

## First Read

# Galapagos NV

## Positive CHMP opinion for filgotinib but US assessment is still to come

### Positive CHMP opinion points towards European approval for filgotinib in RA

A nod from the CHMP today for filgotinib in RA means approval in the EU and the other European states that abide by its work should follow in due course. The brand name will be Jyseleca. This is on schedule for Gilead and partner Galapagos. Approval in the US is expected later this year.

### There is some concern over the content of the label in the US

Whilst most drugs available in Europe are also available in the US and other major pharmaceuticals markets like Australia, Canada and Japan, and vice versa, it is not always the case. Indeed, another drug in the JAK inhibitor class (Pfizer's Xeljanz) was approved by the US regulator in 2012 but took more than one go and launched a lot later in Europe because the European regulator took issue with the safety profile. The point is that a European decision is not linked to a decision in the US. There is some debate about what might happen for a US approval: 1) Will both doses be approved? They have been in Europe. 2) Will there be a class-based black box for thromboembolic events as for the rest of the class? Consensus, and we, assume there will be but Galapagos believes its drug to be differentiated on safety and if filgotinib escapes without this, it will likely drive the shares higher. 3) Will the sperm tox issue make a comeback? Early animal studies for filgotinib showed some sperm toxicity and the MANTA and MANTA RAY studies (in progress, some data used to support the filing) exist to provide more colour. Galapagos tells us that it is not out of the question that the data from the animal studies is mentioned on the label but we are not sure if this is widely noted, or whether its inclusion would be seen as problematic – it probably depends on how prominently it is featured, and if it is prominently featured to begin with whether Gilead and Galapagos can get it removed later. We forecast \$1.5b of Jyseleca sales in RA in 2028, and total filgotinib sales of \$2.8b in the same year (includes IBD).

### Equities

Belgium

Biotechnology

**12-month rating** **Neutral**
**12m price target** **€200.00**
**Price (23 Jul 2020)** **€176.85**
**RIC:** GLPG.AS **BBG:** GLPG NA

### Trading data and key metrics

<b>52-wk range</b>	€249.50-132.70
<b>Market cap.</b>	€11.4bn/US\$13.3bn
<b>Shares o/s</b>	64.7m (ORD)
<b>Free float</b>	92%
<b>Avg. daily volume ('000)</b>	418
<b>Avg. daily value (m)</b>	€77.7
<b>Common s/h equity (12/20E)</b>	€3.08bn
<b>P/BV (12/20E)</b>	3.7x
<b>Net debt / EBITDA (12/20E)</b>	28.5x

### EPS (UBS, diluted) (€)

	UBS	Cons.
<b>12/20E</b>	(0.83)	(0.82)
<b>12/21E</b>	(1.44)	(2.02)
<b>12/22E</b>	(1.47)	1.23

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Highlights (€m)	12/17	12/18	12/19	12/20E	12/21E	12/22E	12/23E	12/24E
<b>Revenues</b>	156	318	896	641	696	730	899	1,089
<b>EBIT (UBS)</b>	(90)	(45)	370	(84)	(149)	(205)	(121)	3
<b>Net earnings (UBS)</b>	(116)	(29)	150	(54)	(97)	(102)	(20)	98
<b>EPS (UBS, diluted) (€)</b>	(2.34)	(0.56)	2.42	(0.83)	(1.44)	(1.47)	(0.28)	1.34
<b>DPS (€)</b>	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
<b>Net (debt) / cash</b>	1,151	1,291	1,836	2,066	2,225	2,416	2,693	3,100
Profitability/valuation	12/17	12/18	12/19	12/20E	12/21E	12/22E	12/23E	12/24E
<b>EBIT margin %</b>	-57.6	-14.1	41.3	-13.0	-21.5	-28.1	-13.5	0.3
<b>ROIC (EBIT) %</b>	50.9	43.0	76.0	(8.1)	(14.5)	(19.9)	(11.8)	0.3
<b>EV/EBITDA (core) x</b>	-30.7	-81.6	14.1	<-100	-66.8	-46.5	-78.9	>100
<b>P/E (UBS, diluted) x</b>	(31.9)	NM	52.8	NM	NM	NM	NM	NM
<b>Equity FCF (UBS) yield %</b>	(4.2)	(3.5)	45.5	(3.7)	(4.4)	(4.2)	(3.6)	(2.5)
<b>Net dividend yield %</b>	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Source: Company accounts, Thomson Reuters, UBS estimates. Metrics marked as (UBS) have had analyst adjustments applied. Valuations: based on an average share price that year, (E): based on a share price of €176.85 on 23 Jul 2020 21:34 BST

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## Forecast returns

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Forecast price appreciation	+13.1%
Forecast dividend yield	0.0%
Forecast stock return	+13.1%
Market return assumption	4.4%
Forecast excess return	+8.7%

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## Valuation Method and Risk Statement

We value Galapagos shares on an NPV sum of the parts basis.

The main risks to our Galapagos thesis include: (1) substantial delay to failure to gain approval for filgotinib in major markets, (2) disappointing early stage data for the Toledo programme (3) failure to commercialise GLPG1690 effectively.

Risks for the pharmaceutical and biotechnology industries generally include political risks, government oversight of the approval and ongoing manufacturing process, discovery bottleneck and pipeline attrition, competitive developments and patent challenges and expiries.

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12-Month Rating	Definition	Coverage <sup>1</sup>	IB Services <sup>2</sup>
<b>Buy</b>	FSR is > 6% above the MRA.	49%	32%
<b>Neutral</b>	FSR is between -6% and 6% of the MRA.	39%	30%
<b>Sell</b>	FSR is > 6% below the MRA.	13%	20%
Short-Term Rating	Definition	Coverage <sup>3</sup>	IB Services <sup>4</sup>
<b>Buy</b>	Stock price expected to rise within three months from the time the rating was assigned because of a specific catalyst or event.	<1%	<1%
<b>Sell</b>	Stock price expected to fall within three months from the time the rating was assigned because of a specific catalyst or event.	<1%	<1%

Source: UBS. Rating allocations are as of 30 June 2020.

1: Percentage of companies under coverage globally within the 12-month rating category.

2: Percentage of companies within the 12-month rating category for which investment banking (IB) services were provided within the past 12 months.

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**UBS AG London Branch:** Laura Sutcliffe, PhD; Michael Leuchten.

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Company Name	Reuters	12-month rating	Short-term rating	Price	Price date
Galapagos NV <sup>16</sup>	GLPG.AS	Neutral	N/A	€176.85	23 Jul 2020

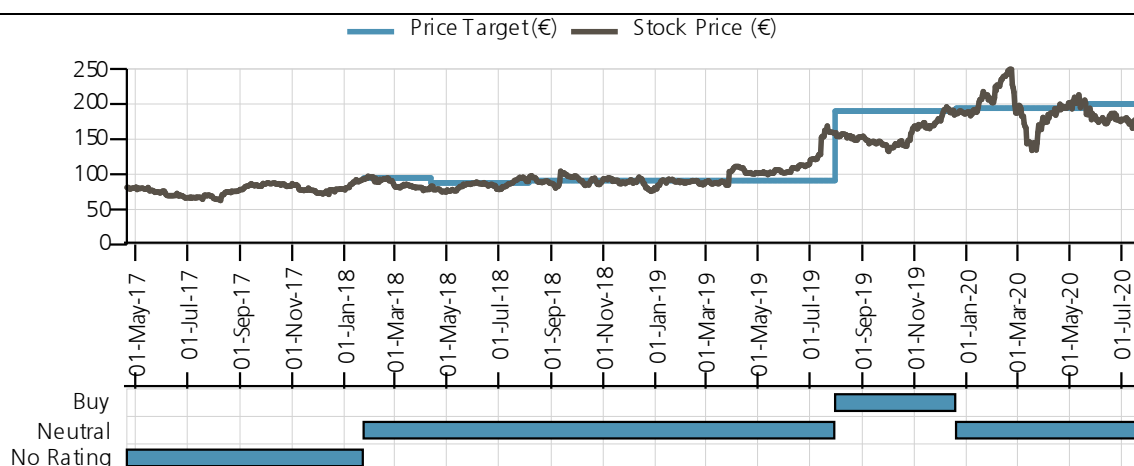
Source: UBS. All prices as of local market close.

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### Galapagos NV (€)



Date	Stock Price (€)	Price Target (€)	Rating
2017-04-21	81.34	-	No Rating
2018-01-24	92.72	95.0	Neutral
2018-04-13	83.0	88.0	Neutral
2018-08-06	94.14	91.0	Neutral
2019-07-31	157.9	190.0	Buy
2019-12-20	186.6	194.0	Neutral
2020-05-16	200.9	200.0	Neutral

Source: UBS; as of 23 Jul 2020

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