NOMURA | INSTINET

Galapagos NV GLPG.OQ GLPG US

EQUITY: AMERICAS BIOTECHNOLOGY

FINCH 1 & 3 Readout Expectations

FINCH Data Key Milestone – Limited Downside, Early MANTA Timeline Upside?

GLPG's FINCH 1 and 3 are set to read out (1Q19). We expect them to confirm filgotinib's highly competitive, best-in-class therapeutic profile in MTX-naïve and MTX-IR settings. The recent FINCH 2 readout (note) informs future filgo results relative to Upa, in our view. We believe filgo's consistent performance in historical trials leaves little to the imagination for FINCH 1 and 3; however, a hiccup (which we view as unlikely) could create downside for the shares. Potential downside risk is limited, in our view, as RA is *only the first indication for filgo* and the *one with the highest competitive hurdle*. IBD represents the next filgo opportunity, just as big as RA, but with greater need for an efficacious oral therapy. Also in IBD, filgo is ahead of Upa. *Reiterate Buy.*

- **FINCH 1 & 3 Readout Expectations.** Our placebo-adjusted efficacy (ACR20/50/70/Remission) expectations for Filgo high-dose arms are 23/33/35/33% for FINCH 3 (wk 24) and 35/40/33/35% for FINCH 1 (wk 12) vs. Upa high-dose arms of 19/33/32/32% for Select-Early (wk24) and 30/37/30/33% for Select-Compare (wk 14); see pp. 4-5 for analysis.
- **FINCH Downside Scenario Unlikely, in Our View.** Subpar efficacy (to Upa) or unexpected safety would reduce filgo's market opportunity in RA. We estimate this could create downside in the shares to $80, priming the company for potential takeout.
- **MANTA Upside to Filgo NDA Submission Timeline?** We expect MANTA recruitment to accelerate, now up to 94 sites from 84 on last update (p. 9). *We see the potential for upside with filgotinib filing by mid-2019 that could set up for concurrent launch with Upa (note).* However, filgo filing by YE19 could hit the shares if MANTA trial becomes a bottleneck.
- **'1690 (Autotaxin Inhibitor) P2a NOVESA Start in Systemic Sclerosis an Oppy Worth $200mn Biobucks on Japan Collaboration Alone.** GLPG estimates 90K prevalence in US and EU and 40-60% 10-year mortality. Recent failures, including Roche's Tocilizumab P3, Bayer's Riociguat P2, and BMY's Abatacept P2, have opened up the playing field. CRBP recently received a $200mn biobucks collab deal from Kaken Pharma for SSc in Japan alone.
- **Holy TOLEDO!: Blanket P2s on the Horizon – Another Filgo-Like Oppy?** Multiple Phase 2s are planned, pending positive P1 data. Target/moa are to be revealed shortly. Upcoming Catalysts: p. 11.

Year-end: Dec	2017A		2018E			2019E	
EPS (€)	Actual	Prev.	Curr.	Cons.	Prev.	Curr.	Cons.
1Q	-0.29A	-0.73A	-0.73A	N/A	0.00E	0.00E	-0.70E
2Q	-0.72A	-0.42A	-0.42A	N/A	-0.87E	-0.87E	-0.90E
3Q	-0.72A	0.28A	0.28A	N/A	-0.70E	-0.70E	-0.82E
4Q	-0.59A	-0.54E	-0.54E	-0.39E	-0.85E	-0.85E	-0.91E
Year	-2.34A	-1.42E	-1.42E	-1.96E	-2.44E	-2.44E	-2.94E
Cash & Equivalents (€000)	1,151,211	1,320,690	1,320,690	1,150,676	1,219,636	1,219,636	983,492

Source: Company data, FactSet, Instinet estimates

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

Instinet, LLC, Equity Research

25 January 2019

Rating Remains	**Buy**
Target Price Remains	USD 140.00
Closing price 24 January 2019	USD 100.96
Potential upside	+38.7%

Research analysts

Americas Biotech

Christopher Marai, Ph.D. - ILLC
Christopher.Marai@Instinet.com
+ 1 212-310-5466

Allen Cha - ILLC
allen.cha@instinet.com
+1 212-310-5488

Jackson Harvey, Ph.D. - ILLC
jackson.harvey@instinet.com
+ 1 212 310 5453

Production Complete: 2019-01-25 20:01 UTC

We anticipate FINCH 1 & 3 Readouts Will Validate Filgo's $6bn+ Market Oppy

We anticipate, this quarter 1Q19, the release of top-line results from pivotal trials FINCH 1 (MTX-IR) and FINCH 3 (MTX-Naive) evaluating filgotinib in moderate to severe rheumatoid arthritis (RA).

- Detailed results will likely be presented at EULAR 2019 Madrid Congress (June 12-15), with abstract submission deadline for late breakers April 5-15.
  - –Abstracts will be posted approximately one month before the Congress (May 12-15).

Our Expectations

Below, we detail our expectations for filgotinib in earlier lines of RA treatment (Figs. 1-6), a lucrative tx line that will allow broad frontline utilization. We anticipate this data will further support filgo's best-in-class therapeutic profile, warranting chronic dosing across multiple settings. We anticipate

- efficacy at least as good as (likely greater than) Upadacitinib based on trial design (Figs. 2-3), and
- safety to be best-in-class (among JAK inhibitors) and better than that of stronger biologics (e.g., TNFα, IL-6); note Adalimumab comparator in FINCH 1.

Fig. 1: FINCH Program Overview

	Trial Name	Patient Characteristics	Enrolled	Length of trial	Primary endpoint
1Q19	**FINCH 1**	**Mtx inadequate responders**	**1759**	**52 wks**	**ACR20 at 12wk**
	~~FINCH 2~~	~~IR-bDMARDs~~	~~449~~	~~24 wks~~	~~ACR20 at 12wk~~
1Q19	**FINCH 3**	**Mtx naive**	**1252**	**52 wks**	**ACR20 at 24wk**

Source: Company data, clinicaltrials.gov, Instinet research

Fig. 2: Pivotal P3 JAK inhibitor Trials in MTX-Naive and MTX-IR RA Population

Company	Filgotinib GLPG/GILD	Upadacitinib ABBV	Tofacitinib PFE	Baricitinib INCY/LLY	Our Comments
MTX-Naive RA	FINCH 3 • Early RA and MTX-naive. • ± MTX Vs. MTX	SELECT-EARLY • Limited to no Tx with MTX • Prior exposure to non-MTX csDMARD accepted with washout • Mono Tx vs. MTX	ORAL Start • <3 yr duration • Mono Tx vs. MTX	RA-BEGIN • Limited to no Tx with MTX • ± MTX Vs. MTX	• FINCH 3 broadly targets early and late MTX naive pts. • SELECT-EARLY has a more stringent criteria but may leave some efficacy on the table as mono tx (See Fig. 2)
MTX-IR RA	FINCH 1 • MTX-IR • + MTX vs. Humira vs. placebo • Radiographic Endpt	SELECT-COMPARE • MTX-IR • Mono Tx vs. Humira vs. placebo • Radiographic Endpt SELECT-MONOTHERAPY • MTX-IR • Mono Tx vs. MTX	ORAL Scan • MTX-IR • +MTX vs. placebo • Radiographic Endpt ORAL Standard • MTX-IR • + MTX • vs. Humira vs. placebo ORAL Strategy • MTX-IR • Mono Tx vs. + MTX vs. Humira + MTX	RA-BEAM • MTX-IR • Min. 10yrs and highly active disease • +MTX vs. placebo • Radiographic Endpt	• FINCH 1's +MTX design may offer additional efficacy vs. Upa's SELECT-MONOTHERAPY, which only tested Upa mono tx – which may offer competitive advantage but likely leave efficacy on the table. • SELECT –COMPARE used only Upa 15mg (lower dose)

Source: Company data, clinicaltrials.gov, Instinet research

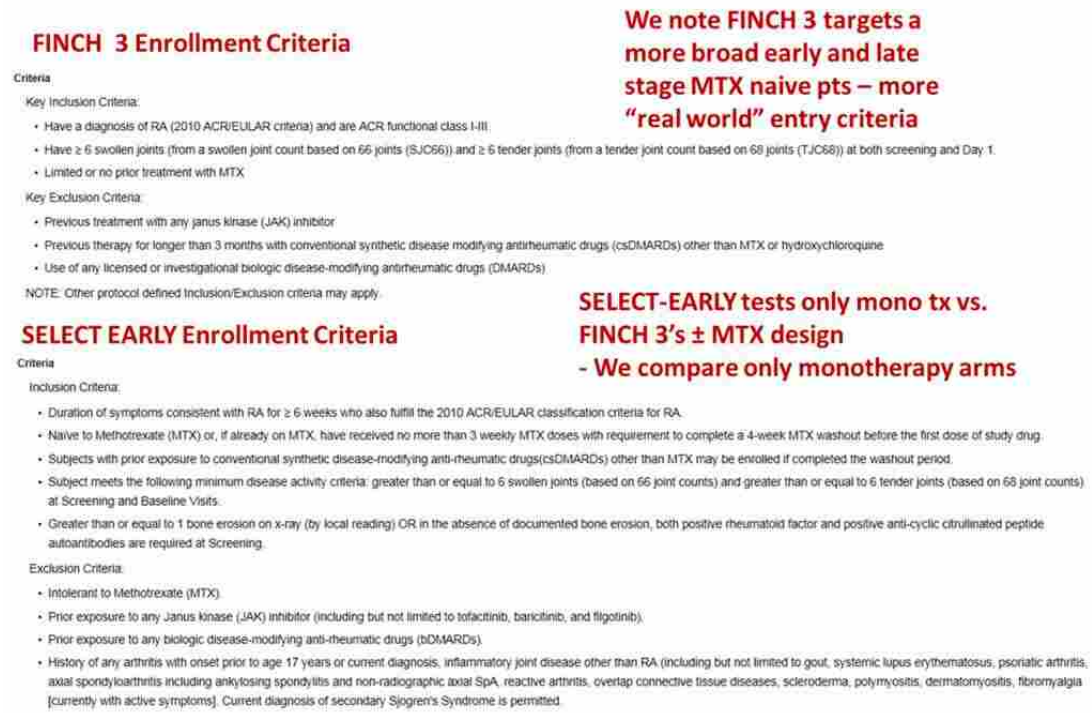
FINCH 3 vs. SELECT-EARLY

MTX-Naïve

Aside from small nuances (noted in Figs. 2-3), we look to Upa's SELECT-EARLY as filgo's FINCH 3 comparator by baseline patient characteristics.

We set our expectations for the monotherapy arms for apples-to-apples comparison.

Fig. 3: Key Differences in FINCH 3 (Filgo) vs. SELECT-EARLY (Upa)



Source: clinicaltrials.gov, Instinet research

FINCH 1 vs. SELECT-MONOTHERAPY

MTX IR

FINCH 1's filgo + MTX design will likely yield greater efficacy than Upa's SELECT-MONOTHERAPY (Upa comparator trial), which evaluated only Upa monotherapy vs. MTX (possibly leaving some efficacy on the table).

We compare Wk 12 from FINCH 1 and Wk 14 from SELECT-MONOTHERAPY, as it had a cross-over design where placebo switched over to 2 doses of Upa post Wk-14.

Fig. 4: Summary of FINCH Data expectations

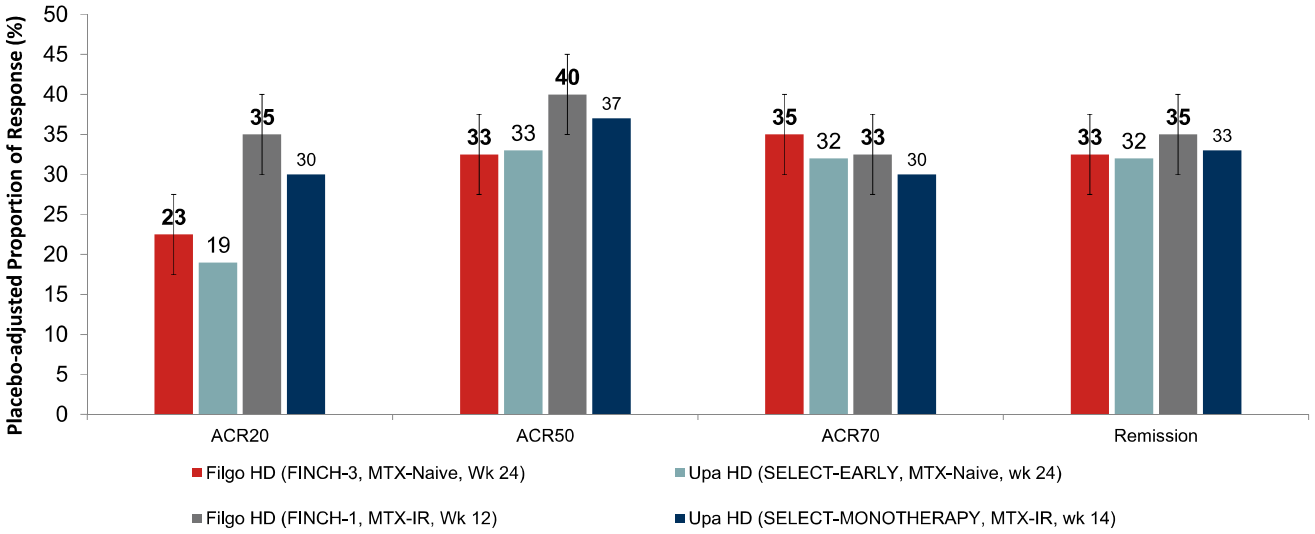
Vs. comparable UPA P3 trials

Phase 3 Early-line RA Trials	ACR20 (%)	ACR50 (%)	ACR70 (%)	Remission (%)
Filgo HD (FINCH-3, MTX-Naive, Wk 24)	**23**	**33**	**35**	**33**
Upa HD (SELECT-EARLY, MTX-Naive, wk 24)	19	33	32	32
Filgo HD (FINCH-1, MTX-IR, Wk 12)	**35**	**40**	**33**	**35**
Upa HD (SELECT-MONOTHERAPY, MTX-IR, wk 14)	30	37	30	33

Source: Company data, Instinet estimates

Fig. 5: Our Expectations of Top-Line Efficacy Measures from Filgo HD Arms vs. Upa HD

Filgo arm in FINCH-3 represents the monotherapy arm for comparison to Upa mono tx high-dose in SELECT-EARLY; FINCH 1 filgo high-dose arm is on top of MTX (wk 12) vs. Upa high-dose mono tx in SELECT-MONOTHERAPY (wk 14)



Source: Company data, Instinet estimates

Safety Expectations – Mounting Exposures but Consistent Profile

- We expect safety results to continue to reflect filgo's best-in-class tolerability profile, warranting the ideal chronic therapy following remission.
  - –Low Infection risks in 0-2% range.
  - –Serious AEs in low- to mid-single-digit %.
  - –PE/DVT's below 1%, lower than background rate and Upa.
- Though safety may be weighted higher in RA (where competition is fierce), we believe any negative read-throughs impact filgo's pipeline indications to lesser degree due to higher unmet need.
- Any single-digit incidences of DVT/PE or deaths are likely noise, considering the large trial population of ~n=3000.

Fig. 6: FINCH 2 Safety Summary

We anticipate FINCH 1 and 3 to be roughly similar to FINCH 2 safety profile

Drug (Name of Pivotal Trial)	Upadacitinib (P3 SELECT-BEYOND)					Filgotinib (P3 FINCH 2)		
Assessment Period	Weeks 0-12			Weeks 12-24*		Week 24		
Trial Arm	PBO	Low Dose	High Dose	Low Dose	High Dose	PBO	Low Dose	High Dose
n	169	164	165	228	223	148	153	147
Serious AE	**0 (0.0%)**	**8 (4.9%)**	**12 (7.3%)**	**10 (4.4%)**	**10 (4.5%)**	**5 (3.4%)**	**8 (5.2%)**	**6 (4.1%)**
PE/DVT	**0 (0.0%)**	**1 (0.6%)**	**1 (0.6%)**	**3 (1.3%)**	**1 (0.4%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**
Deaths	**0 (0.0%)**	**0 (0.0%)**	**1 (0.6%)**	**1 (0.4%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)**	**0 (0.0%)^**
Herpes Zoster	1 (0.6%)	1 (0.6%)	4 (2.4%)	2 (0.9%)	3 (1.3%)	0 (0.0%)	2 (1.3%)	2 (1.4%)
Serious Infections	0 (0.0%)	1 (0.6%)	4 (2.4%)	3 (1.3%)	3 (1.3%)	2 (1.4%)	3 (2.0%)	1 (0.7%)
Opportunistic Infections	0 (0.0%)	1 (0.6%)	2 (1.2%)	0 (0.0%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Malignancy	1 (0.6%)	1 (0.6%)	2 (1.2%)	1 (0.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MACE	0 (0.0%)	1 (0.6%)	1 (0.6%)	0 (0.0%)	1 (0.4%)	1 (0.7%)	1 (0.7%)	0 (0.0%)

** Week 12-24 Includes PBO switches to Upa 15 or Upa 30mg*

^ 1 case of retinal vein occlusion, non-serious

Source: Company data, Instinet estimates