

## Unprecedented PSA data supports competitive profile in RA

European Life Sciences

31 May 2018, 08:40

**Galapagos reported unprecedented efficacy with filgotinib in psoriatic arthritis (PSA) and confirmed its clean safety profile which should demand the leading role in the treatment paradigm ahead of biologics. The results also surpassed efficacy of tofacitinib in PSA by a wide margin, thus in our view, supporting filgotinib's competitive profile in RA and giving comfort for FINCH 1/2/3 readouts. Filgotinib also moved to the phase III trial in UC, and while futility criteria were said not to be challenging, a difference in endoscopic response would suggest an objective benefit in this indication. We move PSA to phase III and add €3 to our PT bringing it to €115 (\$135 for ADR).**

### Best efficacy ever seen in PSA

The phase II EQUATOR trial met the primary endpoint, showing a highly stat sig difference across ACR scores: ACR20 80% with 200mg QD filgotinib vs. 33% (p<0.001), ARC50 48% vs. 15% and ACR70 23% vs. 6%, surpassing efficacy of biologic and oral therapies by a wide margin on placebo-adj scores (see Fig. 1). Such efficacy, once confirmed in the phase III trial, combined with a clean safety and the convenience of oral administration should demand a leading market share in the first-line therapy for PSA ahead of TNFs and Otezla.

### Safety in line with RA dataset

There were only 1 serious infection and 1 herpes case and no DVT/PE or malignancies reported with filgotinib, which appears to be at par with the RA dataset and tofa's data in PSA. There was one death following pneumonia in the filgotinib arm which we don't see as a reason to worry as the recent AdCom in RA and PSA showed that rheumatologists are not significantly concerned with infections and herpes associated with JAKs and have already adopted risk mitigation protocols.

### Superior data in PSA gives credence to competitive profile in RA

As we wrote in our last note, there is a significant overlap in PSA and RA pathogenesis that allows for a rather straightforward readthrough across indications. While remission rates are higher in PSA vs. RA (Saber et al., 2010) filgotinib's outstanding efficacy data in PSA, miles ahead of that of tofa, in our view supports the expectation of competitive efficacy levels in the upcoming phase III FINCH 1/2/3 trial readouts in RA.

### UC also moves ahead

The partners also announced that following the interim futility analysis in 350 patients (~1/4 of trial) the DMC recommended advancing to the phase III part, triggering a \$15m milestone. While Galapagos previously commented that the bar for futility analysis is to show some differentiation over placebo, Gilead also mentioned in its Q1 call that the analysis is conducted on an endoscopic response, not on a bit more subjective Mayo Clinic Score, suggesting an objective efficacy benefit with filgotinib. We expect to see full result from the induction part of the trial in H2'19.

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Rating	BUY
Price Target	€115.00
Closing price (30 May 2018)	€85.84

#### Previous rating and Price target

Change	Revision	Old
PT	29 May 2018	€112.00

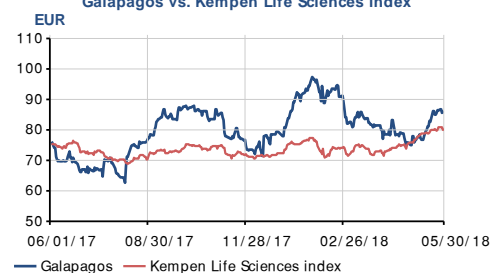
#### Company data

Market capitalization	€4,398.0m
52-week range	€61.88 - €98.82
Number of shares	51.2m
Free float	57.8%
Avg. daily volume (20d)	317,683
Avg. daily turnover (20d)	€25,912,300
Daily turnover	€16,330,310
Next announcement date	02 August 2018
Reporting Period	H1'18 results

FY 31-Dec, EUR	2018E	2019E	2020E
Total revenues	177.4	227.5	428.3
EBITDA	(129.0)	(71.8)	156.6
EBIT	-133.3	-76.1	152.3
Net profit	-133.3	-76.1	152.3
EPS	-3	-2	3.30
EV/EBITDA	nm	nm	19.4x
P/E	nm	nm	26.0x
DPS	--	--	--
Dividend yield (%)	na	na	na

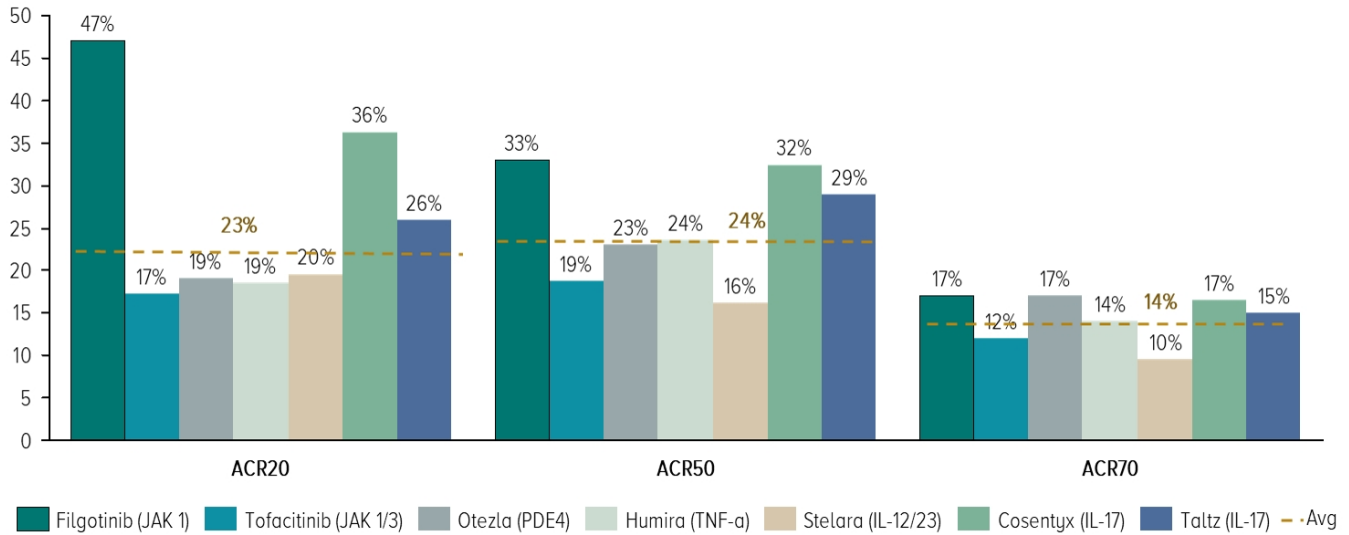
Source: Kempen estimates

Galapagos vs. Kempen Life Sciences index



Source: Bloomberg

Figure 1 - Filgotinib outperforms available therapies in biologics-naive PSA



Source: Galapagos, Tofacitinib 5mg BID at 12w, OPAL BROADEN, Mease, 2017; Otezla 30mg BID at 16w, ACTIVE, Nash, 2018; Humira 40mg q2w at 12w, OPAL BROADEN, Mease, 2017; Stelara 45mg at 24w, PSUMMIT1, McInnes, 2013; Cosentyx 300mg at 16w, FUTURE 5, Mease 2018;

# Galapagos - Company Profile

## Company description

Galapagos is a biotechnology company that carries out small molecule drug discovery in a number of therapeutic areas. The company's research and development activities are based on novel drug targets identified using Galapagos' unique proprietary target discovery technology.

## SWOT analysis

### Strength

Lead candidate with differentiated mechanism and profile, clean safety, with strong partner, in blockbuster indication

Strong proposition for combination therapy in CF

Unique, proprietary target discovery and validation capabilities

### Opportunities

Initiation and progress of new drug discovery programs against first in class targets

New partnering deals

Branching out into mAb development

### Weakness

Early-stage product pipeline focused on novel targets results in high risk drug candidates

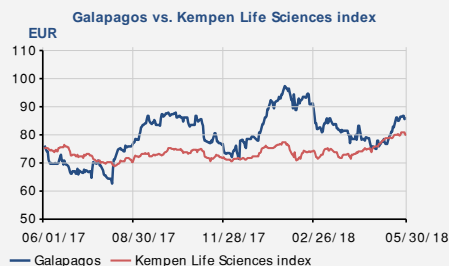
Competitor in second major indication, CF, has strong position

### Threats

Clinical failures

Litigation/Infringement

Rating	<b>BUY</b>
Price Target	€115.00
Closing price (30 May 2018)	€85.84
Date	31 May 2018, 08:40



Source: Bloomberg

## Company data

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## Major shareholders **42.2%**

Gilead	13.3%
FMR	9.7%
van Herk	8.7%
Sands Capital	3.6%
Capital Global	4.3%
Federated	2.6%

Source: Company data, AFM

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Source: Kempen estimates

<b>Income Statement (FY 31-Dec, EUR m)</b>	<b>2015A</b>	<b>2016A</b>	<b>2017A</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
<b>Total revenues</b>	<b>60.6</b>	<b>151.6</b>	<b>155.9</b>	<b>177.4</b>	<b>227.5</b>	<b>428.3</b>
COGS	0.0	0.0	0.0	0.0	0.0	-3.5
<b>Gross profit</b>	<b>60.6</b>	<b>151.6</b>	<b>155.9</b>	<b>177.4</b>	<b>227.5</b>	<b>424.8</b>
SG&A	-20.3	-23.5	-27.2	-25.8	-26.5	-39.5
R&D	-129.7	-139.6	-218.5	-285.0	-277.0	-233.0
Other operating expenses/income (net)	3.4	4.2	4.3	4.3	4.3	4.3
<b>EBITDA</b>	<b>(86.0)</b>	<b>(7.3)</b>	<b>(85.5)</b>	<b>(129.0)</b>	<b>(71.8)</b>	<b>156.6</b>
Depreciation and amortization	-2.4	-3.3	-3.6	-3.6	-3.6	-3.6
<b>EBIT</b>	<b>-89.4</b>	<b>-11.5</b>	<b>-89.8</b>	<b>-133.3</b>	<b>-76.1</b>	<b>152.3</b>
Interest expense	0.4	8.3	-25.7	0.0	0.0	0.0
Taxes	1.2	-0.2	-0.2	0.0	0.0	0.0
Other financial items	-30.6	57.5	0.0	0.0	0.0	0.0
<b>Net profit</b>	<b>-118.4</b>	<b>54.0</b>	<b>-115.7</b>	<b>-133.3</b>	<b>-76.1</b>	<b>152.3</b>
<b>Balance Sheet (FY 31-Dec, EUR m)</b>	<b>2015A</b>	<b>2016A</b>	<b>2017A</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
Cash and cash equivalents	347.2	979.8	1,151.2	954.7	819.1	913.1
Receivables	3.9	9.7	28.0	6.3	8.1	15.3
Inventories	0.3	0.3	0.3	0.7	1.0	1.7
Deferred tax assets	1.7	2.0	2.0	5.1	6.5	12.2
Financial assets and other current assets	15.5	11.2	9.9	13.2	15.9	26.9
Tangible fixed assets	13.8	15.0	16.7	12.7	11.0	10.8
Intangible fixed assets	1.6	1.0	2.5	2.5	2.5	2.5
Goodwill	--	--	--	--	--	--
Other non-current assets	58.5	64.3	75.8	75.8	75.8	75.8
<b>Total assets</b>	<b>442.5</b>	<b>1,083.3</b>	<b>1,286.3</b>	<b>1,070.9</b>	<b>939.9</b>	<b>1,058.3</b>
Payables	29.5	31.3	47.1	47.1	47.1	52.8
Other current liabilities	42.9	289.7	223.5	141.5	86.5	46.9
Provisions	2.7	3.6	3.6	3.6	3.6	3.6
Long-term liabilities	2.4	0.0	0.0	0.0	0.0	0.0
<b>Total liabilities</b>	<b>77.5</b>	<b>324.6</b>	<b>274.3</b>	<b>192.3</b>	<b>137.3</b>	<b>103.4</b>
<b>Total liabilities and shareholder's equity</b>	<b>442.5</b>	<b>1,083.3</b>	<b>1,286.3</b>	<b>1,070.9</b>	<b>939.9</b>	<b>1,058.3</b>
<b>Cash Flow Statement (FY 31-Dec, EUR m)</b>	<b>2015A</b>	<b>2016A</b>	<b>2017A</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
EBITDA	-86.0	-7.3	-85.5	-129.0	-71.8	156.6
Cash interest income/expenses	-30.2	65.7	-25.7	0.0	0.0	0.0
Cash taxes	1.2	-0.2	-0.2	0.0	0.0	0.0
Changes in provisions	-0.3	0.8	0.1	0.0	0.0	0.0
Changes in working capital	-1.3	-4.0	-2.4	21.2	-2.0	-2.2
Changes in deferred revenue (milestones)	--	--	--	--	--	--
Other cash adjustments	-271.2	-99.5	-443.5	-109.6	-57.1	-54.1
<b>Cash flow from operating activities</b>	<b>-387.8</b>	<b>-44.4</b>	<b>-557.3</b>	<b>-217.4</b>	<b>-131.0</b>	<b>100.3</b>
<b>Cash flow from investments</b>	<b>-10.0</b>	<b>5.7</b>	<b>-1.6</b>	<b>-0.7</b>	<b>-0.7</b>	<b>-0.7</b>
Proceeds from equity issues	277.3	339.7	369.0	0.0	0.0	0.0
Debt drawdowns/(repayments)	-0.0	-0.1	-0.0	0.0	0.0	0.0
<b>Cash flow from financing activities</b>	<b>277.3</b>	<b>339.6</b>	<b>369.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<b>Ratios</b>	<b>2015A</b>	<b>2016A</b>	<b>2017A</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
EV/revenues	24.5x	8.3x	14.7x	16.9x	13.8x	7.1x
EV/EBITDA	nm	nm	nm	nm	nm	19.4x
P/E	nm	41.5x	nm	nm	nm	26.0x
Net debt / EBITDA (x)	4.0x	134.3x	13.5x	7.4x	11.4x	-5.8x
<b>Metrics</b>	<b>2015A</b>	<b>2016A</b>	<b>2017A</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
Total revenue growth	nm	nm	2.8%	nm	nm	nm
COGS as % of revenue	0	0	0	0	0	0.8%
SG&A as % of revenue	-33.5%	-15.5%	-17.5%	-14.5%	-11.7%	-9.2%
R&D as % of revenue	-214.1%	-92.1%	-140.1%	-160.6%	-121.8%	-54.4%
EBITDA margin (%)	-142.0%	-4.8%	-54.8%	-72.7%	-31.6%	36.6%
EBIT margin (%)	-147.6%	-7.6%	-57.6%	-75.1%	-33.4%	35.6%
Net profit margin (%)	-195.5%	35.6%	-74.2%	-75.1%	-33.4%	35.6%
Cash as % of market cap	19.0%	43.7%	33.5%	24.1%	20.7%	23.1%

Source: Kempen estimates