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Galapagos NV GLPG.OQ GLPG US

EQUITY: AMERICAS BIOTECHNOLOGY

EULAR 2018 Pipeline Abs: GLPG1972 in OA

Quick Note

Galapagos and partner Servier will be presenting at EULAR 2018 Amsterdam a poster (#:FRI0539) with biomarker data from P1b study with GLPG1972 (ADAMTS-5 inhibitor) in osteoarthritis (OA) patients of the hip and/or knee and an oral presentation (#OP0258) on a preclinical rat meniscectomy model. The topline P1b in OA results were originally announced on Jan 2018 (See Fig 1). The pre-clinical abstract highlighted histological data from the mice's tibial plateau demonstrating significant chondroprotection in GLPG1972-treated surgery-induced OA mice vs. vehicle control. We anticipate GLPG and Servier will announce the initiation of a P2 shortly as the company should be finalizing P2 design and protocol. We remain excited about GLPG1972's potential to be the only approved disease-modifying osteoarthritis drug in an indication impacting more than **118mn patients** in US, Europe, and Japan. **GLPG at ATS this Week**: GLPG presented/will present three abstracts at ATS 2018 the past weekend/week and Tues on GLPG1690, its wholly owned asset being developed in IPF (Pg 2). Additionally, a recent Lancet publication highlighted consistency of results across pts, and biomarkers (LPA) and FVC in patients with IPF.

- **Compelling MOA: ADAMTS-5 Inhibition Protects Cartilage Degradation.** GLPG1972 is a highly potent and selective inhibitor of ADAMTS-5 protease, implicated in the cleaving of aggrecans (a core cartilage-specific proteoglycan protein) in the cartilage's extracellular matrix that are crucial to the joint's ability to resist compressive loads. Higher concentrations of aggrecan are necessary to produce the swelling pressure that counters compressive loads on the tissue. In OA patients and animal models, detectable fragments generated by aggrecan cleavage in the cartilage and synovial fluid have been well-documented. In vitro, ADAMTS-5 has one of the highest aggrecanolytic activities of the ADAMTS protease enzyme family with expression localized in areas of aggrecan depletion. ARGS neoepitope is a marker of aggrecanase activity. Based on this well-defined MOA, we believe the inhibition of ADAMTS-5's aggrecanolytic activity may translate into slower disease progression through improved preservation of cartilage and functional benefits.
- **Promising P1b Biomarker Data; P2 Likely to De-Risk GLPG 1972 on Imaging and Functional Endpoints.** Notably, the PK of GLPG1972 in the trial's elderly OA patients was similar to those seen in earlier P1 trial in healthy volunteers. There was only one discontinuation (at the highest dose of 300mg) due to reversible abnormal liver function test on Day 15. The tight SE bars on biomarker reductions indicate no meaningful difference between hip vs. knee OA patients. We find the robust and durable dose-dependent mean ARGS % reduction through Day 15 and 29 as encouraging and expect a significant de-risking event if biomarker data translate into improvements in MRI/X-Ray imaging and functional clinical endpoints in the soon-to-be initiated P2. We await the announcement of P2 study design, which will likely be in 100s of patients with less than half of the patients in the US. GLPG has commented on a previous earnings

Instinet, LLC, Equity Research

21 May 2018

Rating Remains	**Buy**
Target Price Remains	USD 124.00
Closing price 18 May 2018	USD 97.59

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call that the P2 will likely be a 1-yr trial with the typical endpoints looking at imaging using MRI, X-Ray, as well as functional endpoints.

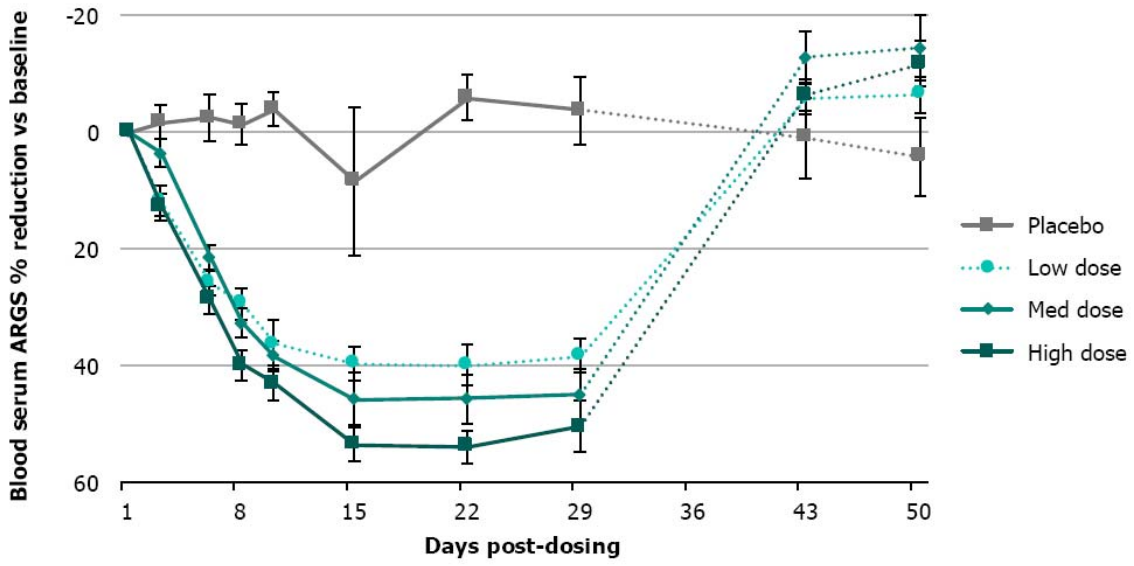
- **Blockbuster Market Opportunity.** As a reminder, GLPG has full US commercial rights to GLPG1972 and is eligible to receive development, regulatory, and other milestone payments as well as royalties OUS from Servier. As the most common form of arthritis, OA affects over **30 million US adults** and is expected to rise in prevalence with an aging population and sedentary lifestyle. Though we conservatively remain on the sidelines in assigning value to this asset until development pathway and target population has been further clarified, we are attracted to the blockbuster potential of GLPG1972 as the first disease-modifying therapy for OA with full US and OUS royalty economics. However, for the same reason and considering GLPG's limited footprint in the US, we anticipate GLPG will commercialize the drug with a partner.

Fig. 1: Compiled P1b Trial of GLPG1972 in OA of Hip/Knee: ARGS Biomarker Data

P1b OA Biomarker Data		Placebo QD	100mg QD	200mg QD	300mg QD
Patients (n)		6	8	8	8
Mean ARGS % reduction vs. baseline (±SE)	Day 15	NA	-40% (±2.9)	-46% (±4.5)	-53% (±2.8)
	Day 29	-3.64% (±5.95)	-38.43% (±2.91)	-44.93% (±4.46)	-50.43% (±4.47)

Source: Company data, Instinet research

Fig. 2: ARGS Reduction in Ph1b Trial in OA Patients



Dose-dependent reduction of ARGS, well-tolerated in OA patients

Source: Company presentations, Instinet research

Full GLPG1690 P1b Data at ATS 2018 Congress San Diego

- **Abstract/Poster: A1649/P1249 – Pharmacodynamics and Pharmacokinetics of the Autotaxin Inhibitor GLPG1690 in the FLORA Trial: A Randomized, Placebo-Controlled, Double Blind Phase IIa Clinical Trial of 12 Weeks in Individuals with Idiopathic Pulmonary Fibrosis.** May 20, 11:15AM-1:00PM Area K (Hall A-B2, Ground Level)
  - Proof of target engagement with fast and sustained reduction in LPA 18:2 plasma levels (biomarker of autotaxin inhibition) in IPF patients. LPA levels were measured before dosing and 1.5, 4, and 6 hours post-dosing. LPA reduction was similar at 1.5 and 6h post-dosing. Similar PK/PD to those in healthy volunteers. PK/PKD supports QD.
- **Abstract/Oral Presentation: A2436 - A Randomized, Placebo-Controlled, Double Blind Phase Iia Clinical Trial to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of 12 Weeks of Treatment of an Autotaxin Inhibitor (GLPG1690) in Individuals with Idiopathic Pulmonary Fibrosis (FLORA Trial).** May 20, 2:45PM-3:00PM Room A (Upper Level)
  - Updated data published in The Lancet over the weekend confirmed and improved on efficacy at 12 weeks (+25ml mean change from baseline in FVC vs. -70ml for placebo). Safety Data demonstrated comparable safety and discontinuation rates vs. placebo with lower serious and severe TEAEs in the GLPG1690 arm.
  - Prev. announced topline data at 12 weeks showed FVC increase of 8ml (vs. baseline) in GLPG1690-treated IPF pts vs. FVC reduction of 87ml in placebo pts indicating disease stabilization in the treatment arm.
- **Session/Abstract: C97/A5928 – Assessment of the Effects of GLPG1690 in Idiopathic Pulmonary Disease (IPF) Patients Using Functional Respiratory Imaging (FRI).** May 22, 3:45PM – 4:00PM Grand Ballroom 5-6 (North Tower, Lobby Level)
  - Suggests functional respiratory imaging (FRI) may be a more sensitive and accurate tool for monitoring IPF progression and regression. Using GLPG1690, specific airway volume changes could be measured in regional lung structures; the change from baseline for this metric was significantly different. Supports MOA and Efficacy.

Appendix A-1

Analyst Certification

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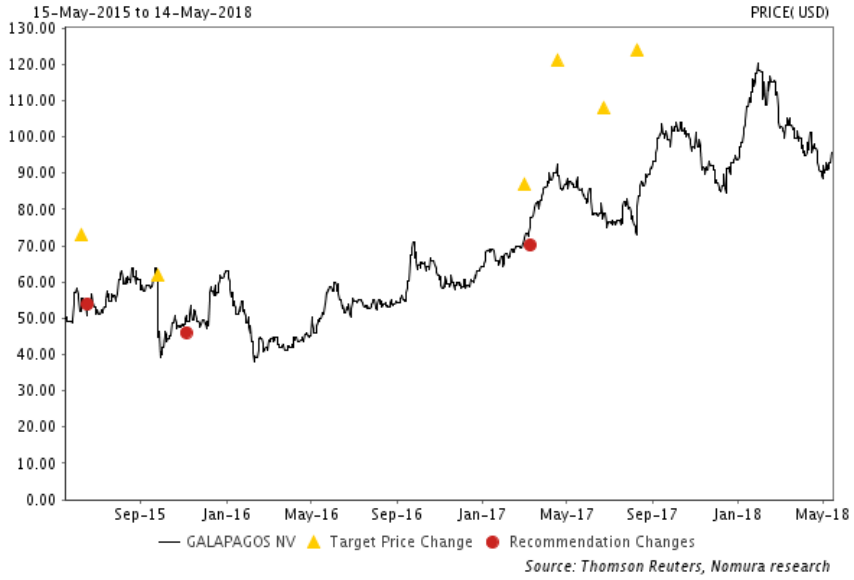
Materially mentioned issuers

Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Galapagos NV	GLPG US	USD 97.59	18-May-2018	Buy	Not rated	A6

A6 The Nomura Group expects to receive or intends to seek compensation for investment banking services from the subject company in the next three months.

Galapagos NV (GLPG US) **USD 97.59 (18-May-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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