### Results from the FLORA Study

Galapagos reported results of the Phase 2 FLORA study during August 2017, with the full dataset subsequently being presented at the American Thoracic Society annual meeting and published within The Lancet Respiratory Medicine<sup>1</sup>. The design of the study was a 12 week course of therapy, with GLPG1690 dosed at 600mg QD. The active arm was randomized 3:1 versus placebo, for an enrollment of 18 patients receiving GLPG1690 and six patients receiving placebo. Oral administration of GLPG1690 resulted in a significant reduction in plasma LPA over the course of the study (Exhibit 19), validating the effect of GLPG1690 as a potent autotaxin inhibitor.

Plasma LPA 18:2, % Reduction Over Time -60 -40 % reduction (mean ±SE) -20 0 20 40 60 80 BSL Week 12 FU Placebo N=6N=5N=5 N=5 N=17 N=16 600mg N = 15N=15 → Placebo ---600 mg

Exhibit 19: GLPG1690 Reduction in Plasma LPA

Source: Galapagos

<sup>&</sup>lt;sup>1</sup> Safety, tolerability, pharmacokinetics, and pharmacodynamics of GLPG1690, a novel autotaxin inhibitor, to treat idiopathic pulmonary fibrosis (FLORA): a phase 2a randomized placebo-controlled trial; Maher and Wuyts et al.; The Lancet Respiratory Medicine; August 2018, Vol 6, Issue 8, Pg 627 - 635

The FLORA study was not appropriately powered to demonstrate statistical differentiation between the active and placebo arms on standard clinical outcomes such as Forced Vital Capacity (FVC), but there was *trend* differentiation in the GLPG1690 arm relative to placebo (Exhibit 20). At week 12, the GLPG1690 treated arm experienced no degradation in FVC relative to baseline, versus a deterioration recorded within the placebo arm.

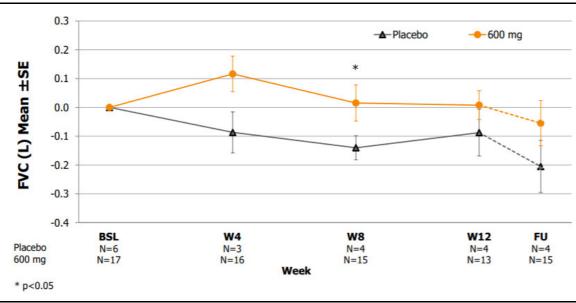


Exhibit 20: GLPG1690 FVC Outcome Relative to Placebo

Weekly averages of FVC taken by home spirometry also suggested a *trend* difference between the two arms, although the placebo group seemed to remain stable post week four and the GLPG1690 arm deteriorated at week six (Exhibit 21).

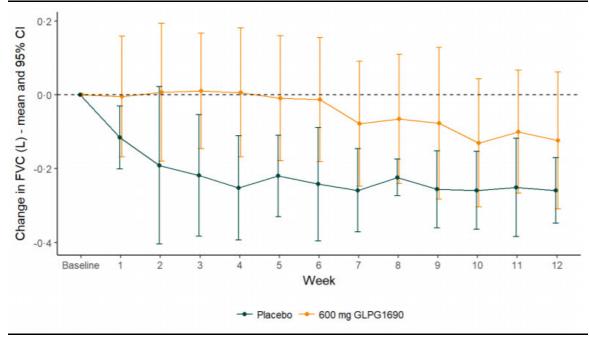


Exhibit 21: GLPG1690 FVC Outcome Relative to Placebo (Home Spirometry)

Source: Galapagos

GLPG1690 was generally well tolerated with most treatment emergent adverse events being recorded as mild to moderate (Exhibit 22). That said, the limited size and timeline of the Phase 2 study precludes a full understanding of the adverse event report relative to the placebo arm.

Exhibit 22: GLPG1690 Adverse Event Summary from FLORA

Treatment Emergent Adverse Events (TEAE)	Placebo Group (n=6)	GLPG1690 (n=17)
% of Patients with a TEAE	67%	65%
% of Patients with a Moderate to Severe TEAE	67%	41%
Number of patients discontinuing due to AE	1	1

Source: Raymond James research, Galapagos

Two new drugs designed to slow the progression of IPF were approved by the U.S. FDA during 2014, nintedanib (Ofev) and pirfenidone (Esbriet). The two drugs have very different mechanisms of action versus each other, and relative to GLPG1690. Nintedanib is a tyrosine kinase inhibitor that targets FGFR/PDGFR/VEGFR, and is dosed at 150mg orally twice daily, while pirfenidone is a pyridone derivative that is dosed at ~801mg orally three times daily. Despite both drugs having notable discontinuation rates (Exhibit 23), and only slowing the progression of IPF (HR 0.53 nintedanib², HR 0.57 pirfenidone³), they each generate ~\$1B in global sales on an annual basis. We estimate that nintedanib and pirfenidone are used to treat approximately 15-20% of the U.S. IPF market on an annual basis, and around 5-10% within the G5 + Japan population.

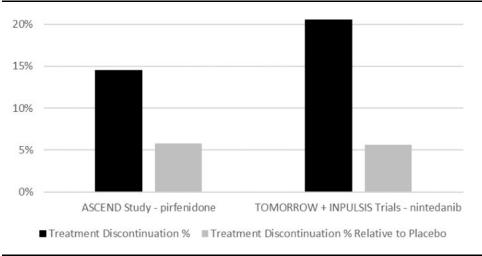


Exhibit 23: Treatment Discontinuation Rates of Ofev and Esbriet for IPF patients

Source: Raymond James research, Takeda, Boehringer Ingelheim

<sup>&</sup>lt;sup>2</sup> Nintedanib in patients with idiopathic pulmonary fibrosis: Combined evidence from the TOMORROW and INPULSIS trials, Richeldi and Brown et al.; The Lancet Respiratory Medicine; February 2016; Vol 113, Pg 74 - 79

<sup>&</sup>lt;sup>3</sup> A Phase 3 Trial of Pirfenidone in Patients with Idiopathic Pulmonary Fibrosis; King and Noble et al.; N Engl J Med; May 2014; 370:2083-92

GLPG1205 is a GPR84 inhibitor also being tested for the treatment of patients with IPF. Galapagos announced the PINTA Phase 2 trial to evaluate GLPG1205 during July 2018 and enrollment beginning during 2H2018. Importantly, the PINTA study will be longer and larger than the FLORA study design, with up to 60 IPF patients being enrolled for an evaluation period of 26 weeks. In our view, this should help better elucidate improvement trends relative to the small dataset from the FLORA study. Interestingly, GLPG1205 was previously tested for the treatment of ulcerative colitis, and although well tolerated, the drug decidedly had no clinical impact on the disease<sup>4</sup>. Targeting GPR84 has shown promise in IPF, evidenced by the Phase 2 results of the study evaluating PBI-4050 (ProMetic BioTherapeutics), which supported moving into Phase 3 studies (Exhibit 24).

% Predicted FVC Change from Baseline at 12 wks

0.00%

-0.50%

-1.00%

-1.50%

-2.00%

-2.50%

PBI-4050 mono

PBI-4050 + nintedanib

PBI-4050 + pirfenidone

Exhibit 24: PBI-4050 FVC Outcome at 12 Weeks Relative to Baseline

Source: Raymond James research

 $<sup>^{\</sup>rm 4}$  European Crohn's and Colitis Organisation Annual Meeting 2017, Vermeire and Beetens et al.

### GLPG1972: Osteoarthritis (Galapagos/ Servier)

GLPG1972 is an ADAMTS-5 inhibitor in development as a disease-modifying drug for osteoarthritis. Servier in-licensed the rights to GLPG1972 during July 2017, but Galapagos retains exclusive U.S. commercialization rights. During June 2018, the companies announced the start of the Phase 2 ROCCELLA study in patients with osteoarthritis. This effort builds upon the PK/PD biomarker data presented for GLPG1972 that was presented during EULAR 2018<sup>5</sup>. Given the early stage of the OA program and the history of failures developing disease-modifying agents for OA, we think that it is too early to model a commercial timeline for GLPG1972.

The most important disease modifying signal from the Phase 1b study in patients with hip and/or knee OA was the significant decreases in serum ARGS levels within the active arm, relative to the placebo control group. Serum ARGS levels were reduced in a dose-dependent manner and a maximal reduction of 53% was recorded (Exhibit 25).

Regarding safety, 24 patients received GLPG1972, and all adverse events were mild and transient. A female patient within the 300mg cohort did discontinue the study after 15 days due to a drug-related ALT increase >3x upper limit of normal, although bilirubin was normal and the enzyme elevation was reversible.

Mean (SEM) % Reduction Over Time in Serum ARGS Levels -20 PD sampling scheme -10 Predose on days 1, 3, 6, 8, 0 10, 15, 22, 29, 43 and 50 20 -placebo 30 GLPG1972 100mg 40 GLPG1972 200mg 50 GLPG1972 300mg 60 70 1 8 15 22 29 36 43 50 Days

Exhibit 25: GLPG1972 Reduction in Serum ARGS Levels

Source: Galapagos

The biologic rationale for using an ADAMTS-5 inhibitor is that aggrecan is a primary component of articular cartilage, and ADAMTS-5 along with ADAMTS-4 cleave aggrecan, which forms ARGS-neoepitope fragments. The hope of the biomarker data from the GLPG1972 Phase 1b study is that the reduction in serum ARGS levels implies that ADAMTS-5 is being blocked by the drug and will support retention of aggrecan within the cartilage. Direct validation of serum ARGS levels as a biomarker are incomplete, but studies have correlated upregulation of TIMP-3 during acute injury (ACL rupture), which as a primary aggrecanase inhibitor, would support the idea of ADAMTS-5 inhibition as a strategy for prevention of aggrecan degradation<sup>6</sup>.

<sup>&</sup>lt;sup>5</sup> A Safety, Tolerability, Pharmacokinetics and Pharmacodynamics Study with increasing Oral Doses of GLPG1972 Administered Daily for 29 Days Shows a Strong Biomarker Effect in Patients with Knee and/or Hip OA (NCT03311009); Deckx and Fieuw et al.; EULAR 2018. FRI0539

<sup>&</sup>lt;sup>6</sup> Relationship Between Synovial Fluid ARGS-Aggrecan Fragments, Cytokines, MMPs, and TIMPs Following Acute ACL Injury: A Cross-Sectional Study; Tourville and Beynnon et al; Journal of Orthopaedic Research; December 2015, DOI 10,1002/jor.22961

### Cystic Fibrosis Program-Galapagos & AbbVie

The Galapagos cystic fibrosis program began as a joint venture with AbbVie during 2013, and the collaboration was expanded during May 2016 to push Phase 2 studies into Phase 3 efforts that the AbbVie team would then carry through to commercialization. The Cystic Fibrosis market has been dominated by Vertex Pharmaceuticals ever since the approval of Kalydeco during 2012, with the Vertex CF portfolio expected to record ~\$3B in sales during 2018. The AbbVie/ Galapagos partnership had promised to be on a parallel track of development for a triple-combination therapy heading into 2017, but the program became delayed, and reports out of multiple small Phase 2 studies left questions regarding competitive efficacy relative to the Vertex triplet efforts.

During June 2018, AbbVie announced that it did not intend to move GLPG2737 forward, which was a second corrector (C2) within the triplet regimen. The external view of the situation was that GLPG2737 underperformed the clinical efficacy target within a Phase 2 study in combination with Orkambi, only increasing the percent predicted forced expiratory volume in one second (ppFEV1)  $\pm 3.4\%$  by day 28, versus the  $\pm 10\%$  increase that many external watchers of the study thought was needed to compete with the Vertex efforts.

The decision not to move forward with the GLPG2737 program sparked a public argument between Galapagos and AbbVie that seemed to move the collaboration towards a dissolution. During October 2018, AbbVie and Galapagos announced that AbbVie would take over all further development activities related to the CF program (Exhibit 26), in exchange for a \$45M upfront payment to Galapagos, and \$200M in potential milestones. If a therapeutic regimen is ultimately commercialized from the CF development program, Galapagos would be eligible to receive single to double-digit royalties on net sales. Interestingly, Galapagos did retain rights to GLPG2737 for indications outside of cystic fibrosis.

Exhibit 26: GLPG Cystic Fibrosis Pipeline

Preclinical	Ph1	Ph2
Potentiator '2451		
Potentiator `3067		
C1 corrector '2222		
C1 corrector `2851		
C2 corrector '2737		
C2 corrector '3748		

### **MOR106** in Collaboration with Morphosys and Novartis

During 2008, Galapagos and Morphosys entered into a collaboration to develop novel antibodies for bone and joint diseases. This partnership eventually produced MOR106, an IL-17c targeted human mAb for the treatment of atopic dermatitis. During July 2018, Galapagos and Morphosys announced that Novartis had acquired full development and commercial rights for MOR106, which includes transfer of the Phase 2 study in moderate-to-severe atopic dermatitis patients (IGUANA) that had been started during May 2018. Novartis agreed to pay ~\$111M upfront for the program, along with ~\$1B in potential milestones and tiered royalties on net commercial sales in the range of low-teens to low-twenties. Any payments or royalties from the program will be shared equally between Galapagos and Morphosys. The development of MOR106 still lacks a clinical profile that can properly be evaluated against other Th17 targeted drugs, and also will need to be reformulated for sub-cutaneous administration, to be competitive with dupilumab (Dupixent). We think that the interest from Novartis is likely around approximately 85% of patients achieving EASI-50 by week four in the highest dose group (Exhibit 27), which looks solid in comparison to the ~59% of patients achieving EASI-50 (placebo ~19%) within a Phase 3 study of dupilumab for adults with moderate to severe Atopic Dermatitis. That said, it is unclear whether a weekly 10mg/kg infusion of MOR106 is comparable to the weekly 300mg subcutaneous dose level of dupilumab.

**EASI-50 Score** % of Patients with 50% EASI Improvement 90 80 of subjects 70 60 Placebo 50 MOR106 1mg/kg 40 → MOR106 4mg/kg 30 MOR106 10mg/kg 20 10 0 3 baseline 2 4 Weeks since start of treatment Infusion

Exhibit 27: MOR106 Clinical Results for Atopic Dermatitis

Regarding the current safety profile of MOR106, we would highlight that there was a patient recorded with anti-drug antibodies, and a number of treatment related adverse events were characterized as moderate (Exhibit 28). Generally, the tolerance for treatment related adverse events is low within the indication of atopic dermatitis.

Exhibit 28: MOR106 Adverse Event Summary

	MOR106 1mg/kg	MOR106 4mg/kg	MOR106 10mg/kg	Placebo
	n(%)	n (%)	n (%)	n (%)
TEAE	5 (83.3)	5 (83.3)	3 (50.0)	2 (28.6)
Serious	0	0	0	0
Death	0	0	0	0
Worst TEAE				
intensity				
Mild	2 (33.3)	2 (33.3)	1 (16.7)	
Moderate	3 (50.0)	3 (50.0)	2 (33.3)	2 (28.6)
Severe	0	0	0	0
Treatment related	2 (33.3)	1 (16.7)	1 (16.7)	0
Permanently stopped	1 (16.7)	0	0	1 (14.3)

# **Management Team**

Galapagos NV Manageme	nt Team
Onno van de Stolpe, Chief Executive Officer	Onno van de Stolpe is the Founder and CEO of Galapagos NV. Prior to founding Galapagos, Mr. Stolpe was the Managing Director of Genomics at IntroGene B.V. (acquired by Johnson & Johnson), and prior to that, the Managing Director at Molecular Probes Europe B.V. Before that, Mr. Stolpe worked at The Netherlands Foreign Investment Agency in California, and began his career as Management of Business Development at MOGEN International NV. Onno received his MSc from Wageningen University.
<b>Piet Wigerinck, Ph.D.,</b> Chief Scientific Officer	Dr. Piet Wigerinck is the Chief Scientific Officer at Galapagos. Prior to Galapagos, Dr. Wigerinck was the Vice President of Drug Discovery, Early Development and CM&C at Tibotec-Virco Comm. VA (subsidiary of Johnson & Johnson), helping the company move TMC114 (Prezista™) and TMC435 (Olysio™) into clinical trials. Dr. Wigerinck started his biopharma career as a medicinal chemist at Janssen Research Foundation. Dr. Piet received his PhD from the K.U. Leuven, and is an author on more than 25 patent applications.
Bart Filius, MBA, Chief Operating Officer & Chief Financial Officer	Bart Filius is the COO and CFO at Galapagos. Previously, Mr. Filius worked in a variety of executive positions at Sanofi S.A., most recently as the CFO at Sanofi Europe, providing guidance through its library of IP's. Prior to that, Mr. Filius was the CFO and Country Manager of Sanofi in the Netherlands, and before that, was Vice President for Mergers & Acquisitions at Sanofi. Before his tenure at Sanofi, Mr. Filius was a strategy consultant at Arthur D. Little. Bart received his bachelor's in business from Nyenrode University, and his MBA from INSEAD.
Andre Hoekema, Ph.D., Chief Business Officer	Dr. Andre Hoekema is the Chief Business Officer at Galapagos. Previously, he worked as Managing Director of Corporate Development-Europe at Invitrogen Corporation. Before that, he worked in a variety of research and business development positions with increasing responsibilities at Molecular Probes Europe B.V., Crucell N.V., DSM Life Sciences N.V., Syngenta MOGEN B.V., and Genentech, respectively. Dr. Andre Hoekema received his PhD from Leiden University, and is authored on more than 20 patent applications, 15 of which were issued in the US.
<b>Walid Abi-Saab, M.D.,</b> Chief Medical Officer	Dr. Walid Abi-Saab, MD is the Chief Medical Officer at Galapagos. Previously, Dr. Abi-Saab held clinical management positions at Shire Pharmaceuticals, focusing on gastrointestinal, endocrinology, and metabolism fields. Prior to that, he led clinical development programs at Novartis, Abbott, and Pfizer, respectively. Before his transition to biopharma industry, Dr. Abi-Saab was Assistant Professor of Psychiatry and Neurosurgery at Yale University Medical School, where he was also the head of both Schizophrenia Clinical Research unit, and the Neurosurgery Epilepsy Microdialysis Research program. Dr. Abi-Saab received his MD from Université Saint Joseph in Beirut, Lebanon.

## **Collaboration Agreements**

	Gilead	Servier	MorphoSys/Novartis
	<b>GILEAD</b>	* SERVIER	morphosus
			U NOVARTIS
Program	Filgotinib	GLPG 1972	MOR106
Upfront Payment	\$300m upfront license fee \$425 million equity investment	€6 million (~\$6.8m USD) upfront	\$111m initial upfront payment
Milestone Payments	Up to \$1.35B in milestone payments	€290 million (~\$330m USD) in total milestones, with royalties on ex-US commercialization	Up to \$1b in milestones + 10- 20% royalties  Milestones shared with MorphoSys
US rights	70% revenue to Gilead 30% revenue to Galapagos	Galapagos has US exclusive commercialization rights  Servier in-licensed GLPG1972, and is responsible for further clinical development, registration, and commercialization	Novartis bares commercialization rights
Ex-US rights	Co-promote in 8 EU countries Gilead responsible for manufacturing and worldwide marketing and sales activities	Servier licensed ex-US rights	Novartis bares commercialization rights

Source: Raymond James research, Galapagos NV, Gilead, Servier, Morphosys, Novartis

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## **Investment Risks**

### **Key Risks to our Rating and Recommendation for Galapagos NV include:**

1) The company is currently not profitable, and is unanticipated to be profitable for a number of years. As such, if the company is unable to secure financing for its activities, it could cease operations.

- 2) Stronger data from competitors to filgotinib could reduce our optimism for the program, along with our current commercial sales estimates.
- 3) Filgotinib may not be approved by the U.S. FDA for rheumatoid arthritis, which could significantly alter our revenue forecasts for the company, and endanger the Gilead partnership.

# **Valuation Scenario Analysis**

Galapagos NV (GLPG)								
<u>Bear</u> <u>Base</u> <u>Bull</u>								
Valuation (USD per share)	\$50	\$157	\$318					
Key Points	Filgotinib proves to be less effective than competing JAK inhibitors	Filgotinib commercial approval during 2019 for Rheumatoid Arthritis	Filgotinib and IPF drug portfolio achieve Best-in- Class status					

GLPG	5 Year Forward Sales Analysis											
	\$PT	-50%	-40%	-30%	-20%	-10%	0%	10%	20%	30%	40%	50%
	1x	\$39	\$41	\$43	\$45	\$48	\$50	\$52	\$54	\$56	\$58	\$60
es	2x	\$50	\$54	\$58	\$63	\$67	\$71	\$75	\$80	\$84	\$88	\$93
Sales	3x	\$60	\$67	\$73	\$80	\$86	\$93	\$99	\$106	\$112	\$118	\$125
Year Forward	4x	\$71	\$80	\$88	\$97	\$106	\$114	\$123	\$131	\$140	\$149	\$157
NJC.	5x	\$82	\$93	\$103	\$114	\$125	\$136	\$146	\$157	\$168	\$179	\$189
r F	6x	\$93	\$106	\$118	\$131	\$144	\$157	\$170	\$183	\$196	\$209	\$222
	7x	\$103	\$118	\$133	\$149	\$164	\$179	\$194	\$209	\$224	\$239	\$254
/ 5	8x	\$114	\$131	\$149	\$166	\$183	\$200	\$217	\$234	\$252	\$269	\$286
EV/	9x	\$125	\$144	\$164	\$183	\$202	\$222	\$241	\$260	\$280	\$299	\$318
	10x	\$136	\$157	\$179	\$200	\$222	\$243	\$265	\$286	\$308	\$329	\$350

## **Company Citations**

Company Name	Ticker	Exchange	Currency	Closing Price	RJ Rating	RJ Entity
AbbVie Inc.	ABBV				NC	
Gilead Sciences, Inc.	GILD	NASDAQ	\$	70.49	1	RJ & Associates

Notes: Prices are as of the most recent close on the indicated exchange and may not be in US\$. See Disclosure section for rating definitions. Stocks that do not trade on a U.S. national exchange may not be registered for sale in all U.S. states. NC=not covered.