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EQUITY: AMERICAS BIOTECHNOLOGY

Filgo Ph3 FINCH2 Data Soon: Our Expectations

Expecting Similar Efficacy in RA as Upa, but with a Superior Safety Profile

We anticipate imminent release of top-line results from FINCH2, a Ph3 trial of filgo in rheumatoid arthritis (RA) patients who are **i**nadequate **r**esponders to **b**iologic **d**isease-**m**odifying **a**nti-**r**heumatic **d**rugs (IR-bDMARDs). We estimate that complete data will be presented as a late-breaker at ACR/ARHP 2018 (Chicago, Oct. 19-24). The late-breaking abstract deadline is Sept. 13, with late-breaking abstracts available mid-Oct., according to the ACR abstract website (regular abstracts available mid-Sept.). Here, we examine expectations and provide a comparative analysis with competitor JAKis, including ABBV's SELECT-BEYOND P3 trial of upadacitinib (also tested in IR-bDMARD patients; data on p. 4). We believe filgo remains well positioned as potential best-in-class drug based on data to date. *Reiterate buy.*

- **FINCH 2 Top-Line Efficacy Likely in Line with Upadacitinib (Upa); Filgo Expected to Show Better Safety.** Upa sets the bar for efficacy in IR-bDMARD RA patients (Fig. 5), exceeding responses from Xeljanz (PFE) and Olumiant (LLY/INCY). To estimate filgo responses in the current FINCH2 study, we look to SELECT-BEYOND, ABBV's Ph3 trial of upa in a similar patient population (analysis on p. 3). Filgo remains competitive, as long as efficacy remains similar to that of Upa. We expect ACR20, ACR50, ACR70, and clinical remission rates over placebo to be about 25%, 20%, 12.5%, and 12.5%, respectively (ranges p. 3). We also look for no new safety signals; we expect sAEs in the low single digits, no DVT/PE (at most, <1%), and low rates (1-2%) of serious infections/malignancies (**Fig. 11**).
- **ABBV Currently in the Lead with Upa, but GILD's Priority Review Voucher (PRV) May Be Utilized to Partially Close 12-Mo Trailing Time to Market to 8 Mo.** ABBV is currently enjoying a 12-mo lead with upa; however, we believe it is highly likely GILD will utilize a PRV to shorten the FDA review period to partially offset the ABBV upa lead. PFE/ABBV's prior marketing efforts to bring JAKi to front-line RA therapy will serve as the ideal launching platform for filgo in mid-2020, in our view.
- **MANTA to Provide Important Safety Information on Possible Testicular Side Effects:** see prior note and discussion in this note.
- **Next Catalysts:** FINCH 2 (bDMARD-IR); top-line PR any day now (3Q18E). Presentation likely Oct. ACR 2018 Chicago; filgo pathway/timeline Fig. 12.

Instinet, LLC, Equity Research

22 August 2018

Rating Remains	**Buy**
Target Price Remains	USD 124.00
Closing price 21 August 2018	USD 101.79
Potential upside	+21.8%

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Year-end: Dec	2017A	2018E			2019E		
EPS (€)	Actual	Prev.	Curr.	Cons.	Prev.	Curr.	Cons.
1Q	-0.29A	-0.73A	-0.73A	N/A	-0.84E	-0.84E	-0.62E
2Q	-0.72A	-0.42A	-0.42A	N/A	-1.03E	-1.03E	-0.23E
3Q	-0.72A	-0.84E	-0.84E	-0.79E	-0.82E	-0.82E	-0.82E
4Q	-0.59A	-1.06E	-1.06E	-0.94E	-0.98E	-0.98E	-1.18E
Year	-2.34A	-3.07E	-3.07E	-3.14E	-3.67E	-3.67E	-2.72E
Cash & Equivalents (€000)	1,151,211	960,763	960,763	953,813	878,110	878,110	771,743

Source: Company data, FactSet, Instinet estimates

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

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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 21 August 2018

(%)	1M	3M	12M
Absolute	-5.1	1.9	15.9
Relative to Nasdaq Biotechnology Index	-4.2	-8.5	0.3

Market data

Current Stock Price ($)	101.79
Market Cap ($mn)	5,225.7
52-week Low ($)	84.15
52-week High ($)	121.08
Shares Outstanding (mn)	51.34

Source: Thomson Reuters, Instinet research

Valuation

Year-end: Dec	2017A	2018E	2019E
EV/Sales (x)	N/A	18.1	15.6

Source: Company data, Instinet estimates

Summary Income Statement

Year-end: Dec; €000	2017A	2018E	2019E
Revenue	155,918	236,171	278,565
Income Tax	198	137	0
Net Income (adj.)	-99,168	-138,257	-165,870
GAAP EPS	-2.34	-3.07	-3.67
EPS (adj.)	-2.00	-2.69	-3.16
Diluted Shares (000)	51,378	54,072	54,993

Summary Balance Sheet

€000	2017A	2018E	2019E
Cash & Equivalents	1,151,211	960,763	878,110
PP&E	16,692	18,362	21,076
Total Assets	1,286,274	1,124,246	1,056,723
Total Debt	9	9	9
Total Liabilities	274,291	250,520	348,866
Shareholders' Equity	1,011,983	873,726	707,856
Total Liabilities & Equity	1,286,274	1,124,246	1,056,723

Summary Cash Flow Statement

€000	2017A	2018E	2019E
Cash from Operations	-147,030	-184,605	-75,349
Change in Working Capital	-77,693	-50,521	85,931
Cash from Investing	-549	-5,843	-7,304
Capital Expenditures	-5,312	-5,843	-7,304
Cash from Financing	353,357	0	0
Free Cash Flow	-154,089	-190,448	-82,653

Other Metrics

	2017A	2018E	2019E
Enterprise Value (€000)	N/A	4,265	4,348

Source: Company data, Instinet estimates

Framing Expectations with SELECT-BEYOND

Summary: Our FINCH 2 Expectations from Comparative Analysis with High-Dose JAKi

We estimate ACR and remission response rates as outlined below, using 200mg dosing as the base case from our analysis. We anticipate filgotinib's higher dose (200mg QD) will be utilized more frequently than the low dose (100mg QD), given the likely superior safety profile. Higher response rates represent upside potential to our market opportunity estimates.

ACR20: 25% (22.5-27.5%)

ACR50: 20% (17.5-22.5%)

ACR70: 12.5% (10.0-15%)

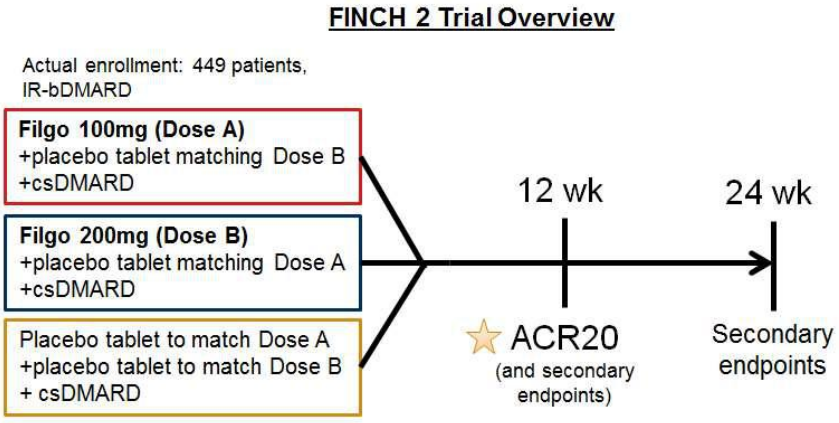
Clinical Remission (DAS28-CRP<2.6): 12.5% (10.0-15%)

The FINCH2 Trial Design and ABBV's SELECT-BEYOND

FINCH 2 is one of three trials testing filgotinib in RA. Each of the three trials uses different patient populations, as summarized below. FINCH 2 focuses on patients who are IR-bDMARDs.

Fig. 1: Overview of the FINCH Trials and the Design of FINCH 2

	Trial Name	Patient Characteristics	Trial size	Length of trial	Primary endpoint
on-going	FINCH 1	Mtx inadequate responders	1650	52 wks	ACR20 at 12wk
	FINCH 2	IR-bDMARDs	423	24 wks	ACR20 at 12wk
on-going	FINCH 3	Mtx naive	1200	52 wks	ACR20 at 24wk



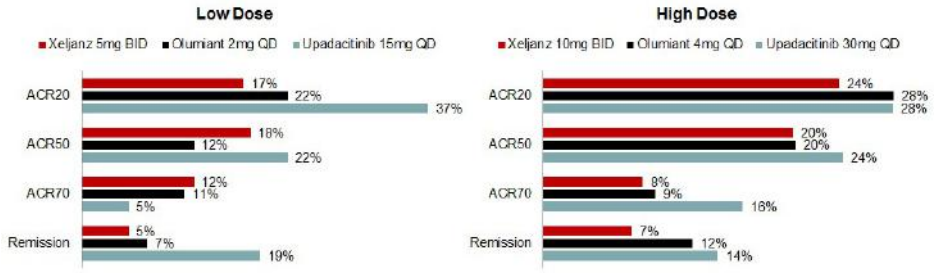
Source: Instinet research

Several secondary endpoints will be measured; these can be broadly divided into other ACR percentage improvements, disease activity scores according to DAS28, and other survey-/questionnaire-based measures of disease status and quality of life.

AbbVie's upadacitinib, the primary competitor, has already demonstrated efficacy superior to Xeljanz and Olumiant; see below:

Fig. 2: Key Efficacy Summary Across JAK Inhibitors in Ph3 IR-bDMARD RA Patients

Data at wk12; represents activity observed over placebo (variance omitted). Data drawn from the following: Upa: SELECT-BEYOND / Xeljanz: Study V / Olumiant: RA-Beacon



Source: Instinet research

Upa is being tested in the SELECT trials, summarized below:

Fig. 3: Overview of Abbvie's SELECT Trials of Upadacitinib

Topline Reported	Trial Name	Patients Characteristics	NCT
7-Jun-17	SELECT-NEXT	IR-csDMARDs	NCT02675426
11-Sep-17	SELECT-BEYOND	IR-bDMARDs	NCT02706847
20-Dec-17	SELECT-MONOTHERAPY	IR-Mtx	NCT02706951
9-Apr-18	SELECT-COMPARE	On stable dose of mtx	NCT02629159
5-Jun-18	SELECT-EARLY	Treatment naive	NCT02706873
2019	SELECT-CHOICE	Intolerant to bDMARDs	NCT03086343

Source: Instinet research

The trial most directly comparable to FINCH 2 is SELECT-BEYOND; a comparison of the inclusion criteria shows that the patient populations are essentially identical. SELECT-BEYOND was more explicit concerning which small-molecule drugs (conventional synthetic DMARDs, or csDMARDs) were allowable, but these are all the major drugs patients would be receiving.

Fig. 4: Inclusion Criteria of SELECT-BEYOND and FINCH 2 Reveal Similar Patient Populations

SELECT-BEYOND	FINCH 2
Inclusion Criteria:	**Inclusion Criteria:**
Diagnosis of rheumatoid arthritis (RA) for >= 3 months.	Have a diagnosis of RA (2010 ACR/EULAR criteria for RA), and are ACR functional class I-III.
Subjects have been treated for >= 3 months with >= 1 bDMARD therapy, but continue to exhibit active RA or had to discontinue due to intolerability or toxicity, irrespective of treatment duration prior to the first dose of study drug.	Have received at least one biologic disease modifying antirheumatic drug (bDMARD) for the treatment of RA to which they have had an inadequate response or intolerance
Subjects have been receiving csDMARD therapy >= 3 months and on a stable dose for >= 4 weeks prior to the first dose of study drug. The following csDMARDs are allowed: methotrexate (MTX), sulfasalazine, hydroxychloroquine, chloroquine, and leflunomide. A combination of up to two background csDMARDs is allowed except the combination of MTX and leflunomide.	Ongoing treatment with a stable prescription of 1 or 2 csDMARDs
Meets the following criteria: >= 6 swollen joints (based on 66 joint counts) and >= 6 tender joints (based on 68 joint counts) at Screening and Baseline Visits.	Have ≥ 6 swollen joints (from a swollen joint count based on 66 joints (SJC66)) and ≥6 tender joints (from a tender joint count based on 68 joints (TJC68)) at screening and Day 1
Exclusion Criteria:	**Exclusion Criteria:**
Prior exposure to any Janus kinase (JAK) inhibitor (including but not limited to tofacitinib, baricitinib, and filgotinib).	Previous treatment with any janus kinase (JAK) inhibitor
Current diagnosis of inflammatory joint disease other than RA. Current diagnosis of secondary Sjogren's Syndrome is permitted.	--

Source: Instinet research