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## Galapagos NV | North America

# Catalyst Driven Idea: US Filgotinib Outcomes

A potential decision on the commercial path forward for filgotinib in the US specifically for RA or potentially even more broadly could be made after a meeting with the FDA in late October or November. With a variety of outcomes, GLPG could move +/-15-20%.

#### What and when is the catalyst? Filgotinib US commercialization decision

potentially in coming weeks: Galapagos has previously licensed rights to JAK inhibitor filgotinib to Gilead. While management received approval in the lead indication for Rheumatoid Arthritis in both the EU and Japan, the US FDA issued a complete response letter requesting more data on male toxicity and questioning the relative safety profile of the 200mg dose versus the 100mg dose (see our prior note here). While we had originally expected data from the male toxicity study in 1Q21 and a potential refiling with the FDA subsequently, Gilead management is conducting a Type A meeting with FDA in the near-term and has indicated that if it believes approval of the 200mg dose is unlikely to have a path forward after that meeting, it may adjust its commercial stance in the US related to the marketing of filgotinib. Such actions could include a full return of US commercial rights, a decision to not pursue the RA indication, but continue to pursue the IBD indications or a decision to move ahead based on a positive outcome related to 200mg.

What are the potential outcomes for this event? Scenario 1: Gilead returns US commercial rights to Galapagos. In this scenario we would expect some additional consideration such as a renegotiation of European rights where Galapagos may take over commercialization in the EU. Scenario 2: Gilead decides not to file RA in the US, but continues with the IBD indications. Scenario 3: The Type A meeting suggests 200mg is potentially approvable and there is no change to the commercialization agreement.

## What are the potential stock implications from these outcomes? Scenario 1:

Removing US filgotinib from our model decreases our Galapagos valuation by ~20%. We would expect some offset if Galapagos regains European rights and see GLPG down 10-15% **Scenario 2:** Removing US filgotinib in RA from our model decreases our Galapagos valuation by ~10%. However, we would expect some investor relief if Gilead reaffirms its commitment to the US IBD indications and see GLPG down 5-7% **Scenario 3:** We expect broad investor relief and see GLPG up 10-20%.

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#### Galapagos NV (GLPG.O, GLPG US)

#### **Biotechnology / United States of America**

Stock Rating	Equal-weight
Industry View	In-Line
Price target	\$159.00
Shr price, close (Oct 16, 2020)	\$128.83
Mkt cap, curr (mm)	\$3,947
52-Week Range	\$274.03-112.00

Fiscal Year Ending	12/19	12/20e	12/21e	12/22e
ModelWare EPS (\$)	5.91	(1.92)	(3.65)	(6.08)
Prior ModelWare EPS	-	-	-	-
(\$)				
P/E	35.0	NM	NM	NM
EPS (\$)§	4.69	(5.10)	(5.80)	(5.19)
Div vld (%)	_		_	

Unless otherwise noted, all metrics are based on Morgan Stanley ModelWare framework

- § = Consensus data is provided by Thomson Reuters Estimates
- e = Morgan Stanley Research estimates

QUARTERLY MODELWARE EPS (\$)						
Quarter	2019	2020e Prior	2020e Current	2021e Prior	2021e Current	
Q1	(1.14)	-	(0.21)a	-	-	
Q2	(1.12)	-	(2.11)a	-	-	
Q3	8.89	-	(1.40)	-	-	
Q4	(1.43)	-	1.87	-	(0.29)	

e = Morgan Stanley Research estimates, a = Actual Company reported data

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What is our base case expectation for this event? Our base case expectation is Scenario 2, where we believe a filing in RA will not proceed in the US, but development will continue with the IBD indications. We base this on the fact that other JAK inhibitors have been approved at higher doses in IBD compared to RA and that management is unlikely to gain clarity on the acceptability of the 200mg dose in RA at the Type A meeting.

Details of the scenario	Scenario 1	Scenario 2	Scenario 3
US commercialization outcomes	US rights returned	Only IBD moves ahead	Both RA and IBD progress
Probability	30%	55%	15%
GLPG - POTENTIAL CHANGE IN STOCK PRICE (%)	-10-15%	-5-7%	+10-20%
GLPG - CORRESPONDING PROJECTED STOCK PRICE	~\$143 - \$135	~\$151 - \$148	~\$175 - \$191

Source: Morgan Stanley Research; The probabilities shown are only illustrative. They do not forecast a precise series of events and do not account for all possible outcomes but instead illustrate our sense of the relative plausibility of selected scenarios, based on current industry dynamics.

Morgan Stanley is acting as financial advisor to Gilead Sciences, Inc. ("Gilead"), in relation to its agreement with Arcus Biosciences, Inc. ("Arcus") to co-develop and co-commercialize current and future therapeutic candidates in Arcus's pipeline, as announced on May 27, 2020. The proposed transaction is subject to regulatory approvals and other customary closing conditions. Gilead has agreed to pay fees to Morgan Stanley for its financial services, including transaction fees that are contingent upon the consummation of the transaction. Please refer to the notes at the end of the report.



## Valuation Methodology and Risks

### Gilead Sciences Inc.(GILD.O)

We Derive Our PT From A Discounted Cash Flow Analysis That Uses A WACC Of 10% And A 0% Terminal Growth Rate.

#### Risks to Upside

Better than expected pipeline success on key late-stage drugs

#### **Risks to Downside**

- Unexpected competition in HIV
- More rapid HCV erosion than appreciated by consensus
- Failure of CAR-T to achieve significant market penetration & failure to meaningfully expand CAR-T label
- Significant delays with regulatory progress for JAK inhibitor filgotinib

## Galapagos NV(GLPG.O)

GLPG: Our price target is based on a DCF that uses a 12.5% discount rate, a 2% terminal growth rate, and explicit revenue projections until 2030E. Our revenue projections incorporate filgotinib royalties for various inflammatory diseases, including RA, CD, UC, AS, and PsA, in addition to sales of GLPG1690 in IPF, sales of GLPG1972 in OA. Key risks include regulatory risk, development risk in IPF, and competition in these markets.

### Risks to Upside

Products with greater risk-adjustments may succeed in late stage trials

### **Risks to Downside**

- MANTA and/or MANTA-RAy studies may uncover unexpected male testicular toxicity safety signals, potentially further delaying commercialization for filgotinib
- FDA may reject the 200mg dose for filgotinib in RA
- Phase II safety profiles may not assure protection from unknown side-effects in broader Phase III programs



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Fulcrum Therapeutics Inc, Fusion Pharmaceuticals Inc, Gilead Sciences Inc., Global Blood Therapeutics Inc, Imara Inc, Incyte Corp, Innoviva Inc, Insmed Inc, Ionis Pharmaceuticals Inc, Ironwood Pharmaceuticals, Inc., Karyopharm Therapeutics Inc, Kodiak Sciences Inc, Kymera Therapeutics Inc, Legend Biotech Corp, MacroGenics Inc, Moderna Inc, Neurocrine Biosciences Inc, NextCure Inc., Prevail Therapeutics Inc, Radius Health Inc, Regeneron Pharmaceuticals Inc., Repare Therapeutics Inc, Rhythm Pharmaceuticals Inc, Schrodinger Inc., Seagen Inc, Theravance Biopharma Inc, Ultragenyx Pharmaceutical Inc, Vertex Pharmaceuticals, Zealand Pharma A/S, Zentalis Pharmaceuticals Inc.

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(as of September 30, 2020)

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	COVERAGE UN	NIVERSE	INVESTMENT BANKING CLIENTS (IBC)		OTHER MATERIAL		
						INVESTMENT	SERVICES
						CLIENTS (	(MISC)
STOCK RATING	COUNT	% OF	COUNT	% OF	% OF	COUNT	% OF
CATEGORY		TOTAL		TOTAL IBC	RATING		TOTAL
					CATEGORY		OTHER
							MISC
Overweight/Buy	1326	40%	360	46%	27%	590	39%
Equal-weight/Hold	1444	43%	341	43%	24%	676	45%
Not-Rated/Hold	4	0%	1	0%	25%	3	0%
Underweight/Sell	557	17%	85	11%	15%	226	15%
TOTAL	3,331		787			1495	

Data include common stock and ADRs currently assigned ratings. Investment Banking Clients are companies from whom Morgan Stanley received investment banking compensation in the last 12 months. Due to rounding off of decimals, the percentages provided in the "% of total" column may not add up to exactly 100 percent.

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## Stock Price, Price Target and Rating History (See Rating Definitions)

Galapagos NV (GLPG.O) – As of 10/18/20 in USD Industry : Biotechnology



Stock Rating History: 10/1/15 : 0/I; 7/14/19 : NA/I; 9/8/19 : 0/I; 12/17/19 : E/I

Price Target History: 8/10/15 : 75; 1/7/16 : 89; 4/8/16 : 92; 5/2/16 : 89; 1/17/17 : 90; 4/13/17 : 92; 5/1/17 : 93; 7/19/17 : 87; 7/31/17 : 92; 10/6/17 : 123; 1/18/18 : 127; 2/26/18 : 124; 4/13/18 : 125; 7/13/18 : 126; 8/6/18 : 127; 11/5/18 : 131; 2/25/19 : 130; 4/12/19 : 138; 4/29/19 : 139; 7/14/19 : NA; 9/8/19 : 200; 10/28/19 : 193; 12/17/19 : 215; 2/26/20 : 220; 4/15/20 : 226; 7/14/20 : 224; 8/7/20 : 221; 8/20/20 : 158; 10/12/20 : 159

Source: Morgan Stanley Research Date Format: MM/DD/YY Price Target → No Price Target Assigned (NA)

Stock Price (Not Covered by Current Analyst) → Stock Price (Covered by Current Analyst) →

Stock and Industry Ratings (abbreviations below) appear as ◆ Stock Rating/Industry View

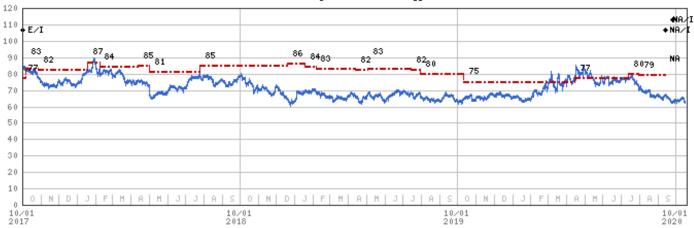
Stock Ratings: Overweight (O) Equal-weight (E) Underweight (U) Not-Rated (NR) No Rating Available (NA)

Industry View: Attractive (A) In-line (I) Cautious (C) No Rating (NR)

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#### Gilead Sciences Inc. (GILD.0) - As of 10/18/20 in USD Industry : Biotechnology



Stock Rating History: 10/1/15 : E/NR; 10/1/15 : 0/I; 9/13/20 : NA/I; 9/25/20 : NA/I

(or industry team's) coverage.

Price Target History: 8/26/15 : 127; 10/7/15 : 121; 10/28/15 : 123; 12/15/15 : 125; 1/15/16 : 120; 2/3/16 : 111; 4/8/16 : 108; 4/29/16 : 107; 5/26/16 : 103; 7/11/16 : 100; 10/6/16 : 97; 11/2/16 : 95; 12/19/16 : 91; 1/17/17 : 85; 2/8/17 : 77; 4/13/17 : 75; 7/27/17 : 77; 10/6/17 : 83; 10/27/17 : 82; 1/18/18 : 87; 2/7/18 : 84; 4/13/18 : 85; 5/2/18 : 81; 7/26/18 : 85; 12/19/18 : 86; 1/18/19 : 84; 2/5/19 : 83; 4/12/19 : 82; 5/3/19 : 83; 7/15/19 : 82; 7/31/19 : 80; 10/11/19 : 75; 4/15/20 : 77; 7/14/20 : 80; 7/31/20 : 79; 9/13/20 : NA

Source: Morgan Stanley Research Date Format: MM/DD/YY Price Target - No Price Target Assigned (NA)
Stock Price (Not Covered by Current Analyst) - Stock Price (Covered by Current Analyst) Stock and Industry Ratings (abbreviations below) appear as + Stock Rating/Industry View
Stock Ratings: Overweight (O) Equal-weight (E) Underweight (U) Not-Rated (NR) No Rating Available (NA)

Industry View: Attractive (A) In-line (I) Cautious (C) No Rating (NR)

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#### **INDUSTRY COVERAGE: Biotechnology**

COMPANY (TICKER)	RATING (AS OF)	PRICE* (10/16/2020)
David N Lebowitz, CFA, MPH		
Akebia Therapeutics Inc (AKBAO) Anylam Pharmaceuticals Inc (ALNY.O) Ascendis Pharma A'S (ASND.O) AVROBIO Inc (AVRO.O) Blueprint Medicines Corporation (BPMC.O) Epizyme Inc (EPZMO) Ionis Pharmaceuticals Inc (IONS.O) Ironwood Pharmaceuticals, Inc. (IRWD.O) Karyopharm Therapeutics Inc (KPTI.O) MacroGenics Inc (MGNX.O) Nabriva Therapeutics PLC (NBRV.O) Rhythm Pharmaceuticals Inc (RYTM.O) Schrodinger Inc. (SDGR.O) Syndax Pharmaceuticals Inc (SNDX.O) Y-mABs Therapeutics Inc. (YMAB.O) Zealand Pharma A'S (ZEAL.O)	E (09/07/2018) O (03/05/2019) O (10/11/2019) O (07/16/2018) O (04/03/2019) O (12/05/2019) U (11/07/2019) E (03/27/2019) O (07/01/2020) U (11/21/2019) E (03/17/2020) O (09/07/2018) E (03/02/2020) E (10/29/2018) E (04/29/2020) O (09/07/2018)	\$3.78 \$145.40 \$158.47 \$15.68 \$102.33 \$13.38 \$47.13 \$10.37 \$15.80 \$24.41 \$0.58 \$24.40 \$57.94 \$17.60 \$40.35

Jeffrey Hung



Acadia Pharmaceuticals Inc (ACAD.O) Acceleron Pharma Inc (XLRN.O) Aprea Therapeutics Inc (APRE.O) Cytokinetics Inc (CYTK.O) Evofem Biosciences Inc (EVFMO) Exelixis Inc. (EXEL.O) MyoKardia Inc (MYOK.O) Neurocrine Biosciences Inc (NBIX.O) NextCure Inc. (NXTC.O) Prevail Therapeutics Inc (PRVL.O) Repare Therapeutics Inc (RPTX.O) Ultragenyx Pharmaceutical Inc (RARE.O) Vela Bio (VIE.O) Voyager Therapeutics Inc (WGR.O)	O (08/20/2020) O (02/03/2020) E (10/28/2019) O (04/09/2020) E (08/20/2020) E (03/18/2019) E (10/05/2020) O (09/10/2018) E (07/13/2020) O (07/14/2020) O (03/27/2019) O (10/28/2019) E (09/10/2018)	\$42.61 \$116.81 \$24.04 \$16.47 \$2.86 \$23.23 \$222.00 \$102.51 \$11.39 \$9.75 \$25.27 \$91.97 \$33.46 \$12.28
Matthew Harrison		
ADC Therapeutics SA (ADCT.N)	O (06/09/2020)	\$27.73
Akero Therapeutics Inc (AKRO.O)	O (09/10/2020)	\$28.35
Alector Inc (ALEC.O)	O (03/04/2019)	\$10.29
Alexion Pharmaceuticals (ALXN.O)	E (12/17/2019)	\$124.13
AlloVir Inc (ALVR.O)	O (08/24/2020)	\$28.10
Amgen Inc. (AMGN.O)	O (12/17/2019)	\$235.72
argenx SE (ARGXO)	O (01/04/2019) O (01/17/2020)	\$269.90
BeiGene Ltd (6160.HK) BeiGene Ltd (BGNE.O)	O (01/17/2020)	HK\$187.70 \$316.61
Biogen Inc (BIIB.O)	O (07/27/2020)	\$280.01
Biohaven Pharmaceutical Holding Company (BHVN.N)	E (04/09/2019)	\$77.93
Biomarin Pharmaceutical Inc (BMRN.O)	E (07/08/2020)	\$79.25
Bluebird Bio Inc (BLUE.O)	E (11/03/2017)	\$56.10
Cabaletta Bio Inc (CABAO)	O (11/19/2019)	\$12.15
Denali Therapeutics Inc (DNLI.O)	O (01/02/2018)	\$44.15
Editas Medicine (EDIT.O)	E (02/29/2016)	\$33.66
Evelo Biosciences Inc (EVLO.O)	E (05/21/2020)	\$4.93 \$16.00
Freeline Therapeutics Holdings plc (FRLN.O) Fulcrum Therapeutics Inc (FULC.O)	O (09/01/2020) E (08/12/2020)	\$16.09 \$10.93
Fusion Pharmaceuticals Inc (FUSN.O)	O (07/21/2020)	\$12.65
Galapagos NV (GLPG.O)	E (12/17/2019)	\$128.83
Genmab A/S (GMAB.CO)	O (08/12/2019)	DKr 2,306.00
Genmab A/S (GMAB.O)	O (08/12/2019)	\$36.79
Gilead Sciences Inc. (GILD.O)	++	\$62.00
Global Blood Therapeutics Inc (GBT.O)	E (03/21/2018)	\$62.90
Imara Inc (IMRAO)	O (04/06/2020)	\$19.47
Immunomedics Inc (IMMU.O) Innoviva Inc (INVAO)	++ U (08/14/2014)	\$87.56 \$9.94
Insmed Inc (INSMO)	O (03/21/2018)	\$36.30
Kaleido Biosciences Inc. (KLDO.O)	E (05/21/2020)	\$8.80
Kodiak Sciences Inc (KOD.O)	O (10/29/2018)	\$76.49
Legend Biotech Corp (LEGN.O)	O (06/30/2020)	\$28.10
Moderna Inc (MRNAO)	O (01/02/2019)	\$73.94
Regeneron Pharmaceuticals Inc. (REGN.O)	E (10/01/2015)	\$599.74
Regenxbio Inc (RGNXO)	O (11/09/2017)	\$28.74
Rubius Therapeutics Inc. (RUBY.O) SAGE Therapeutics Inc (SAGE.O)	E (03/13/2020) O (02/26/2018)	\$5.41 \$69.09
Sarepta Therapeutics Inc (SRPT.O)	O (08/01/2018)	\$142.42
Seagen Inc (SGEN.O)	E (12/10/2019)	\$200.93
Taysha Gene Therapies Inc. (TSHAO)	O (10/19/2020)	\$21.80
Unity Biotechnology Inc. (UBXO)	E (08/18/2020)	\$4.06
Vertex Pharmaceuticals (VRTXO)	E (07/08/2020)	\$218.08
Zentalis Pharmaceuticals Inc (ZNTL.O)	O (04/28/2020)	\$42.00
Vikram Purohit		
	O (00/40/0000)	<b>₱</b> 70.74
Assome Therapeutics (AXSMO) Incyte Corp (INCY.O)	O (09/10/2020)	\$73.74 \$90.63
Kymera Therapeutics Inc (KYMR.O)	E (04/29/2020) E (09/15/2020)	\$90.63 \$38.38
Pandion Therapeutics (PAND.O)	O (08/11/2020)	\$11.03
Radius Health Inc (RDUS.O)	E (05/13/2020)	\$13.44
Theravance Biopharma Inc (TBPH.O)	O (10/14/2020)	\$18.53
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Stock Ratings are subject to change. Please see latest research for each company. \* Historical prices are not split adjusted.