

## Equity Research

April 9, 2018

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## Biotechnology

### Galapagos N.V.

#### Next-Gen JAK Inhibitors Continue to Differentiate

Monday, before Mkt-Open, AbbVie (ABBV, Not Rated) announced positive results from their Phase 3 Rheumatoid Arthritis study evaluating their JAK inhibitor, upadacitinib, in patients with an inadequate response to methotrexate. The data showed a significant efficacy advantage to adalimumab, and appears competitive to the 1<sup>st</sup> generation JAK inhibitor, tofacitinib. Overall, we think the balanced safety and efficacy profile sets a good precedent for the next generation of JAK inhibitors in autoimmune disorders, including Galapagos' filgotinib. The results today leave us optimistic for the next readout from Galapagos' pivotal FINCH RA program in 2H2018. **We reiterate out Buy rating and \$118 Price Target.**

**GLPG** **\$94.88**

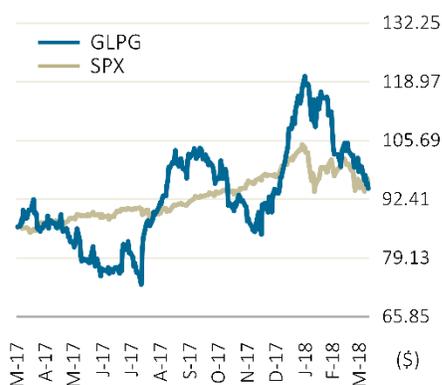
12 month target \$118.00

### BUY

52 week range \$73.17 - \$120.23

Market Cap (m) \$4,826

#### Price Performance



Source: IDC

- ▶ **The efficacy profile of upadacitinib appears competitive to tofacitinib's:** Upadacitinib's efficacy appears similar to what was reported for tofacitinib in the Phase 3 ORAL Scan study evaluating a somewhat comparable patient population of ~80% biologically naive patients and ~20% experienced patients, including TNF- $\alpha$ . We do note, however, an efficacy advantage of upadacitinib vs tofacitinib on higher-level response criteria including ACR70 (20% vs 14%) and clinical remission (23% vs 14%) when benchmarked to the placebo group.
- ▶ **The safety data for upadacitinib is limited but seems generally undifferentiated from tofacitinib on infection rates:** Upadacitinib does not appear to have an advantage to tofacitinib on rate of serious infections (1.0% vs 0.6%) when benchmarked to placebo, but with the limited data set, definitive conclusions cannot be made. The rate of DVTs/PEs, that has been a point of contention, was low and generally in line with placebo (0.3% vs 0.15%), and this is encouraging.
- ▶ **Next Readout from Galapagos's RA Program Expected in 2H2018:** Filgotinib showed positive efficacy results in RA (in the Phase 2 DARWIN Studies), and a competitive safety profile, and we expect data from the ongoing Phase 3 Study (FINCH 2) in patients with an inadequate response to biologics in 2H2018. A comparable study in methotrexate inadequate responders (FINCH 1) will also complete enrollment in 2Q2018, and data will likely be forthcoming during 2019.
- ▶ **Valuation:** Our \$118PT values GLPG at ~4x EV/ 2022E Sales.

## Estimates

	1Q17 A	2Q17 A	3Q17 A	4Q17 A	FY17 A	1Q18 E	2Q18 E	3Q18 E	4Q18 E	FY18 E	FY19 E
Sales	40	33	33	50	156	39	39	39	39	154	154
EBITDA (Adj.)	(7)	(21)	(29)	(26)	(82)	(37)	(46)	(48)	(53)	(185)	(251)
Diluted EPS (Adj.)	(0.28)	(0.71)	(0.78)	(0.57)	(2.34)	(0.79)	(0.87)	(0.92)	(1.02)	(3.59)	(4.78)

Source: BTIG Estimates and Company Documents (\$ in millions, except per share amount)

Please Read: Important disclosures and analyst's certification appear in Appendix

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**Figure 1. Comparison of Upadacitinib and Tofacitinib's Efficacy in Methotrexate Inadequate RA Patients**

Drug (Dosing)	Upadacitinib (15mg BID)	Tofacitinib (10 mg BID)
Response at 12 weeks ( $\Delta$ of Treatment vs Placebo)	SELECT-COMPARE	ORAL Scan
ACR20	35%	40%
ACR50	30%	29%
ACR70	20%	14%
Clinical Remission (DAS28)	23%*	14%**

\*DAS28 based on CRP, \*\*DAS28 based on ESR

Source: Company Report, Xeljanz Label

**The safety data for upadacitinib is limited but seems generally undifferentiated from tofacitinib on infection rates:** Upadacitinib does not appear to have an advantage to tofacitinib on rate of serious infections (1.0% vs 0.6%) when benchmarked to placebo, but with the limited data set, definitive conclusions cannot be made. The rate of DVTs/PEs, that has been a point of contention, was low and generally in line with placebo (0.3% vs 0.15%), and this is encouraging.

**Figure 2. Comparison of Upadacitinib and Tofacitinib's Safety in Methotrexate Inadequate RA Patients**

Drug (Dosing)	Upadacitinib (15mg BID)*	Tofacitinib (10 mg BID)**
AEs ( $\Delta$ of Treatment vs Placebo)	SELECT-COMPARE	ORAL Scan
SAEs	0.8%	0.1%
Serious Infections	1.0%	0.6%
MACE	-0.5%	-
DVT	0.2%	-
PE	0.0%	-
Discontinuations	-	1.3%

Source: Company Report, Xeljanz Label

**Next Readout from Galapagos’s RA Program Expected in 2H2018:** Filgotinib showed positive efficacy results in RA (in the Phase 2 DARWIN Studies), and a competitive safety profile, and we expect data from the ongoing Phase 3 Study (FINCH 2) in patients with an inadequate response to biologics in 2H2018. A comparable study in methotrexate inadequate responders (FINCH 1) will also complete enrollment in 2Q2018, and data will likely be forthcoming during 2019.

**Figure 3. Comparison of the Safety Profile of 1<sup>st</sup> and 2<sup>nd</sup> Gen JAK Inhibitors**

Drug (Dosing) Event Per 100 PYE	Filgotinib (200mg QD)	Upadacitinib (6 and 12 mg BID)	Tofacitinib (5 mg BID)	Baracitinib (2mg and 4mg QD)
Patient Year Exposure	1708	725	5891	6637
Serious Infection	1.5	2.3	2.2	2.9
Herpes Zoster	1.2	3.7	3.6	3.2
DVT or PEs/100 PY	0.1	0.7	0.2	0.5

Source: Company Report

## Income Statement

Galapagos, Inc. Income Statement		Mar-17	Jun-17	Sep-17	Dec-17		Mar-18	Jun-18	Sep-18	Dec-18		Mar-19	Jun-19	Sep-19	Dec-19		2019E	2020E	2021E	2022E
EUR € mm		2016	1Q17	2Q17	3Q17	4Q17	2017	1Q18E	2Q18E	3Q18E	4Q18E	2018E	1Q19E	2Q19E	3Q19E	4Q19E	2019E	2020E	2021E	2022E
<b>Total Revenue</b>		<b>152</b>	<b>40</b>	<b>33</b>	<b>33</b>	<b>50</b>	<b>156</b>	<b>39</b>	<b>39</b>	<b>39</b>	<b>39</b>	<b>154</b>	<b>39</b>	<b>39</b>	<b>39</b>	<b>39</b>	<b>154</b>	<b>194</b>	<b>457</b>	<b>886</b>
Product Revenues								0	0	0	0	0	0	0	0	0	0	40	303	732
Reimbursement Revenues		130	34	27	27	39	127	33	33	33	33	130	33	33	33	33	130	130	130	130
Other Income		22	6	6	6	10	29	6	6	6	6	24	6	6	6	6	24	24	24	24
Cost of Goods Sold		0.00	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	-2.00	-15.16	-36.59
<b>Gross Profit</b>		<b>152</b>	<b>40</b>	<b>33</b>	<b>33</b>	<b>50</b>	<b>156</b>	<b>39</b>	<b>39</b>	<b>39</b>	<b>39</b>	<b>154</b>	<b>39</b>	<b>39</b>	<b>39</b>	<b>39</b>	<b>154</b>	<b>192</b>	<b>442</b>	<b>849</b>
Gross Margin %								100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	99%	97%	96%
<b>Operating Expenses</b>		<b>-163.1</b>	<b>-51</b>	<b>-55</b>	<b>-63</b>	<b>-77</b>	<b>-246</b>	<b>-80</b>	<b>-84</b>	<b>-87</b>	<b>-92</b>	<b>-343</b>	<b>-96</b>	<b>-99</b>	<b>-102</b>	<b>-108</b>	<b>-405</b>	<b>-537</b>	<b>-815</b>	<b>-723</b>
Research and Development		-140	-45	-48	-56	-69	-219	-73	-76	-79	-83	-311	-87	-90	-93	-98	-368	-410	-485	-512
Research and Development % of Sales		138%	1.127	145%	169%	140%	142%	189%	198%	205%	216%	202%	227%	234%	242%	255%	239%	1025%	160%	70%
General and administrative expenses		-22	-6	-6	-6	-7	-24	-6	-6	-6	-7	-25	-6	-7	-6	-7	-26	-26	-27	-28
G & A % of Sales		22%	0.141	19%	18%	13%	16%	15%	17%	16%	18%	16%	15%	17%	16%	18%	17%	14%	6%	3%
Sales and marketing expenses		-2	-1	-1	-1	-1	-3	-2	-2	-2	-2	-7	-3	-3	-3	-3	-11	-100	-303	-183
Sales and marketing % of Sales		2%	0.014	2%	2%	2%	2%	4%	4%	5%	5%	4%	7%	7%	7%	8%	7%	250%	100%	25%
<b>Operating Profit</b>		<b>-11</b>	<b>-11</b>	<b>-22</b>	<b>-30</b>	<b>-27</b>	<b>-90</b>	<b>-42</b>	<b>-46</b>	<b>-48</b>	<b>-53</b>	<b>-189</b>	<b>-57</b>	<b>-61</b>	<b>-63</b>	<b>-69</b>	<b>-251</b>	<b>-345</b>	<b>-373</b>	<b>126</b>
Operating Profit Margin %		-8%	-28%	-65%	-89%	-55%	-58%	-108%	-119%	-125%	-139%	-123%	-149%	-158%	-165%	-181%	-163%	-178%	-82%	14%
Fair value re-measurement of Share Sub Agreement		57	0	0	0	0	0													
Other financial income		10	1	1	1	1	5													
Other financial expenses		-2	-3	-15	-8	-4	-31					0.00					0.00	0.00	0.00	0.00
<b>Pretax Income</b>		<b>54</b>	<b>-14</b>	<b>-36</b>	<b>-37</b>	<b>-30</b>	<b>-116</b>	<b>-42</b>	<b>-46</b>	<b>-48</b>	<b>-53</b>	<b>-189</b>	<b>-57</b>	<b>-61</b>	<b>-63</b>	<b>-69</b>	<b>-251</b>	<b>-345</b>	<b>-373</b>	<b>126</b>
Income Tax Provision		0	0.0	-0.1	-0.1	0.0	0													
Tax Rate		1%	0%	0%	-0.2%	-0.1%	-1%													
<b>Net Income</b>		<b>54</b>	<b>-14</b>	<b>-36</b>	<b>-37</b>	<b>-30</b>	<b>-116</b>	<b>-42</b>	<b>-46</b>	<b>-48</b>	<b>-53</b>	<b>-189</b>	<b>-57</b>	<b>-61</b>	<b>-63</b>	<b>-69</b>	<b>-251</b>	<b>-345</b>	<b>-373</b>	<b>126</b>
<b>Basic Shares Outstanding</b>		<b>45.06</b>	<b>46.26</b>	<b>48.04</b>	<b>45.53</b>	<b>58.09</b>	<b>49.48</b>	<b>52.55</b>												
<b>Diluted Shares Outstanding</b>		<b>46.43</b>	<b>48.33</b>	<b>49.99</b>	<b>47.05</b>	<b>52.55</b>	<b>49.48</b>	<b>52.55</b>												
<b>Basic EPS</b>			-0.29	-0.74	-0.80	-0.51	-2.34	-0.79	-0.87	-0.92	-1.02	-3.59	-1.09	-1.16	-1.21	-1.32	-4.78	-6.56	-7.10	2.41
<b>Diluted EPS</b>			-0.28	-0.71	-0.78	-0.57	-2.34	-0.79	-0.87	-0.92	-1.02	-3.59	-1.09	-1.16	-1.21	-1.32	-4.78	-6.56	-7.10	2.41
Diluted EPS Growth % YoY																				

Source: Company Report, Bloomberg, FactSet, BTIG Research Estimates, April 2018

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## BTIG Covered Companies Mentioned in this Report

GALAPAGOS N.V. (GLPG, Buy, \$118.00 PT; Current Price: \$94.88; Analyst: Dane.Leone)

## Appendix: Analyst Certification and Other Important Disclosures

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#### Galapagos N.V. (GLPG, Buy, \$118.00 PT)

**Valuation:** Our \$118PT values GLPG at ~4x EV/ 2022E Sales.

**Risks:** Our Buy rating and \$118 price target may prove inaccurate due to a number of risks related to Galapagos (GLPG) being an unprofitable early stage company with limited clinical data across the Cystic Fibrosis, Rheumatoid Arthritis, and Inflammatory Bowel Disease Portfolios.

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