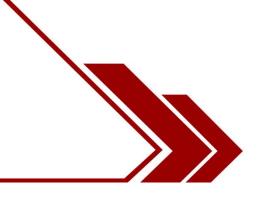


# Galapagos NV GLPG.OQ GLPG US

**EQUITY: AMERICAS BIOTECHNOLOGY** 



# Our Est vs. Consensus: Focus on Oppy in UC

Ahead of R&D Day and ACR/ARP – Consensus View Underestimates Filgo in UC; Ph3 Data 1H20

- GLPG will present data in RA and PsA for filgo at ACR/ARP on Nov 8-13, followed by an R&D day on Nov 14 in NYC. At ACR/ARP, GILD/ GLPG will present further FINCH2 analysis at the American College of Rheumatology, including pooled safety data (p. 7 for complete list of abstracts). However, we believe these near-term events have drawn attention away from the opportunity in ulcerative colitis US), which we view as an underappreciated source of potential upside (and less competitive filgo launch for GILD/GLPG). Ph3 data in UC from SELECTION1 is expected in 1H20; tofacitinib was approved in UC in 2018, which we view as derisking proof of efficacy for JAK inhibitors in this indication. The superior safety and tolerability of filgo should enhance market uptake, particularly in IBD where higher JAK doses appear to be required, and in the wake of renewed safety warnings on tofa's label, which makes our estimates highly differentiated vs. consensus. See pp. 3-6 for a review on our market assumptions and estimates, as well as a comparison to consensus in UC, CD, and RA. We make minor updates to our model ahead of the R&D day; p.8. Reiterate Buy.
- Ulcerative Colitis Ph3 Data in 1H20: Consensus Underestimates
   Opportunity and Derisking, in Our View. SELECTION1 data in 1H20 is
   the next source of value for filgo, in our view. We believe the consensus
   view around this indication underestimates filgo's potential to provide a safer
   JAKi option in light of ongoing Xeljanz safety scrutiny; Xeljanz was approved
   in UC (with broad label) in 2018, providing proof of efficacy for JAKi
   approaches in UC (and likely CD, in our view); pp. 3-6 for comparison.
- Next Up ACR/ARP Nov 8-13: Data in RA and PsA: Summary P. 7. The
  majority of GILD/GLPG's presentations are related to subgroup analyses in
  FINCH2, pooled safety results from the three FINCH trials (NCT02889796,
  NCT02873936, NCT02886728), and LT safety from DARWIN-3
  (NCT02065700). GILD to submit NDA by YE19 in U.S.; p. 7 for abstract list.
- R&D Day Nov 14, Probably Still No Toledo Target. Mgmt. has previously indicated the Toledo target would be disclosed on the launch of Ph2 programs (next year). Until then, we do not anticipate significant value of Toledo to be incorporated into GLPG's share price.

Year-end: Dec	2018A		2019E			2020E	
EPS (€)	Actual	Prev.	Curr.	Cons.	Prev.	Curr.	Cons.
1Q	-0.73A	-0.89A	-0.89A	N/A	-0.44E	-0.18E	N/A
2Q	-0.42A	-0.86A	-0.86A	-0.59E	-0.78E	-0.51E	N/A
3Q	0.28A	6.03A	6.03E	-0.20E	-1.24E	-0.93E	N/A
4Q	0.27A	-0.22E	0.04E	-0.33E	-1.64E	-1.32E	N/A
Year	-0.56A	6.82E	4.63E	-2.32E	-4.11E	-2.94E	-2.77E
O 0 F	4 000 700	E 000 74E	F 700 440	4 00 4 400	F 400 004	F 000 000	075 070

Cash & Equivalents (€000) 1,290,796 5,862,715 5,732,449 1,004,138 5,168,361 5,093,892 875,676

Source: Company data, FactSet, Instinet estimates

Key company data: See next page for company data and detailed price/index chart.

## Instinet, LLC, Equity Research

#### 5 November 2019

Rating Remains	Buy
Target Price Remains	USD 209.00
Closing price 4 November 2019	USD 182.93
Potential upside	+14.3%

#### Research analysts

#### Americas Biotech

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# **Key data on Galapagos NV**

# Rating

Stock	Buy
Sector	Not rated

### Relative performance chart



Source: Thomson Reuters, Instinet research

#### Performance as of 4 November 2019

(%)	1M	3M	12M
Absolute	20.6	6.1	71.2
Relative to Nasdaq	10.7	1.9	70.1
Biotechnology Index			

### Market data

Current Stock Price (\$)	182.93
Market Cap (\$mn)	11,333.2
52-week Low (\$)	85.00
52-week High (\$)	191.63
Shares Outstanding (mn)	61.95

Source: Thomson Reuters, Instinet research

#### Valuation

Year-end: Dec	2018A	2019E	2020E
EV/Sales (x)	19.6	7.4	17.1

Source: Company data, Instinet estimates

# **Summary Income Statement**

Year-end: Dec; €000	2018A	2019E	2020E
Revenue	317,845	924,355	662,559
Income Tax	50	-16,699	0
Net Income (adj.)	-11,027	299,111	-114,321
GAAP EPS	-0.56	4.63	-2.94
EPS (adj.)	-0.21	5.17	-1.95
Diluted Shares (000)	54,397	57,859	59,529

### **Summary Balance Sheet**

€000	2018A	2019E	2020E
Cash & Equivalents	1,290,796	5,732,449	5,093,892
PP&E	23,137	30,343	38,995
Total Assets	1,439,496	6,110,613	5,451,085
Total Debt	0	0	0
Total Liabilities	225,247	3,497,253	2,952,046
Shareholders' Equity	1,214,249	2,613,360	2,499,039
Total Liabilities & Equity	1,439,496	6,110,613	5,451,085

### **Summary Cash Flow Statement**

€000	2018A	2019E	2020E
Cash from Operations	-142,466	3,358,800	-622,320
Change in Working Capital	-133,390	3,053,905	234,450
Cash from Investing	-15,914	-17,146	-16,238
Capital Expenditures	-10,392	-12,990	-16,238
Cash from Financing	287,876	1,100,000	0
Free Cash Flow	-156,182	3,341,654	-638,557

#### **Other Metrics**

	2018A	2019E	2020E		
Enterprise Value (€000)	6,239	6,827	11,333		

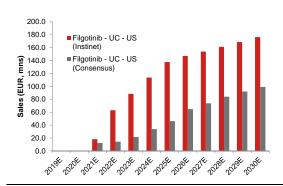
Source: Company data, Instinet estimates

# Filgotinib in Ulcerative Colitis: Our Estimates vs. Consensus

Filgotinib in ulcerative colitis (UC) and Crohn's disease (CD) make up \$19 of our \$209 target price.

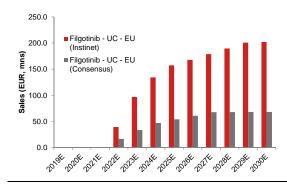
- Filgo is being tested in a Ph3 trial (SELECTION1) for ulcerative colitis (NCT02914522).
- Top-line data for UC will be available in 1H20.
- Filgotinib in UC is derisked by tofacitinib, which was approved for ulcerative colitis in 2018 (based on data from the Ph3 trials OCTAVE).
  - -However, tofacitinib has been dogged by warnings related to increased risks of blood clots and death.
  - -These ongoing safety problems will make filgotinib a superior choice, in our view.
- We highlight our market expectations for filgotinib in UC below and compare them to consensus.
- We anticipate a much stronger launch with greater peak sales compared to consensus in the US and EU.

Fig. 1: Filgotinib in UC, US



Source: Visible Alpha Consensus, Instinet estimates

Fig. 2: Filgotinib in UC, EU



Source: Visible Alpha Consensus, Instinet estimates

Fig. 3: Filgotinib in UC, US

Ulcerative Colitis Disease, United States (€)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Overall ulcerative colitis Patients, U.S. (000s)	913.8	920.7	927.6	934.5	941.5	948.6	955.7	962.9	970.1	977.4	984.7	992.1
% Growth y/y	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%
Mild to Moderate UC												
Mild to Moderate ulcerative colitis patients	721.9	727.3	732.8	738.3	743.8	749.4	755.0	760.7	766.4	772.1	777.9	783.7
% of Overall ulcerative colitis Patients	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.09
Mild to Moderate on filgotinib	0.0	0.0	0.0	1.8	3.7	5.6	7.6	7.6	7.7	7.7	7.8	7.8
% filgotinib	0.0%	0.0%	0.0%	0.3%	0.5%	0.8%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
Moderate to Severe UC												
Moderate to Severe ulcerative colitis patients	191.9	193.3	194.8	196.2	197.7	199.2	200.7	202.2	203.7	205.2	206.8	208.3
% of Overall ulcerative colitis Patients	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%
Moderate to Severe on filgotinib	0.0	0.0	4.9	9.8	12.9	15.9	18.1	19.2	19.9	20.5	21.2	21.9
% filgotinib	0.0%	0.0%	2.5%	5.0%	6.5%	8.0%	9.0%	9.5%	9.8%	10.0%	10.3%	10.5%
Gross Monthly Cost		4,167	4,250	4,335	4,422	4,510	4,600	4,692	4,786	4,882	4,980	5,079
Price Increase/Decrease			2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Discount		15.0%	17.5%	20.0%	22.5%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Net Monthly Cost		3,542	3,506	3,468	3,427	3,383	3,450	3,519	3,590	3,661	3,735	3,809
Duration of therapy, average (months)		4.0	7.5	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0
Compliance Rate		85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
Annual Cost Per Patient		\$12,042	\$22,352	\$32,426	\$32,041	\$31,627	\$32,260	\$32,905	\$33,563	\$34,234	\$34,919	\$35,617
US Filgotinib Sales (\$mn) - Probability Adjusted	\$0	\$0	\$109	\$378	\$531	\$682	\$826	\$882	\$924	\$967	\$1,012	\$1,058
					40.5%	28.4%	21.2%	6.8%	4.7%	4.7%	4.6%	4.6%
Filgotinib Ulcerative Colitis -US Sales (€mn)	€0.0	€0.0	€95.5	€331.6	€465.7	€598.1	€724.8	€774.0	€810.4	€848.2	€887.5	€928.3
Operating margin		95.0% 20.0%										
Royalty rate Royalties paid to Galapagos		20.0%	20.0%	20.0%	20.0%	20.0% € 114	20.0% € 138	20.0% € 147	20.0% € 154	20.0%	20.0% € 169	€ 176

Source: Instinet estimates

Fig. 4: Filgotinib in UC, EU

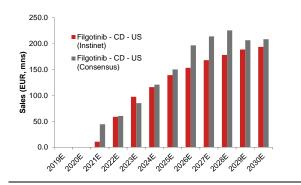
Ulcerative Colitis Disease, Europe	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Overall ulcerative colitis Patients, E.U. (000s)	1,368.7	1,376.9	1,385.1	1,393.4	1,401.8	1,410.2	1,418.7	1,427.2	1,435.8	1,444.4	1,453.0	1,461.8
% Growth y/y	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%
Mild to Moderate UC												
Mild to Moderate ulcerative colitis patients	1,081.2	1,087.7	1,094.3	1,100.8	1,107.4	1,114.1	1,120.8	1,127.5	1,134.2	1,141.1	1,147.9	1,154.8
% of Overall ulcerative colitis Patients	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%	79.0%
Mild to Moderate on filgotinib	0.0	0.0	0.0	0.0	2.8	3.3	3.4	3.9	4.5	5.1	5.7	5.8
% filgotinib	0.0%	0.0%	0.0%	0.0%	0.3%	0.3%	0.3%	0.4%	0.4%	0.5%	0.5%	0.5%
Moderate to Severe UC												
Moderate to Severe ulcerative colitis patients	287.4	289.1	290.9	292.6	294.4	296.1	297.9	299.7	301.5	303.3	305.1	307.0
% of Overall ulcerative colitis Patients	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%	21.0%
Moderate to Severe on filgotinib	0.0	0.0	0.0	5.9	10.3	14.8	17.9	18.7	19.6	20.5	21.4	21.5
% filgotinib	0.0%	0.0%	0.0%	2.0%	3.5%	5.0%	6.0%	6.3%	6.5%	6.8%	7.0%	7.0%
Net Monthly Cost			2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125
Price Increase/Decrease				0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Duration of therapy, average (months)			2.0	10.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0
Compliance Rate			85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
Annual Cost Per Patient			\$3,613	\$18,063	\$19,869	\$19,869	\$19,869	\$19,869	\$19,869	\$19,869	\$19,869	\$19,869
EU filgotinib Sales (\$mn) - Probability Adjusted	\$0.0	\$0.0	\$0.0	\$105.7	\$259.7	\$360.6	\$422.0	\$450.6	\$479.5	\$508.8	\$538.4	\$541.7
				#DIV/0!	145.7%	38.8%	17.0%	6.8%	6.4%	6.1%	5.8%	0.6%
Filgotinib Ulcerative Colitis - EU Sales (€mn)	€0.0	€0.0	€0.0	€92.7	€227.8	€316.3	€370.1	€395.3	€420.6	€446.3	€472.3	€475.1
Operating margin		85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Profit Share rate		50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
Profit paid to Galapagos		€0.0	€0.0	€39.4	€96.8	€134.4	€157.3	€168.0	€178.8	€189.7	€200.7	€201.9

Source: Instinet estimates

# Filgotinib in Crohn's Disease: Our Estimates vs. Consensus

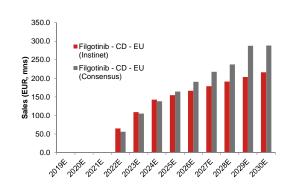
• Our estimates are closely aligned with consensus.

Fig. 5: Filgotinib in CD, US



Source: Visible Alpha Consensus, Instinet estimates

Fig. 6: Filgotinib in CD, EU



Source: Visible Alpha Consensus, Instinet estimates

Fig. 7: Filgotinib in CD, US

Crohn's Disease, United States (€)	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Overall Crohn's Patients, U.S. (000s)	785.9	791.7	797.7	803.7	809.7	815.8	821.9	828.0	834.3	840.5	846.8	853.2
% Growth y/y	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%	0.75%
Mild to Moderate Crohn's patients	432.2	435.5	438.7	442.0	445.3	448.7	452.0	455.4	458.8	462.3	465.8	469.2
% of Overall Crohn's Patients	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%
Mild to Moderate on filgotinib	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
% filgotinib	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Moderate to Severe Crohn's patients	353.6	356.3	359.0	361.6	364.4	367.1	369.8	372.6	375.4	378.2	381.1	383.9
% of Overall Crohn's Patients	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%
Moderate to Severe on filgotinib	0.0	0.0	3.6	10.8	18.2	22.0	25.9	27.9	30.0	31.2	32.4	32.6
% filgotinib	0.0%	0.0%	1.0%	3.0%	5.0%	6.0%	7.0%	7.5%	8.0%	8.3%	8.5%	8.5%
Gross Monthly Cost		4,167	4,250	4,335	4,422	4,510	4,600	4,692	4,786	4,882	4,980	5,079
Price Increase/Decrease			2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
Discount		15.0%	17.5%	20.0%	22.5%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Net Monthly Cost		3,542	3,506	3,468	3,427	3,383	3,450	3,519	3,590	3,661	3,735	3,809
Duration of therapy, average (months)		10.0	6.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0
Compliance Rate		85%	85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
Annual Cost Per Patient		\$30,104	\$17,882	\$32,426	\$32,041	\$31,627	\$32,260	\$32,905	\$33,563	\$34,234	\$34,919	\$35,617
US filgotinib Sales (\$mn) - Probability Adjusted	\$0	\$0	\$64	\$352	\$584	\$697	\$835	\$920	\$1,008	\$1,068	\$1,131	\$1,162
				448.1%	65.9%	19.3%	19.9%	10.1%	9.6%	6.0%	5.9%	2.8%
filgotinib US Crohn's Sales (4mn)	€0.0	€0.0	€56.3	€308.6	€512.0	€611.1	€732.6	€806.7	€884.2	€937.1	€992.2	€1,019.6
Operating margin		95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%
Royalty rate		20.0%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%	20.0%
Royalties paid to Galapagos		€0	€ 11	€ 59	€ 97	€ 116	€ 139	€ 153	€ 168	€ 178	€ 189	€ 194

Source: Instinet estimates

Fig. 8: Filgotinib in UC, EU

Crohn's Disease, Europe	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
Overall Crohn's Patients, E.U. (000s)	1,279.5	1,287.2	1,294.9	1,302.7	1,310.5	1,318.3	1,326.2	1,334.2	1,342.2	1,350.3	1,358.4	1,366.5
% Growth y/y	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%	0.6%
Mild to Moderate Crohn's patients	703.7	707.9	712.2	716.5	720.8	725.1	729.4	733.8	738.2	742.6	747.1	751.6
% of Overall Crohn's Patients	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%	55.0%
Mild to Moderate on filgotinib	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
% filgotinib	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Moderate to Severe Crohn's patients	575.8	579.2	582.7	586.2	589.7	593.3	596.8	600.4	604.0	607.6	611.3	614.9
% of Overall Crohn's Patients	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%	45.0%
Moderate to Severe on filgotinib	0.0	0.0	0.0	8.8	14.7	19.3	20.9	22.5	24.2	25.8	27.5	29.2
% filgotinib	0.0%	0.0%	0.0%	1.5%	2.5%	3.3%	3.5%	3.8%	4.0%	4.3%	4.5%	4.8%
Net Monthly Cost			2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125
Price Increase/Decrease				0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Duration of therapy, average (months)			10.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0
Compliance Rate			85%	85%	85%	85%	85%	85%	85%	85%	85%	85%
Annual Cost Per Patient			\$18,063	\$19,869	\$19,869	\$19,869	\$19,869	\$19,869	\$19,869	\$19,869	\$19,869	\$19,869
EU filgotinib Sales (\$mn) - Probability Adjusted	\$0.0	\$0.0	\$0.0	\$174.7	\$292.9	\$383.1	\$415.0	\$447.3	\$480.0	\$513.1	\$546.5	\$580.4
				#DIV/0!	67.7%	30.8%	8.3%	7.8%	7.3%	6.9%	6.5%	6.29
filgotinib EU Crohn's Sales (4mn)	€0.0	€0.0	€0.0	€153.2	€256.9	€336.0	€364.1	€392.4	€421.1	€450.1	€479.4	€509.
Operating margin		85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.09
Profit Share rate		50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.09
Profit paid to Galapagos		€0.0	€0.0	€65.1	€109.2	€142.8	€154.7	€166.8	€179.0	€191.3	€203.7	€216.

Source: Instinet estimates

# Filgotinib in RA: Our Estimates vs. Consensus

- We expect the launch in RA in both the US and EU to ramp faster than consensus expectations.
- We believe filgotinib's superior safety profile will promote a relatively quick sales ramp.

Fig. 9: Filgotinib in RA, US

600.0

500.0

Filgotinib - RA - US
(Instinet)

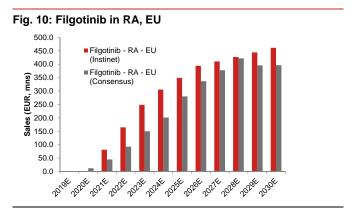
Filgotinib - RA - US
(Consensus)

100.0

100.0

100.0

Source: Visible Alpha Consensus, Instinet estimates



Source: Visible Alpha Consensus, Instinet estimates

Fig. 11: Filgotinib in RA, US

RA, United States	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
US population (000's)	357,934	360,619	363,323	366,048	368,794	371,560	374,346	377,154	379,983	382,832	385,704	388,596
Prevalence RA	2,506	2,524	2,543	2,562	2,582	2,601	2,620	2,640	2,660	2,680	2,700	2,720
Prevalence rate	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%
% Progressing to Therapies	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Total Treatable Patients	2,004	2,019	2,035	2,050	2,065	2,081	2,096	2,112	2,128	2,144	2,160	2,176
Mild RA												
% Patients	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Total Mild RA Patients	501	505	509	512	516	520	524	528	532	536	540	544
Patients on filgotinib	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
% penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Moderate RA												
% Patients	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Moderate RA Patients	1,002	1,010	1,017	1,025	1,033	1,040	1,048	1,056	1,064	1,072	1,080	1,088
Patients on filgotinib	0.0	2.5	5.1	7.7	10.3	13.0	15.7	18.5	21.3	24.1	27.0	27.2
% penetration	0.0%	0.3%	0.5%	0.8%	1.0%	1.3%	1.5%	1.8%	2.0%	2.3%	2.5%	2.5%
Severe RA												
% Patients	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Total Severe RA Patients	501	505	509	512	516	520	524	528	532	536	540	544
Patients on filgotinib	0.0	3.8	10.2	20.5	25.8	31.2	32.8	34.3	35.9	37.5	39.1	40.8
% penetration	0.0%	0.8%	2.0%	4.0%	5.0%	6.0%	6.3%	6.5%	6.8%	7.0%	7.3%	7.5%
Total Patients on filgotinib	0.0	6.3	15.3	28.2	36.1	44.2	48.5	52.8	57.2	61.6	66.1	68.0
Gross Price Per Patient/month (\$)		4,167	4,250	4,335	4,422	4,510	4,600	4,692	4,786	4,882		5,079
price increase/decrease			2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%	2.0%
discount		15.0%	17.5%	20.0%	22.5%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Net Price Per Patient/month (\$)	42,500.0	3,541.7	3,506.3	3,468.0	3,426.8	3,382.6	3,450.3	3,519.3	3,589.6	3,661.4	3,734.7	3,809.4
Duration of therapy (# of months)		3.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0
Compliance		85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Price Per Patient/Year (\$)		9,031	32,783	32,426	32,041	31,627	32,260	32,905	33,563	34,234	34,919	35,617
GLPG0634 US RA Sales (\$mn) - Probability Adjus	\$0.0	\$57.0	\$500.3	\$913.9	\$1,158.0	\$1,398.4	\$1,563.9	\$1,737.4	\$1,919.4	\$2,110.1	\$2,309.8	\$2,422.1
% Growth			777.7%	82.7%	26.7%	20.8%	11.8%	11.1%	10.5%	9.9%	9.5%	4.9%
GLPG0634 US RA Sales (€mn)	€0.0	€50.0	€438.8	€801.7	€1,015.8	€1,226.7	€1,371.8	€1,524.1	€1,683.7	€1,850.9	€2,026.2	€2,124.7
% Growth			777.7%	82.7%	26.7%	20.8%	11.8%	11.1%	10.5%	9.9%	9.5%	4.9%
Operating margin		95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%	95.0%
Royalty rate		20.0%	20.0%	21.0%	22.0%	23.0%	24.0%	24.0%	24.0%	24.0%	24.0%	24.0%
Royalties paid to Galapagos		€9	€ 83	€ 160	€212	€ 268	€ 313	€ 347	€ 384	€ 422	€ 462	€ 484

Source: Instinet estimates

Fig. 12: Filgotinib in RA, EU

RA, EUROPE	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EU addressable population (000's)	520,207	523,328	526,468	529,627	532,804	536,001	539,217	542,453	545,707	548,982	552,275	555,589
Prevalence RA	3,641	3,663	3,685	3,707	3,730	3,752	3,775	3,797	3,820	3,843	3,866	3,889
Prevalence rate	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%	0.70%
% Progressing to Therapies	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%	80%
Total Treatable Patients	2,913	2,931	2,948	2,966	2,984	3,002	3,020	3,038	3,056	3,074	3,093	3,111
Mild RA												
% Patients	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Total Mild RA Patients	728	733	737	741	746	750	755	759	764	769	773	778
Patients on filgotinib	0	0	0	0	0	0	0	0	0	0	0	0
% penetration	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Moderate RA												
% Patients	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%	50%
Total Moderate RA Patients	1,457	1,465	1,474	1,483	1,492	1,501	1,510	1,519	1,528	1,537	1,546	1,556
Patients on filgotinib	0	1	4	7	11	15	19	23	23	23	23	23
% penetration	0.0%	0.1%	0.3%	0.5%	0.8%	1.0%	1.3%	1.5%	1.5%	1.5%	1.5%	1.5%
Severe RA												
% Patients	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%	25%
Total Severe RA Patients	728	733	737	741	746	750	755	759	764	769	773	778
Patients on filgotinib	0	2	7	15	22	26	28	30	32	35	37	39
% penetration	0.0%	0.3%	1.0%	2.0%	3.0%	3.5%	3.8%	4.0%	4.3%	4.5%	4.8%	5.0%
Total Patients on filgotinib	0	3	11	22	34	41	47	53	55	58	60	62
Price Per Patient/month (\$)		2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125	2,125
price increase/decrease				0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Duration of therapy (# of months)		1.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0
Compliance		85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Price Per Patient/Year (\$)		1,806	19,869	19,869	19,869	19,869	19,869	19,869	19,869	19,869	19,869	19,869
filgotinib EU RA Sales (\$mn) - Probability Adjusted		\$6.0	\$219.7	\$442.0	\$666.9	\$820.0	\$937.4	\$1,056.2	\$1,100.5	\$1,145.3	\$1,190.6	\$1,236.4
% Growth				101.2%	50.9%	23.0%	14.3%	12.7%	4.2%	4.1%	4.0%	3.8%
filgotinib EU RA Sales (€mn)	€0.0	€5.2	€192.7	€387.7	€585.0	€719.3	€822.3	€926.5	€965.4	€1,004.6	€1,044.4	€1,084.5
% Growth				101.2%	50.9%	23.0%	14.3%	12.7%	4.2%	4.1%	4.0%	3.8%
Operating margin		85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%	85.0%
Profit Split (%)		50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%	50.0%
Profits paid to Galapagos		€2	€82	€ 165	€ 249	€ 306	€ 349	€ 394	€ 410	€ 427	€ 444	€ 461

Source: Instinet estimates

# **ACR/ARP Abstracts**

GLPG will present new data on filgotinib in rheumatoid arthritis (RA) and psoriatic arthritis at ACR/ARP on Nov. 8-13.

#### **RA Abstracts**

- A Subgroup Analysis of the Efficacy of Filgotinib in Demographic and Clinical Subgroups of Patients with Refractory Rheumatoid Arthritis
  - -Poster, #504, Sunday, Nov. 10; 9:00am
- A Subgroup Analysis of Clinical Efficacy Response and Quality of Life Outcomes from Phase 3 Study of Filgotinib in Patients with Inadequate Response to Biologic DMARDs
  - -Poster, #517, Sunday, Nov. 10; 9:00am
- Effects of Filgotinib on Anemia, Thrombocytopenia and Leukopenia: Results from a Phase 3 Study in Patients with Active Rheumatoid Arthritis and Prior Inadequate Response or Intolerance to Biologic DMARDs
  - -Oral, #2875, Wednesday, Nov. 13; 9:00am
- Pooled Safety Analyses from Phase 3 Studies of Filgotinib in Patients with Rheumatoid Arthritis
  - -Poster, #1329, Monday, Nov. 11; 9:00am
- Rheumatoid Arthritis Treatment with Filgotinib: Week 156 Safety and Efficacy Data from a Phase 2b Open-Label Extension Study
  - -Poster, #550, Sunday, Nov. 10; 9:00am
- bDMARD-Experienced Filgotinib-Treated Patient Samples Exhibit a Partial Reversion to the Peripheral Molecular Profile of a Demographically Matched Healthy Population
  - -Poster, #45, Sunday, Nov. 10; 9:00am
- Key Inflammatory Biomarkers at Baseline are Associated with Filgotinib Response at Week 12 in Rheumatoid Arthritis Patients with Inadequate Response or Intolerance to Biologic DMARDs
  - -Poster, #46, Sunday, Nov. 10; 9:00am
- A Composite IFN-Based Signature is Associated with a Filgotinib-Specific Clinical Response in bDMARD-Experienced Rheumatoid Arthritis Patients
  - -Poster, #2012, Tuesday, Nov. 12; 9:00am
- bDMARD-Experienced Filgotinib-Treated Patient Samples Exhibit a Partial Reversion to the Peripheral Molecular Profile of a Demographically Matched Healthy Population
- -Poster, #45, Sunday, Nov. 10; 9:00am
- Key Inflammatory Biomarkers at Baseline are Associated with Filgotinib Response at Week 12 in Rheumatoid Arthritis Patients with Inadequate Response or Intolerance to Biologic DMARDs
- -Poster, #46, Sunday, Nov. 10; 9:00am
- A Composite IFN-Based Signature is Associated with a Filgotinib-Specific Clinical Response in bDMARD-Experienced Rheumatoid Arthritis Patients
  - -Poster, #2012, Tuesday, Nov. 12; 9:00am
- Treatment Patterns and Persistency Following First Biologic DMARD in Patients with Rheumatoid Arthritis: Real-World Analysis of 2012-2016 U.S. Medicare data
  - -Oral, #953, Sunday, Nov. 10; 4:30pm
- Real-World Evidence: Clinical and Economic Burden of Anemia, Venous Thromboembolism, and Malignancy Among Rheumatoid Arthritis Patients Switching from First Biologic DMARD to Another Treatment in the U.S.
  - -Poster, #204, Sunday, Nov. 10; 9:00am

• Real-World Evidence: Infections Among Rheumatoid Arthritis Patients Switching from First Biologic DMARD to Another Treatment in the U.S.

-Poster, #1374, Monday, Nov. 11; 9:00am

## **Psoriatic Arthritis**

Long-Term Safety of Filgotinib in Patients with Psoriatic Arthritis, Week 52 Safety
 Data from a Phase 2 Open-Label Extension Study

-Poster, #1534, Monday, Nov. 11; 9:00am

# **Financial Models**

Fig. 13: Income Statement

(€1000s, except per share data) [FY - Dec]	2018	1Q19A	2Q19A	3Q19A	4Q19E	2019E	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E	2023E
US Filgotinib Royalties (RA)	0	0	0	0	0	0	0	0	2,850	6,649	9,499	83,377	159,940	212,302
EU Filgotinib Profits (RA)	0	0 0	0 0	0 0	0	0	0 0	0 0	0 0	1,998 0	1,998	81,893	164,768	248,635
US Filgotinib Royalties (UC)	0	0	0	0	0	0	0	0	0	0	0	18,142	63,004	88,490
EU Filgotinib Profits (UC)	0	0	0	0 0	0	0	0	0	0	0	0	0	39,410	96,826
US Filgotinib Royalties (Crohn's)	0	0	0	0	0	0	0	0	0	0	0	10,698	58,634	97,287
EU Filgotinib Profits (Crohn's)	0	0	0	0	0	0	0	0	0	0	0	0	65,131	109,203
US Filgotinib Royalties (PsA)	0	0	0	0	0	0	0	0	0	0	0	0	19,423	70,899
EU Filgotinib Profits (PsA)	0	0	0	0	0	0	0	0	0	0	0	0	0	35,578
Total Filgotinib Royalties/Profit Share	0	0	0	0	0	0	0	0	2,850	8,647	11,497	194,109	570,310	959,220
GLPG1690 (IPF) Royalties	0	0	0	0	0	0	0	0	0	0	0	0	34,061	93,142
GLPG1690 (IPF) EU profits	0	0	0	0	0	0	0	0	0	0	0	0	0	41,292
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R&D revenue	288,836	33,047	58,738	633,934	163,375	889,094	153,500	153,500	153,500	153,500	614,000	395,000	720,000	395,000
Other Income	29,009	7,872	8,852	10,020	8,517	35,261	8,091	8,900	9,790	10,280	37,062	37,247	37,433	37,620
Total Revenues	317,845	40,919	67,590	643,954	171,892	924,355	161,591	162,400	166,140	172,427	662,559	626,356	1,361,804	1,526,275
Costs & Expenses:														
Cost of Goods Sold	0	0	0	0	0	0	0	0	0	0	0	19,411	48,350	73,665
R&D	322,876	83,195	94,372	120,680	126,714	424,961	126,714	136,218	149,839	161,077	573,848	545,156	586,042	615,344
G&A	35,631	10,966	13,711	28,565	36,135	89,377	36,135	38,845	42,729	47,002	164,711	191,345	216,816	239,192
Sales and Marketing	4,147	0	3,875	4,078	0	7,953	10,195	15,293	26,762	40,143	92,392	0	0	0
Belenux Region revenues	0	0	0	0	0	0	0	0	0	444	444	16,379	53,862	98,049
Total Operating Expenses	362,653	94,161	111,958	153,323	162,849	522,291	173,044	190,355	219,330	248,666	831,395	772,290	905,070	1,026,250
Operating Income	(44,808)	(53,242)	(44,368)	490,631	9,043	402,064	(11,453)	(27,955)	(53,190)	(76,239)	(168,837)	(145,934)	456,734	500,025
Financial Income	18,335	4,655	(1,349)	34,755	1,452	39,513	7,882	7,452	6,879	6,449	28,662	25,469	22,529	22,096
Financial Expense	(2,736)		(1,472)	(38,631)	(8,050)	(48,153)	(6,794)	(9,100)	(8,400)	(8,050)	(32,344)	(24,258)	(18,194)	(13,645)
Other Income (Expense)	0			(142,349)		(142,349)					0	0	0	0
Pretax Income (Loss)	(29,209)	(48,588)	(47,189)	344,406	2,445	251,075	(10,364)	(29,602)	(54,712)	(77,840)	(172,518)	(144,722)	461,069	508,475
Income tax expense (Benefit)	50	68	61	(16,828)	0	(16,699)	0	0	0	0	0	0	0	0
Net Income (Loss) as reported GAAP	(29,259)	(48,656)	(47,250)	361,234	2,445	267,774	(10,364)	(29,602)	(54,712)	(77,840)	(172,518)	(144,722)	461,069	508,475
Basic Earnings Per Share as reported	(€ 0.56)	(€0.89)	(€ 0.86)	€6.26	€0.04	€4.76	(€0.18)	(€ 0.51)	(€0.93)	(€1.32)	(€2.94)	(€2.46)	€7.72	€8.39
Diluted Earnings Per Share GAAP	(€0.56)	(€0.89)	(€0.86)	€6.03	€0.04	€4.63	(€0.18)	(€0.51)	(€0.93)	(€1.32)	(€2.94)	(€2.46)	€7.62	€8.32
Basic Shares Outstanding (th)	52,125	54,615	54,888	57,705	57,994	56,300	58,284	58,575	58,868	59,162	58,722	58,840	59,722	60,618
Diluted Shares Outstanding (th)	54,397	56,117	56,260	59,906	59,154	57,859	59,304	59,454	59,604	59,754	59,529	59,880	60,480	61,084

Source: Company data, Instinet estimates

Fig. 14: Cash Flow

(€1000s, except per share data) [FY - Dec]	2018	2019E	2020E	2021E	2022E	2023E
CASH FLOWS FROM OPERATING ACTIVITIES						
Net Income (Loss)	(29,259)	267,774	(172,518)	(144,722)	461,069	508,475
Adjustments						
Tax income/expenses	(8)	0	0	0	0	0
Other net financial income	3,495	0	0	0	0	0
Depreciation and amortization	0	5,784	7,586	9,749	12,386	15,632
Net realized loss for foreign exchange transaction	16,696	0	0	0	0	0
Stock based compensation	0	31,337	58,198	54,060	63,355	71,838
Change in assets and liabilities:						
Increase/decrease in provisions	0	0	0	0	0	0
Increase pension liabilities	0	0	0	0	0	0
Inventories	0	(13,865)	(19,263)	1,810	(36,772)	(8,224)
Account receivables	0	(166,262)	52,359	7,241	(113,044)	9,374
Prepaid expenses & other assets	0	(37,974)	(3,474)	(12,944)	(73,545)	21,710
Accounts payable and accrued expenses	0	10,982	47,293	(9,043)	20,315	18,541
Interest paid	0	0	0	0	0	0
Interest received	0	0	0	0	0	0
Income taxes paid/received	0	0	0	0	0	0
Deferred revenues & other	(133,390)	3,261,024	(592,500)	(474,000)	(395,000)	(395,000)
Net cash provided by (used in) operating activities	(142,466)	3,358,800	(622,320)	(567,850)	(61,236)	242,346
	(0.005)	(4.450)				
Purchase of and expenditure of intangible fixed assets	(3,325)	(4,156)	0	0	0	0
Proceeds from disposal of PPE  CASH FLOWS FROM FINANCING ACTIVITIES	1	0	0	U	0	U
Proceeds from issuance of shares, net cost	280,224	1,100,000	0	0	0	0
Exercise of options	7.657	1,100,000	0	0	0	0
Repayment obligations under finance and other debt	(5)	0	0	0	0	0
Repurchase of common stock	(5)	0	0	0	0	0
Other	0	0	0	0	0	0
Net cash provided by financing activities	287,876	1,100,000	0	0	0	0
Net increase in cash and cash equivalents	139,585	4,441,654	(638,557)	(588,146)	(86,608)	210,632
Cash and cash equivalents at beginning of period	1,151,211	1,290,796	5,732,449	5,093,892	4,505,746	4,419,138
Cash and cash equivalents at end of period	1,290,796	5,732,449	5,093,892	4,505,746	4,419,138	4,629,770

Source: Company data, Instinet estimates

Fig. 15: Balance Sheet

(€1000s, except per share data) [FY - Dec]	2018	2019E	2020E	2021E	2022E	2023E
ASSETS						
Current assets:						
Cash and cash equivalents	1,290,796	5,732,449	5,093,892	4,505,746	4,419,138	4,629,770
Current R&D incentives receivables	11,203	11,203	11,203	11,203	11,203	11,203
Trade & other receivables	18,609	184,871	132,512	125,271	238,316	228,941
Inventory	0	13,865	33,128	31,318	68,090	76,314
Prepaid expenses and other current assets	8,244	46,218	49,692	62,636	136,180	114,471
Total current assets	1,328,851	5,988,606	5,320,427	4,736,173	4,872,927	5,060,699
Property and equipment, net	23,137	30,343	38,995	49,543	62,528	78,610
Intangible assets	3,632	7,788	7,788	7,788	7,788	7,788
Deferred tax assets/receivables	2,514	2,514	2,514	2,514	2,514	2,514
Non-current R&D incentives receivables	73,443	73,443	73,443	73,443	73,443	73,443
Non-current restricted cash	0	0	0	0	0	0
Other non-current assets	7,919	7,919	7,919	7,919	7,919	7,919
Total assets	1,439,496	6,110,613	5,451,085	4,877,380	5,027,119	5,230,973
LIABILITIES AND STOCKHOLDER'S EQUITY						
Current liabilities:						
Trade and other payables	68,928	78,344	124,709	115,843	135,760	153,938
Current obligations under finance lease	0	0	0	0	0	0
Current tax payable	1,175	1,175	1,175	1,175	1,175	1,175
Accrued charges	0	1,567	2,494	2,317	2,715	3,079
Deferred income	149,801	513,500	395,000	395,000	395,000	395,000
Other current liabilities	0	0	0	0	0	0
Total current liabilities	219,905	594,586	523,379	514,336	534,651	553,192
	_	_	_	_	_	_
Long term debt	0	0	0	0	0	0
Deferred Revenue	0	2,897,325	2,423,325	1,949,325	1,554,325	1,159,325
Provisions	0	0	0	0	0 704	0 704
Pension liabilities	3,764	3,764	3,764	3,764	3,764	3,764
Other liabilities Total liabilities	1,578 <b>225,247</b>	1,578 <b>3,497,253</b>	1,578 <b>2,952,046</b>	1,578 <b>2,469,003</b>	1,578 <b>2,094,318</b>	1,578 <b>1,717,859</b>
Total habilities	225,241	3,497,253	2,952,046	2,469,003	2,094,316	1,717,009
Stockholders' equity:						
Common Stock	236,540	236,540	236,540	236,540	236,540	236,540
Additional paid in capital (share premium account)	1,277,780	2,377,780	2,377,780	2,377,780	2,377,780	2,377,780
Other reserves	(735)	(735)	(735)	(735)	(735)	(735)
Translation differences	(1,557)	(1,557)	(1,557)	(1,557)	(1,557)	(1,557)
Accumulated Deficit	(297,779)	1,332	(112,989)	(203,651)	320,773	901,086
Total stockholders' equity	1,214,249	2,613,360	2,499,039	2,408,377	2,932,801	3,513,114
Total liabilities and stockholders' equity	1,439,496	6,110,613	5,451,085	4,877,380	5,027,119	5,230,973

Source: Company data, Instinet estimates

# **Appendix A-1**

# **Analyst Certification**

I, Christopher Marai, hereby certify (1) that the views expressed in this Research report accurately reflect my personal views about any or all of the subject securities or issuers referred to in this Research report, (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this Research report and (3) no part of my compensation is tied to any specific investment banking transactions performed by Nomura Securities International, Inc., Nomura International plc or any other Nomura Group company.

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#### **Materially mentioned issuers**

Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Galapagos NV	GLPG US	USD 182.93	04-Nov-2019	Buy	Not rated	A4,A5,A6

- A4 The Nomura Group has had an investment banking services client relationship with the subject company during the past 12 months.
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#### Galapagos NV (GLPG US) USD 182.93 (04-Nov-2019) Buy (Sector rating: Not rated) Rating and target price chart (three year history) 05-Nov-2016 to 04-Nov-2019 Date Rating Target price Closing price 26-Jul-19 209.00 180.25 30-Oct-18 140 00 99 55 200 00 10-Aug-17 124.00 81.06 22-Jun-17 108.00 78.56 175.00 17-Apr-17 121.00 92.40 01-Mar-17 71.78 150.00 01-Mar-17 87.00 71.78 125.00 100.00 75 00 50.00 25.00 0.00 Jul-17 Oct-17 Jan-18 Apr-18 Jul-18 Oct-18 Jan-19 Apr-19 Jul-19 Oct-19 — GALAPAGOS NV 🛕 Target Price Change 🌘 Recommendation Changes Source: Thomson Reuters, Nomura research For explanation of ratings refer to the stock rating keys located after chart(s)

**Valuation Methodology** Our target price of \$209 for Galapagos NV (GLPG) is based on an SOTP analysis, applying a 16x royalty multiple on peak filgotinib U.S. royalties and 6x multiple on peak filgotinib EU profits in 2025E (in RA, PsA, UC, and Crohn's). We estimate filgotinib peak sales of \$6bn in 2025. For filgotinib in RA, we apply a 15% discount rate, reflecting a lower development risk with the FINCH readouts, and as the target, JAK, is already validated by an approved drug in RA. For filgotinib in UC and Crohn's, we apply a 25% discount rate, reflecting a slightly higher risk for these indications and clinical stage. For filgotinib in PsA, we apply a 40% discount rate, reflecting the P2 clinical stage. For the IPF program, we use an 8x multiple, reflecting a higher value for the higher-margin orphan program and a 40% 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: 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 sales in a saturated

market. Competitive risk: A superior oral agent achieves POC or enters market. If Upadacitinib gets approved without black-box label, it could take lion's share of the market. Competing IPF pipeline agents may achieve a speedier path to approval. 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. Enrollment of patients in studies might take longer than anticipated. Safety signals compromising the compound's therapeutic profile may result in black-box label or discontinuation. Investors should take note of the risk of volatility inherent in the price of Biotech stocks.

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