CF program update. FLAMINGO demonstrated that '2222 monotherapy was safe, well tolerated, and achieved targeted exposures in patients—resulting in a dose-dependent reduction in sweat chloride (up to 18mmol/L at highest dose at 29 days) and trends toward benefit on FEV1 (see previous note).
- GLPG recently started a Ph 1 of backup C1 corrector '2851, with data anticipated at an upcoming medical meeting.
- The first patient was dosed in PELICAN, a P2 of '2737 in combo with Orkambi in homo F508del patients.
- P2 "Triple combo 1" ('2451,'2222,'2737) should start 1Q18, data in 3Q18.
- P1 "Triple combo 2" ('3067,'2222,'2737) also recently started dosing.

JAK 1 or IL-17C in Atopic Dermatitis

- PFE initiated a Ph 3 trial with its JAK1 inhibitor (PF-04965842) in moderate to severe atopic dermatitis.
- ABBV plans to initiate a Ph 3 trial with its JAK1 inhibitor upadacitinib in moderate to severe atopic dermatitis based on positive Ph 2 results.
- Although GLPG has no plans for atopic dermatitis indication for filgotinib, GLPG plans to start Ph 2 trial in atopic dermatitis with its MOR106 (partner MorphoSys), an anti-IL-17C mAb, in 1H18.

IPF Autotaxin

- GLPG1690 to start Phase 3 in IPF based on positive Ph 2a topline FLORA data. Traditionally challenging IPF remains an upside to estimates; initiation of a Ph3 trial is expected in 2018.

Osteoarthritis (OA)

- Ph 1b results, released in early January, showed that the pharmacokinetics of GLPG1972 in the trial's elderly OA patients were similar to those seen in earlier Ph 1 healthy volunteers. Only one discontinuation at highest dose due to reversible abnormal liver function test on Day 15.
- At the highest dose, the average % reduction in ARGS neoepitope vs baseline was 50.43% (±4.47) and 44.93% (±4.46) at the medium dose vs 3.64% (±5.95) "increase " with placebo.
- Earlier Ph 1 study in healthier volunteers demonstrated safety and pharmacokinetic targets and showed GLPG1972 reduced the blood level of ARGS neoepitope by more than 50% within 2 weeks.
- Based on these results, GLPG and Servier are preparing to start a Ph 2 trial, which we anticipate will start later in the year (2H18).
- As a reminder, GLPG has full US commercial rights to GLPG1972 and is eligible to receive development, regulatory, and other milestone payments as well as royalties OUS.

Upcoming Potential Catalysts

Fig. 1: GLPG Upcoming Potential Catalysts

Timing	Impact	Drug	Indication	Details	Phase	Program	NCT (or EU) #
Filgotinib							
2Q18, enroll complete	+	filgotinib	Rheumatoid arthritis	in combo with mtx vs. Humira	3	FINCH 1	NCT02889796
2H18 data	+++	filgotinib	Rheumatoid arthritis	IR to biologics, combo with csDMARDs	3	FINCH 2	NCT02873936
3Q18 enroll complete	+	filgotinib	Rheumatoid arthritis	mono vs mtx combo in mtx naiive pts	3	FINCH 3	NCT02886728
2Q18 fuility analysis	+++	filgotinib	Ulcerative Colitis	interim futility analysis	3	SELECTION 1	NCT02914522
2Q18, complete	++	filgotinib	Ankylosing spondylitis	safety and efficacy	2	TORTUGA	NCT03117270
2Q18, complete	++	filgotinib	Psoriatic arthritis	safety and efficacy	2	EQUATOR	NCT03101670
1H18 data	++	filgotinib	Cutaneous lupus erythematosus	in combo with GS-9876 (SYK inhibitor)	2	n/a	NCT03134222
2H18 data	++	filgotinib	Sjogren syndrome	safety and efficacy	2	n/a	NCT03100942
2H19, enroll complete	++	filgotinib	Crohn's disease	induction and maintanence	3	DIVERSITY	NCT02914561
Cystic Fibrosis							
2018	++	2851	Cystic Fibrosis	Topline results at future med. conference	1	n/a	n/a
1H18 topline results	++	2737 + Orkambi	Cystic Fibrosis	in Orkambi treated F508del patients	2a	PELICAN	2017-002181-42
mid-2018 data	+++	2451 + 2222 + 2737	Cystic Fibrosis	interim readout summer 2018	pivotal?	"triple combo" (1)	n/a
4Q18 data	+++	3067 + 2222 + 2737	Cystic Fibrosis	topline at future med. conference	pivotal?	"triple combo" (2)	n/a
1Q19 data	+++	3067 + 2222 + 3221	Cystic Fibrosis	3Q18 initiation	pivotal?	"triple combo" (3)	n/a
Other Pipeline							
2H18 initiate Ph 2	+	1972	Osteoarthritis	safety and efficacy	2	n/a	NCT03311009
1H18 initiate Ph 2	+	MOR106	Atopic dermatitis	Initiate Ph 2 on SAD/MAD data	1	n/a	NCT02739009
2018 initiate Ph 3	++	1690	Idiopathic pulmonary fibrosis	Initiate Ph 3 on pos Ph 2b	2	FLORA	NCT02738801

Source: Company data, Instinet research

Fig. 2: Upcoming Competitor Events

Timing	Drug	Company	Indication	Details
1Q18	Otezla	Celgene	UC	Full Phase 2 (RELIEF) in UC data presentation at ECCO
1Q18	Orkambi	Vertex	CF	NDA and MAA submission, use in 508del/508del pts age 2-5
1Q18	tezacaftor/ivacaftor	Vertex	CF	US approval (1Q18) and Europe (2H18) in F508del/F508del or F508del/one residual function mutation (age 12+)
1H18	VX-445	Vertex	CF	Ph 2 data triple combo with '445 + teza + '561
1H18	baricitinib	Eli Lilly/Incyte	PsA	Initiate Ph 3 trial w/ baricitinib in psoriatic arthritis
1H18	risankizumab	AbbVie	UC	Initiate Ph 3 trial w/ risankizumab in ulcerative colitis
1H18	upadacitinib	AbbVie	RA	Topline results from Ph 3 SELECT-COMPARE. 12 weeks on ABT-494 on top of stable background of csDMARDs compared with Humira
1H18	upadacitinib	AbbVie	RA	Topline results from Ph 3 SELECT-EARLY. 12 weeks on ABT-494 in compared with MTX in MTX naive patients
1H18	VX-659, tezacaftor, ivacaftor	Vertex	CF	Initiate first triple combo ('659 + teza + iva) trial in F508del/minimal function and F508del/F508del mutations, pending FDA discussion
mid-2018	VX-445, tezacaftor, VX-561	Vertex	CF	Initiate triple combo ('445 + teza + '561) trial in F508del/minimal function and F508del/F508del mutations, pending Ph 2 data and long-term non-clinical tox study
mid-2018	baricitinib	Eli Lilly/Incyte	RA	Potential NDA approval in RA based on NDA resubmission
mid-2018	RHB-104	Redhill	Crohn's Disease	Topline readout of Ph 3 MAP US Study with RHB-104 in Crohn's Disease
2H18	VX-445, 'VX-659	Vertex	CF	Initiate triple combo studies in CF pts with F508del and one second-gating or residual function mutation (for each)
2018	upadacitinib	AbbVie	Atopic Dermatitis	Initiate Ph 3 trial in mod-sev atopic dermatitis
2019	ozanimod	Celgene	UC	Phase 3 study results in UC
2019	upadacitinib	AbbVie	RA	Topline results from Ph 3 SELECT-CHOICE. 12 weeks on ABT-494 on top of stable background csDMARDs in pts w/ IR to bDMARDs vs. Orencia
2019	PF-04965842	Pfizer	Atopic Dermatitis	Ph 3 (JADE Mono-1) topline results w/ JAK1i in mod-sev atopic dermatitis
2019	upadacitinib	AbbVie	RA	Target Year for US Launch

Source: Company data, Instinet research

Appendix A-1

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Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Galapagos NV	GLPG US	USD 112.13	06-Feb-2018	Buy	Not rated	A6

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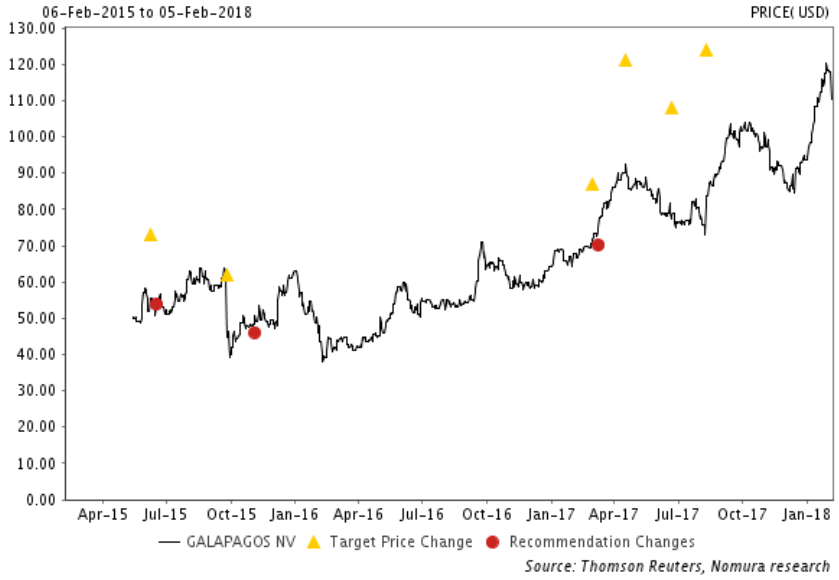
Galapagos NV (GLPG US) **USD 112.13 (06-Feb-2018)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
10-Aug-17		124.00	81.06
22-Jun-17		108.00	78.56
17-Apr-17		121.00	92.40
01-Mar-17	Buy		71.78
01-Mar-17		87.00	71.78
27-Oct-15	Not Rated		47.69
25-Sep-15		62.00	44.60
08-Jun-15	Buy		55.51
08-Jun-15		73.00	55.51

For explanation of ratings refer to the stock rating keys located after chart(s)

Valuation Methodology For Galapagos NV (GLPG), we use a top-line revenue multiple valuation, a method widely used for early-stage biotech companies. Our target price of $124 represents a 6x multiple for EU profit share on filgotinib across inflammatory indications and a 16x multiple for U.S. royalties on filgotinib. In filgotinib for RA, we apply a 15% discount rate, reflecting a lower development risk, as the target, JAK, is already validated by an approved drug in RA. In filgotinib in UC and Crohn's, we apply a 20% discount rate, reflecting a slightly higher risk for these indications, as no JAK inhibitor is approved. For the Cystic Fibrosis program, we use an 18x multiple, reflecting a higher value for the higher-margin orphan program and a 25% discount that reflects a higher development risk. For the IPF program, we use an 8x multiple, reflecting a higher value for the higher-margin orphan program and a 45% discount that reflects a higher development risk. The benchmark for this stock is the Nasdaq Biotechnology Index.

Risks that may impede the achievement of the target price Regulatory risk: The FDA may require Galapagos to present data on the efficacy of the individual triple-combo drugs in the target patient population, which would require the company to conduct a large Phase 2 study. Enrollment of patients in these studies might be challenging, due to the low expectation of efficacy from a single compound. For filgotinib, the FDA may issue a class label on the risk for serious infections and malignancies. This action will not prevent filgotinib from reaching the market, but it could create a negative perception of the drug among patients and physicians, which would affect commercial viability. Competitive risk: Baricitinib, a JAK 1/2 inhibitor, was expected to be approved by January 19, 2017. In clinical studies, the drug presented compelling efficacy superior to adalimumab. If baricitinib is found to be safe and approved without a black-box warning, it could take the lion's share of the market. Celgene's mongersen, an SMAD7 anti-sense RNA, showed compelling safety and efficacy profile in a Phase 2 study in

CD patients. The compound is in a Phase 3 study and is set to report top-line data by 2H18. If approved, mongersen would have first-mover advantage as the only orally available DMT for Crohn's. Clinical risk: The Phase 2 study with filgotinib in CD used the CDAI as the primary outcome measure. The Phase 3 study is using the more traditional PRO as the primary outcome measure. This difference in design may result in a smaller efficacy difference between the placebo and treatment arms in the Phase 3 study.

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