Galapagos

# Two FINCHes with one filgo

European Life Sciences | 29 March 2019, 08:45

**The long-awaited FINCH 1 and FINCH 3 trials with filgotinib in RA demonstrated competitive efficacy and best-case scenario safety profile (only 1 VTE in over 2000 patients). While the high placebo rates have weighted on ACR20 scores against upadacitinib, the higher hurdles establish a competitive profile and support approvals across RA treatment lines. Taken together, the high efficacy, cleanest safety, and attainability of 2 registered dosing regimens positions filgotinib as a leading JAK, deserving market share at par with upa and significantly ahead bari and tofa. We expect more details on the data, MANTA status and filing timelines over the course of the summer, that should remove any remaining concerns regarding filgotinib potential. We reiterate our BUY and increase PT to €135/ $155 (ADR) (from €125) and Galapagos continues to feature on our Favorites list.**

## Best in class safety

Both doses were safe and well tolerated and there were no differences in herpes and serious infections rates compared to Humira or MTX as seen with other JAks (Table 1 below). There were also no imbalances in MACE or malignancies vs control and only 1 case of VTE (!!!) with 200mg vs 3 with MTX. Finally, there were 5 deaths in the trials: 1 with 100mg, 2 with 200mg and 2 with MTX - which does not look dose-depended and considering the size of the patient population and rarity of the events appears to be more of a random distribution. Finally, lab parameters were consistent with the prior findings with improvement in hemoglobin, reduction of platelets, and improvement of lipid profile. Taken together with FINCH 2, the safety looks meaningfully better than other JAKs or biologic therapies, differentiating filgo in RA and supporting the lead position in IBD.

## High placebo weighs on ACR20, but higher hurdles are competitive

The trials met primary endpoints with high stat sig and showed superiority to ada with 200mg dose on DAS28 remission in MTX-IR and superiority to MTX with 200mg/100mg on MTX background and monotherapy in MTX naive (ex. ACR20). There was a clear dose-response, which should support the approval of both doses given equal safety profiles. On absolute scores filgotinib performed at par with upadacitinib and on top of JAK class. The placebo rates were the highest seen in RA trials (almost as good as upa itself one can say) across the scores resulting in comparatively lower ACR20 scores (Fig 1/2) suggesting that at high 80s ACR20 losses sensitivity. According to the company, there was no apparent explanation for such high placebo rates, but the analysis of baseline characteristic and demographics (eg geography FINCHes had meaningful Japanese population in the trial) is ongoing. However, on more robust and clinically relevant ACR50/70 and remission filgotinib looks as efficacious especially considering a clearer separation of the scores in FINCH 2.

*(Continued on the next page)*


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| | |
|---|---|
| Rating | BUY |
| Price Target | €135.00 |
| Closing price (28 Mar 2019) | €85.06 |

**Previous rating and Price target**

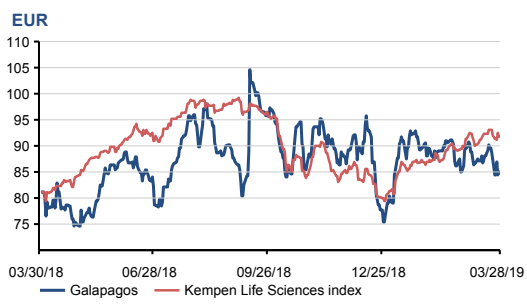
| Change | Revision | Old |
|---|---|---|
| PT | 17 Jan 2019 | €125.00 |

**Company data**

| | |
|---|---|
| Market Cap | €4,645.5m |
| 52-week range | €70.64 - €105.35 |
| Number of shares | 54.6m |
| Free float | 61.6% |
| Avg. daily volume (20d) | 461,553 |
| Avg. daily turnover (20d) | €40,400,025 |
| Daily turnover | €32,863,020 |
| Next announcement date | 25 April 2019 |
| Reporting Period | Q1'19 results |

| FY 31-Dec, EUR | 2018E | 2019E | 2020E |
|---|---|---|---|
| Total revenues | 317.8 | 224.7 | 416.3 |
| EBITDA | (44.8) | (174.8) | 26.2 |
| EBIT | -44.8 | -174.8 | 26.2 |
| Net profit | -29.3 | -174.8 | 26.2 |

Source: Kempen estimates




*DISCLOSURES AND ANALYST CERTIFICATIONS START ON PAGE 6*

**Table 1 - Filgotinib looks the safest among JAKs**

| | N | SAE (%) | Herpes (%) | Serious infections (%) | MACE | DVT/PE | Other |
|---|---|---|---|---|---|---|---|
| **FINCH 2 TNF-IR** | | | | | | | |
| Filgotinib 100mg/200mg/pcb | 153/147/148 | 4/5/3 | 2/2/0 | 0 | 1/0/1 | 0 | 1 retinal vein occlusion |
| Upadacitinib 15mg/30mg/pcb | 164/164/169 | 5/7/0 | 3/7/0 | 2/5/0 | 2/0/0 | 3/1/0 | 1 GI perforation |
| Baricitinib 2mg/4mg/pcb | 174/177/176 | 4/10/7 | 1/4/1 | 2/3/3 | 0/0/1 | NA | |
| Tofacitinib 5mg/10mg/pcb | 133/134/132 | 5/6/4.5 | NR | 3/2/0 | NR | NR | |
| **FINCH 1 MTX IR** | | | | | | | |
| Filgotinib 100mg/200mg/ada/pcb | 201/204/108 | 5/4.4/4.3/4.2 | 0.4/0.4/0.6/0.4 | 1.7/1.7/2.5/0.8 | 1/0/1/2 | 0/1/0/2 | Death: 1/2/0/2<br>Death: 0/2/2 |
| Upadacitinib 15mg/ada/pcb | 652/327/650 | 3.7/4.7/2.9 | 0.8/0.5/0.5 | 1.8/1.5/0.8 | 0/2/3 | 2/3/1 | GI perforations 2 |
| Baricitinib 4mg/ada/pcb | 487/330/488 | 5/3/5 | 7/4/2 # | 5/2/7 # | 1/0/0 | NA | |
| Tofacitinib 5mg/ pcb | 201/204/108 | 10.8/5.4/5.9 | 2/1/0 # | 7/3/1 | | 0/0/0 | |
| **FINCH 3 MTX naïve** | | | | | | | |
| Filgotinib 100mg/200mg/pcb | 207/416/210/416 | 2.4/4.1/4.8/2.9 | 0.50 | 1/1/1.4/1 | 0/2/1/2 | 0/0/0/1 | Death: 0/1/0 |
| Upadacitinib 15mg/pcb | 317/314 | 4.7/4.1 | 2.2/0.3 | 1.6/1.3 | 1/1 | 0/1 | Death: 2/1 |
| Baricitinib 4mg/4mg+MTX/pcb | 159/215/210 | 3/4/4 | 3/3/1 # | 2/4/3 # | 1/0/0 | NA | |
| Tofacitinib 5mg/pcb | 373/186 | 10.7/11.8 | 13/2 # | 11/5 # | NR | 1/2 | |

Source: # - absolute numbers vs %; Galapagos, Kempen analysis

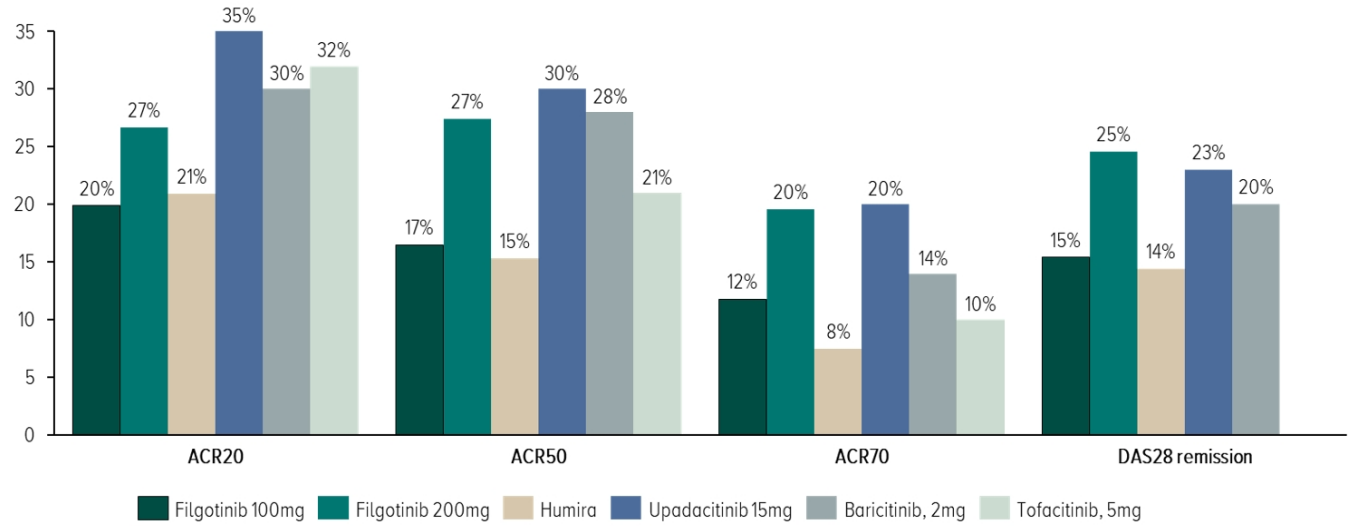
## Widening the divide in the JAK class

In all, the totality data should support the approval across the RA populations from TNF-IR to MTX-naive with the potential for monotherapy inclusion (not stat sig on ACR20, but need to see the separation of the scores over time) - thereby effectively resulting in a similar label as upa's. Admittedly, more straightforward superiority to Humira on ACR50 and remission at 12w and stat sig ACR20 for monotherapy with upa in MTX-naive will aide Abbvie's marketing machinery, but looking at combined data and absolute scores with filgo, it looks more technical than fundamental superior. On the other hand, the cleaner safety profile and potential registration of 2 different doses represent an unmatched competitive advantage for filgo. With the widening gap over tofa and upa, there is definitely sufficient room for upa and filgo to make meaningful sales in RA.

## Off to the market

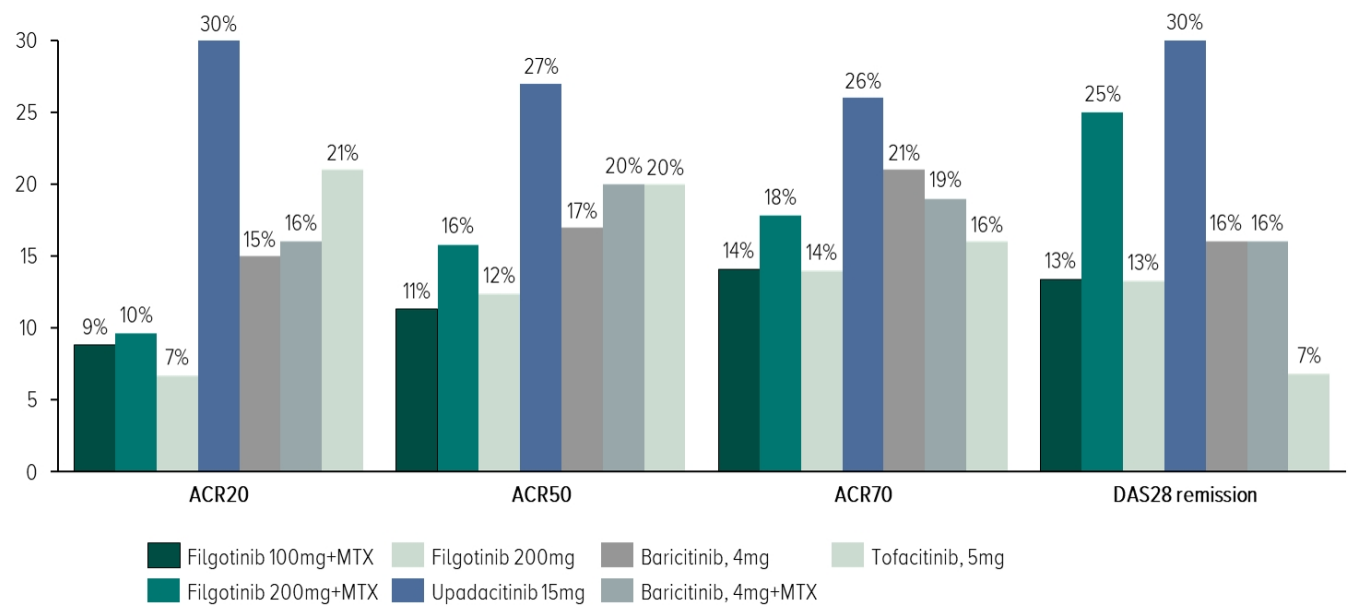
Galapagos CEO reiterated the intention to file for approval in EU, the US and Japan as soon as possible. The exact US timelines are still vague, but there should be more clarity pending the meeting with the FDA which could be disclosed as early as mid-July (75d for the meeting and 30d for back out on minutes). Meanwhile, we expect FINCHes LBAs at EULAR, 52w data from FINCHes at ACR, first filing in EU and Japan in early Q4 (discussions already ongoing) and if MANTAs recruitment matches the speed of site openings - US filing in Q4'19/Q1'20. Finally, we also expect the phase II data in CLE and Sjorjens in H2'19 that are high-risk but could further expand filgo's potential.

**Chart 1 - Placebo-adjusted ACR scores in the phase III trials with JAKs in MTX-IR (FINCH-1)**




Source: ORAL STANDARD, RA BEAM, SELECT COMPARE, 12 week data

**Chart 2 - Placebo-adjusted ACR scores in the phase III trials with JAKs in MTX-naive (FINCH-3)**




Source: ORAL START, RA BEGIN, SELECT EARLY, 24 weeks data

# 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

Filgotinib is potentially best in class JAK inhibitor with a strong partner in blockbuster indications

Broad proprietary pipeline

Unique, proprietary target discovery and validation capabilities

### Weakness

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

High competition in inflammatory indications

### Opportunities

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

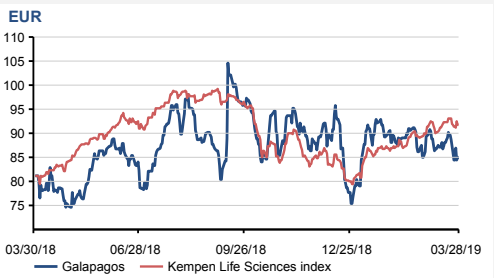
New partnering deals

### Threats

Clinical failures

Litigation/Infringement

| | |
|---|---|
| Rating | BUY |
| Price Target | €135.00 |
| Closing price (28 Mar 2019) | €85.06 |
| Date | 29 March 2019, 08:45 |




Source: Bloomberg

### Company data

| | |
|---|---|
| Bloomberg | GLPG NA |
| Market Cap | €4,645.5m |
| 52-week range | €70.64 - €105.35 |
| Number of shares | 54.6m |
| Free float | 61.6% |
| Avg. daily volume (20d) | 461,553 |
| Avg. daily turnover (20d) | €40,400,025 |
| Daily turnover | €32,863,020 |
| Next announcement date | 25 April 2019 |
| Reporting Period | Q1'19 results |

| Major shareholders | 38.4% |
|---|---|
| Gilead | 12.4% |
| van Herk | 9.4% |
| Sands Capital | 5.5% |
| Federated | 5.2% |
| Capital Research | 4.0% |
| Oppenheimer | 1.9% |

Source: Company data, AFM

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Source: Kempen estimates

| Income Statement (FY 31-Dec, EUR m) | 2015A | 2016A | 2017A | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| **Total revenues** | **60.6** | **151.6** | **155.9** | **317.8** | **224.7** | **416.3** |
| COGS | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 | -4.2 |
| **Gross profit** | **60.6** | **151.6** | **155.9** | **317.8** | **224.7** | **412.1** |
| SG&A | -20.3 | -23.5 | -27.2 | -39.8 | -26.5 | -41.9 |
| R&D | -129.7 | -139.6 | -218.5 | -322.9 | -373.0 | -344.0 |
| Other operating expenses/income (net) | 3.4 | 4.2 | 4.3 | 0.0 | 0.0 | 0.0 |
| **EBITDA** | **(86.0)** | **(7.3)** | **(85.5)** | **(44.8)** | **(174.8)** | **26.2** |
| Depreciation and amortization | -2.4 | -3.3 | -3.6 | 0.0 | 0.0 | 0.0 |
| **EBIT** | **-89.4** | **-11.5** | **-89.8** | **-44.8** | **-174.8** | **26.2** |
| Interest expense | 0.4 | 8.3 | -25.7 | 15.6 | 0.0 | 0.0 |
| Taxes | 1.2 | -0.2 | -0.2 | -0.1 | 0.0 | 0.0 |
| Other financial items | -30.6 | 57.5 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Net profit** | **-118.4** | **54.0** | **-115.7** | **-29.3** | **-174.8** | **26.2** |

| Balance Sheet (FY 31-Dec, EUR m) | 2015A | 2016A | 2017A | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| Cash and cash equivalents | 347.2 | 979.8 | 1,151.2 | 1,290.8 | 1,067.6 | 997.2 |
| Receivables | 3.9 | 9.7 | 28.0 | 18.6 | 8.0 | 14.8 |
| Inventories | 0.3 | 0.3 | 0.3 | 0.0 | 1.0 | 1.6 |
| Deferred tax assets | 1.7 | 2.0 | 2.0 | 2.5 | 6.4 | 11.9 |
| Financial assets and other current assets | 15.5 | 11.2 | 9.9 | 16.2 | 20.2 | 30.7 |
| Tangible fixed assets | 13.8 | 15.0 | 16.7 | 23.1 | 18.2 | 21.7 |
| Intangible fixed assets | 1.6 | 1.0 | 2.5 | 3.6 | 3.6 | 3.6 |
| Goodwill | -- | -- | -- | -- | -- | -- |
| Other non-current assets | 58.5 | 64.3 | 75.8 | 84.6 | 84.6 | 84.6 |
| **Total assets** | **442.5** | **1,083.3** | **1,286.3** | **1,439.5** | **1,209.7** | **1,166.3** |
| Payables | 29.5 | 31.3 | 47.1 | 68.9 | 68.9 | 51.3 |
| Other current liabilities | 42.9 | 289.7 | 223.5 | 152.6 | 97.6 | 45.6 |
| Provisions | 2.7 | 3.6 | 3.6 | 3.8 | 3.8 | 3.8 |
| Long-term liabilities | 2.4 | 0.0 | 0.0 | 0.0 | 0.0 | 0.0 |
| **Total liabilities** | **77.5** | **324.6** | **274.3** | **225.2** | **170.2** | **100.7** |
| **Total liabilities and shareholder's equity** | **442.5** | **1,083.3** | **1,286.3** | **1,439.5** | **1,209.7** | **1,166.3** |

| Cash Flow Statement (FY 31-Dec, EUR m) | 2015A | 2016A | 2017A | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| EBITDA | -86.0 | -7.3 | -85.5 | -44.8 | -174.8 | 26.2 |
| Cash interest income/expenses | -30.2 | 65.7 | -25.7 | 15.6 | 0.0 | 0.0 |
| Cash taxes | 1.2 | -0.2 | -0.2 | -0.1 | 0.0 | 0.0 |
| Changes in provisions | -0.3 | 0.8 | 0.1 | 0.1 | 0.0 | 0.0 |
| Changes in working capital | -1.3 | -4.0 | -2.4 | 31.4 | 9.6 | -25.1 |
| Changes in deferred revenue (milestones) | -- | -- | -- | -- | -- | -- |
| Other cash adjustments | -271.2 | -99.5 | -443.5 | -345.3 | -72.6 | -42.8 |
| **Cash flow from operating activities** | **-387.8** | **-44.4** | **-557.3** | **-343.0** | **-237.8** | **-41.7** |
| **Cash flow from investments** | **-10.0** | **5.7** | **-1.6** | **-5.6** | **0.0** | **0.0** |
| Proceeds from equity issues | 277.3 | 339.7 | 369.0 | 231.5 | 0.0 | 0.0 |
| Debt drawdowns/(repayments) | -0.0 | -0.1 | -0.0 | 0.0 | 0.0 | 0.0 |
| **Cash flow from financing activities** | **277.3** | **339.6** | **369.0** | **231.5** | **0.0** | **0.0** |

| Ratios | 2015A | 2016A | 2017A | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| EV/revenues | 24.5x | 8.3x | 14.7x | 8.6x | 12.7x | 7.0x |
| EV/EBITDA | nm | nm | nm | nm | nm | 111.7x |
| P/E | nm | 41.5x | nm | nm | nm | 149.9x |
| Net debt / EBITDA (x) | 4.0x | 134.3x | 13.5x | 28.8x | 6.1x | -38.1x |

| Metrics | 2015A | 2016A | 2017A | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|
| Total revenue growth | nm | nm | 2.8% | nm | nm | nm |
| COGS as % of revenue | 0 | 0 | 0 | 0 | 0 | 1.0% |
| SG&A as % of revenue | -33.5% | -15.5% | -17.5% | -12.5% | -11.8% | -10.1% |
| R&D as % of revenue | -214.1% | -92.1% | -140.1% | -101.6% | -166.0% | -82.6% |
| EBITDA margin (%) | -142.0% | -4.8% | -54.8% | -14.1% | -77.8% | 6.3% |
| EBIT margin (%) | -147.6% | -7.6% | -57.6% | -14.1% | -77.8% | 6.3% |
| Net profit margin (%) | -195.5% | 35.6% | -74.2% | -9.2% | -77.8% | 6.3% |
| Cash as % of market cap | 19.0% | 43.7% | 33.5% | 32.1% | 27.2% | 25.4% |

Source: Kempen estimates

# Disclosures

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|---|---|
| Method | Company reports include a discussion of valuation methods used in order to determine Price Targets.The resulting conclusions lead to a Rating as below. |
| Sell | Expected negative total return of 0% or more on a 12 month basis. |
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| Price target | Expected share price in 12 months. |

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|---|---|---|
| BUY | 87 (49%) | 65% |
| NEUTRAL | 64 (36%) | 31% |
| SELL | 26 (15%) | 4% |
| Total | 177 (100%) | 100% |

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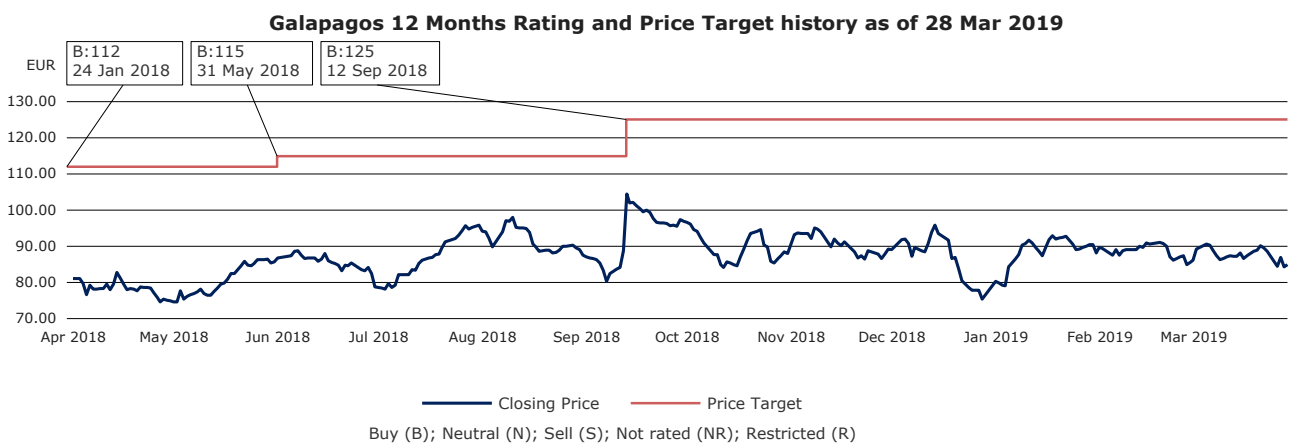


Buy (B); Neutral (N); Sell (S); Not rated (NR); Restricted (R)

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