

Equity Research

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Galapagos N.V. ADR (GLPG- \$98.23, 12:35 PM ET Intraday Price)

Rating: Overweight

Price Target: \$130.00

Bird Watching: What to look for in FINCH 1 & 3

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2017A	—	—	—	—
2018E	44.8A	57.1A	103.2A	113.0A
2019E	87.0E	87.0E	14.0E	15.0E
2020E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2017A	—	—	—	—
2018E	(0.53)A	(0.62)A	0.26A	0.33A
2019E	(0.39)E	(0.50)E	(1.83)E	(1.89)E
2020E	—	—	—	—
<u>FY</u>	<u>2017A</u>	<u>2018E</u>	<u>2019E</u>	<u>2020E</u>
REV	127.1A	318.0A	21.0E	135.0E
EPS	(2.34)A	(0.57)E	(4.61)E	(6.98)E

Note: EPS and revenues in euros.

Investment Summary. Reiterate OW and \$130 PT. FINCH 1 & 3 Ph3 filgotinib data, expected any day now, is an important catalyst for GLPG and partner GILD (Young, OW). Our thoughts on what to look for. The first filgotinib Ph3 study, FINCH 2, read out in Sept. '18 and in our view suggested that filgotinib may have a best in class risk-benefit profile among the JAK inhibitors. In the data from the FINCH 1 & 3 studies (guided for 1Q19), we think investors will be focused on 1) how efficacy compares to other agents, most notably upadacitinib (ABBV, not-covered), 2) safety events such as thrombotic events/infections vs. placebo.

For our detailed RA trial comp. charts, see our prep pack attached or ask us for our excel.

FINCH 1 (head-to-head study versus Humira) an ACR20 benefit over Humira of 8%+ would be competitive with upadacitinib on ACR20 in this population. In MTX-refractory patients, upadacitinib at week 24 (SELECT-COMPARE) showed an 8%, 16% and 12% benefit over Humira on ACR20, ACR50 and ACR70 scores, respectively. We think this will be the study FINCH 1 will be most closely compared to, with the typical caveats/limitations of cross-trial comparisons.

FINCH 3 (Monotherapy study) an ACR20 benefit over MTX of 20% would be competitive with upadacitinib in this population. In MTX- naive patients, upadacitinib (at the filed 15mg dose) at week 24 showed a 20%, 27% and 26% benefit over MTX on ACR20, ACR50 and ACR70, respectively, at the 15mg dose (SELECT-EARLY).

Safety: We are looking for low or minimal thrombotic events or serious/opportunistic infections vs. placebo. There were no thrombotic events (DVT, PE) on either placebo or active filgotinib arms in FINCH 2. FINCH 1 & 3 are much larger studies (~3,000 patients in total vs. ~350 in FINCH 2) and so we expect to see more events. Our key focus will be whether there is any imbalance vs. placebo.

Stock Move: Expectations are high into this data after FINCH 2 set a high bar, but we think the stock could trade up 10-15% on strong efficacy/safety, especially if differentiated from upadacitinib. On the downside, we think a complete failure is unlikely so we see 20-25% downside if data were more mixed or much weaker than upadacitinib. If these studies were a complete failure (highly unlikely), the stock could trade down ~40-50%. Company has ~25% of its value in cash, which provides support.

Data Timing: We have been getting questions around why the data has not yet been released. Our guess that these are very complicated data sets to analyze (~3k patients vs. ~350 in FINCH 2) and our guess is the regulators may have requested various statistical analyses, which take time.

Current Statistics

Market Cap (\$M)	\$5,197	Shares Out (M) :	54.6
ADV (3 mo.) :	81,057	52 Wk. Range	\$122.28 - \$85.00

The Disclosure Section may be found on pages 18 - 19.

Valuation

We use a probability adjusted DCF to value Galapagos shares. We assign a discount rate of 10% and a terminal growth rate of 0% in line with peers of similar size and R&D capacity.

Risks

Key risks to filgotinib include:

- Efficacy seen with FINCH 2 does not hold up in the FINCH 1 & 3 trials.
- Lack of efficacy in Phase 3 trials such as ulcerative colitis, Crohn's or psoriatic arthritis.
- Safety profile from FINCH 2 does not hold up in additional studies such as FINCH 1& 3.
- Greater-than-expected competition commercially, either from additional JAK inhibitors, novel biologics, or biosimilar entrants.
- Testicular toxicity (only seen pre-clinically) is seen clinically with filgotinib.

Looking for the Birds: FINCH 1 & 3 Prep Pack

March 26th, 2019

For our our deep-dive on the JAK inhibitor class [see here](#).

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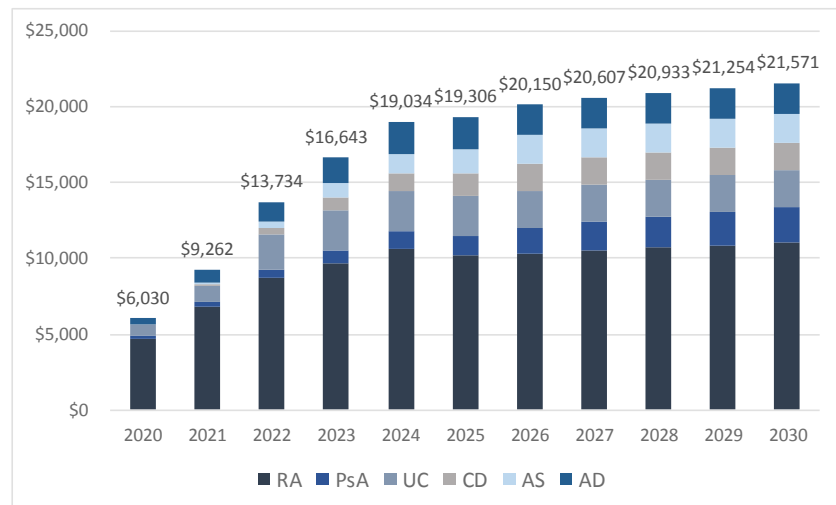
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Key Charts: Overview of the JAKi Class in RA and the Commercial Opportunity in RA and Beyond

Commercial Opportunity for JAK Class in Key I&I Indications:



Source: Company Data, Cantor Fitzgerald Equity Research

Key Players in the RA JAK Space:

Jak Inhibitor	Company	US Launch Date	JAK Target
Xeljanz (tofacitinib)	PFE	2012	JAK1/JAK3
Olumiant (baricitinib)	LLY/INCY	2018	JAK1/JAK2
Upadacitinib	ABBV	Late 2019	JAK1*
Filgotinib	GILD/GLPG	2021-2022**	JAK1

* some evidence to support upadacitinib also inhibits JAK2 and JAK3

** depending on the enrollment timelines for male safety study, MANTA and FDA discussions

Source: Company Data, Cantor Fitzgerald Equity Research

Overview of Indications In Development:

	Tofacitinib	Baricitinib	Upadacitinib	Filgotinib
Approved:	Rheumatoid Arthritis Psoriatic Arthritis Ulcerative Colitis	Rheumatoid Arthritis		
Phase 3:	Psoriasis Ankylosing Spondylitis Juvenile Idiopathic Arthritis	Atopic Dermatitis Systemic Lupus Erythematosus Psoriatic Arthritis (planned)	Rheumatoid Arthritis Psoriatic Arthritis Atopic Dermatitis Crohn's Disease Ulcerative Colitis Giant Cell Arteritis	Rheumatoid Arthritis Crohn's Disease Ulcerative Colitis
Phase 2:	Atopic Dermatitis Uveitis Alopecia Areata Scleroderma	Alopecia Areata Giant Cell Arteritis Primary Biliary Cholangitis	Ankylosing-Spondylitis Giant Cell Arteritis	Psoriatic Arthritis Ankylosing-Spondylitis Small Bowel CD Fistulizing CD Sjogren's Syndrome Cutaneous Lupus Lupus Nephropathy Uveitis

Source: Company Data

Key Catalysts for the JAK Class:

Drug	Company	Indication	What	When (Estimated)*
Baricitinib	LLY/INCY	Atopic Dermatitis	Phase 3 Data	Early 2019
Filgotinib	GILD/GLPG	RA	FINCH 1 & 3 Phase 3 Data	1Q 2019
PF-04965842	PFE	Atopic Dermatitis	Phase 3 Data	Mid 2019
Upadacitinib	ABBV	RA	Potential FDA advisory committee	Mid 2019
Upadacitinib	ABBV	RA	Potential product launch	Late 2019
Upadacitinib	ABBV	Atopic Dermatitis	Phase 3 Data	2020
Upadacitinib	ABBV	Psoriasis Arthritis	Phase 3 Data	2020
Upadacitinib	ABBV	Crohn's Disease	Phase 3 Data	2020
Filgotinib	GILD/GLPG	Ulcerative Colitis	Phase 3 Data	Mid 2020
PF-04965842	PFE	Atopic Dermatitis	Phase 3 Head to Head vs Dupi	2020
Upadacitinib	ABBV	Atopic Dermatitis	Phase 3 Head to Head vs Dupi	2020
Filgotinib	GILD/GLPG	Safety	MANTA Phase 2 Male Health Study	1H 2021**

Source: Cantor Fitzgerald Research, Company Data, Clinicaltrials.gov

* Estimates based on clinicaltrials.gov primary completion dates and company guidance where available

** Depends on enrollment, could be earlier, this is based on CT.gov primary completion of Jan 2021

JAK Phase 3 RA Programs: Wide variety of studies and patient populations can make direct comparisons challenging

	Drug	Study	Regimen	Patient Population	Background Therapy
FINCH 1 comp	tofacitinib	ORAL Standard	Placebo vs. Humira vs. tofacitinib	Inadequate response to MTX	MTX
	tofacitinib	ORAL Solo	Placebo vs. tofacitinib monotherapy	Inadequate response or intolerant to one traditional or biologic DMARD	-
FINCH 2 comp	tofacitinib	ORAL Step	Placebo vs. tofacitinib	Inadequate response or intolerant to TNFs	MTX
	tofacitinib	ORAL Scan	Placebo vs. tofacitinib	Inadequate response to MTX	MTX
FINCH 2 comp	tofacitinib	ORAL Sync	Placebo vs. tofacitinib	Inadequate response or intolerant to one traditional or biologic DMARD	Traditional DMARD
FINCH 3 comp	tofacitinib	ORAL Start	MTX vs. tofacitinib	MTX naïve	-

	Drug	Study	Regimen	Patient Population	Background Therapy
FINCH 1 comp	baricitinib	JADV (RA-BEAM)	Placebo vs. baricitinib 4mg vs. Humira	Inadequate response to MTX	MTX
	baricitinib	JADX (RA-BUILD)	Placebo vs. baricitinib 4mg vs baricitinib 2mg	Inadequate response to csDMARDs	cDMARD
FINCH 2 comp	baricitinib	JADW (RA-BEACON)	Placebo vs. baricitinib 4mg vs baricitinib 2mg	Inadequate response or intolerant to TNFs	cDMARD
FINCH 3 comp	baricitinib	JADZ (RA-BEGIN)	MTX vs. baricitinib 4mg vs. baricitinib 4mg + MTX	Treatment naïve/early RA	-

	Drug	Study	Regimen	Patient Population	Background Therapy
FINCH 2 comp	upadacitinib	SELECT- BEYOND	Placebo vs. upadacitinib Placebo crosses over at week 12	Inadequate response or intolerant to biologic DMARD	A combination of up to two csDMARDs
FINCH 2 comp	upadacitinib	SELECT - CHOICE	Orencia vs. upadacitinib Orencia crosses over at week 24	Inadequate response or intolerant to biologic DMARD	A combination of up to two csDMARDs
FINCH 1 comp	upadacitinib	SELECT- COMPARE	Placebo vs. Humira vs. upadacitinib	Inadequate response to MTX	MTX
FINCH 3 comp	upadacitinib	SELECT - EARLY	MTX vs. upadacitinib	MTX Naïve	-
	upadacitinib	SELECT - MONOTHERAPY	MTX vs. upadacitinib	Inadequate response to MTX	-
	upadacitinib	SELECT - NEXT	Placebo vs. upadacitinib	Inadequate response to csDMARDs alone	A combination of up to two csDMARDs

	Drug	Study	Regimen	Patient Population	Background Therapy
	filgotinib	FINCH 1	Placebo vs. filgotinib vs. Humira	Inadequate response to MTX	MTX
	filgotinib	FINCH 2	Placebo vs. filgotinib	Inadequate response to biologic DMARD	csDMARD
	filgotinib	FINCH 3	MTX + filgotinib vs. filgotinib alone vs. MTX alone	Naïve to MTX	-

Source: Company Data, Cantor Fitzgerald Equity Research

We thought of the Phase 3 RA trials in several buckets to broadly compare efficacy

Least
Severe

Monotherapy

Naïve to methotrexate; studied in monotherapy

- Filgotinib: FINCH 3 – data expected 1Q 2019
- Xeljanz: ORAL Start
- Baricitinib: No Phase 3 data in the 2mg dose
- Upadacitinib: SELECT- EARLY; Also SELECT-MONOTHERAPY, but this is in methotrexate *refractory* patients

Refractory Population:

Failed conventional systemic treatments; studied in combination

- Baricitinib: RA- BUILD
- Upadacitinib: SELECT- NEXT
- Xeljanz: ORAL Sync – *in patients who failed traditional or biologic DMARDs*
- Filgotinib: FINCH 2 could be compared here, but FINCH 2 is in a more severe population (*in biologic failures vs. traditional DMARD failures*)

Head to Head vs. Humira:

Failed methotrexate; studied in combination w/methotrexate

- Filgotinib: FINCH 1 – data expected 1Q 2019
- Xeljanz: ORAL Standard
- Baricitinib: No Phase 3 data in the 2mg dose vs. Humira
- Upadacitinib: SELECT-COMPARE

Most
Severe

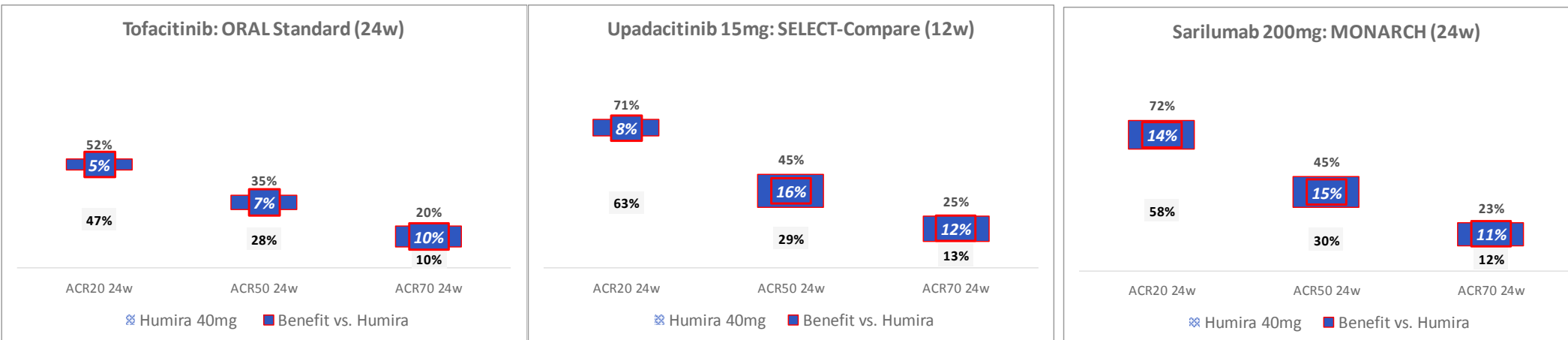
Biologic Refractory:

Failed prior biologics; studied in combination

- Filgotinib: FINCH 2 – Data reported September 2018
- Xeljanz: ORAL Sync – *in patients who failed traditional or biologic DMARDs*
- Baricitinib: RA-BEACON
- Upadacitinib: SELECT-BEYOND; Also SELECT-CHOICE, which is studying head to head vs. Orencia

In FINCH 1, we are looking for filgotinib to show a ~8-14% benefit over Humira on ACR20 to be in the ballpark of what was seen from Kevzara and upadacitinib in this setting

- We note that, in the head to head trials vs. Humira, the Xeljanz data are not as strong as some of the data seen from Kevzara (IL-6 inhibitor) – marketed by SNY (Not Covered) and REGN (Neutral, A. Young)
- **From FINCH 1, we think an ACR20 improvement over Humira of around 8-14% (between what UPA and sarilumab did) would be viewed as strong data**
 - On ACR50, we are looking for improvements over Humira of ~15-16% to be competitive
 - On ACR70, we are looking for improvements over Humira of ~10-12% to be competitive
- We note that upadacitinib was only studied at the lower, 15mg dose, in this setting



Source: Company Data, Cantor Fitzgerald Equity Research

FINCH 1: Detailed data comparisons (head to head vs. Humira)

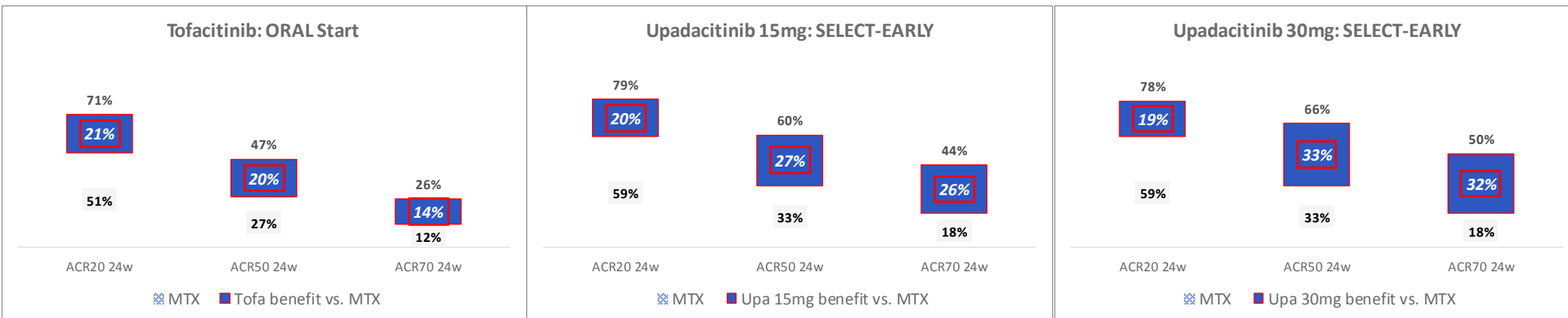
In FINCH 1, showing a strong superiority claim over Humira could be a large commercial advantage

	Tofacitinib: ORAL Standard				Upadacitinib: SELECT-COMPARE				Sarilumab: MONARCH		
	Tofacitinib 5mg BID	Humira 40mg	Placebo	Benefit vs. Humira	Upa 15mg	Humira 40mg	Placebo	Benefit vs. Humira	Sarilumab 200mg q2w	Humira 40mg q2w	Benefit vs. Humira
n	196	199	106		651	327	651		184	185	
ACR20 12w					71%	63%	36%	8%			
ACR50 12w					45%	29%	15%	16%			
ACR70 12w					25%	13%	5%	12%			
ACR20 24w	52%	47%	28%	5%					72%	58%	14%
ACR50 24w	35%	28%	15%	7%					45%	30%	15%
ACR70 24w	20%	10%	5%	10%					23%	12%	11%

Source: Company Data, Cantor Fitzgerald Equity Research

FINCH 3: We think an ACR20 benefit of ~20%+ over methotrexate will be viewed as strong data

- On ACR20 in FINCH3, Xeljanz and upadacitinib showed improvements of ~20%+ over MTX
 - ACR50 rate over MTX of ~27-33%+
 - ACR70 rate over MTX of ~26-32%+
- A key dynamic in this setting is the difference in efficacy between the high and low dose of upadacitinib**
 - Unlike in the biologic refractory population where the upadacitinib high and low doses appear to have comparable efficacy, in the MTX-naïve population in monotherapy, the higher upadacitinib dose has greater efficacy than the low dose
 - ABBV filed upadacitinib only for the 15mg dose in RA



Source: Company Data, Cantor Fitzgerald Equity Research

FINCH 3: Detailed data comparisons (MTX naïve)

- FINCH 3 is a monotherapy study in patients who are naïve to methotrexate; we think studies in this population help move the JAK class to earlier lines in RA
 - FINCH 3 is in an earlier patient population (patients who have not yet tried methotrexate, which typically means these patients are naïve to biologic therapy)
 - We think strong data in this setting could help expand the size of the JAK class to earlier lines of treatment and could help position filgotinib as a first line treatment after conventional DMARDs

Drug	Tofacitinib: ORAL Start			Upadacitinib: SELECT-EARLY				
	Tofacitinib 5mg BID	MTX	Tofa benefit vs. MTX	Upa- 15mg QD	Upa 30mg QD	MTX	Upa 15mg benefit vs. MTX	Upa 30mg benefit vs. MTX
n	373	186		317	314	314		
ACR20 12w				76%	77%	54%	22%	23%
ACR50 12w				52%	56%	28%	24%	28%
ACR70 12w				32%	37%	14%	18%	23%
ACR20 24w	71%	51%	21%	79%	78%	59%	20%	19%
ACR50 24w	47%	27%	20%	60%	66%	33%	27%	33%
ACR70 24w	26%	12%	14%	44%	50%	18%	26%	32%

Source: Company Data, Cantor Fitzgerald Equity Research

We get a lot of questions around thrombotic events; for reference, these are the number of events seen in each of the upadacitinib and baricitinib studies

Data from reported upadacitinib Phase 3 trials					
	MTX	PBO	UPA 15mg	UPA 30mg	Humira
SELECT Monotherapy					
VTE/PE Count	0		1	0	
Patient Number	216		217	215	
Weeks Controlled Period	14		14	14	
SELECT Beyond (Weeks 1-12)					
VTE/PE Count		0	1	1	
Patient Number		169	164	165	
Weeks Controlled Period		12	12	12	
SELECT Beyond (Weeks 12-24)					
VTE/PE Count			3	1	
Patient Number			228	223	
Weeks Controlled Period			12	12	
SELECT NEXT					
VTE/PE Count		0	0	0	
Patient Number		221	221	219	
Weeks Controlled Period		12	12	12	
SELECT SUNRISE					
VTE/PE Count		0	0		
Patient Number		48	48		
Weeks Controlled Period		12	12		
SELECT EARLY					
VTE/PE Count	1		0	1	
Patient Number	314		317	314	
Weeks Controlled Period	24		24	24	
SELECT COMPARE					
VTE/PE Count		1	2		3
Patient Number		651	651		327
Weeks Controlled Period		26	26		26
Total Patient Weeks Controlled	10560	22182	35504	17830	8502
Total Patient Years	203	427	683	343	164
Total VTE/PE Count	1	1	7	3	3

	Bari 4mg	Bari 2mg	PBO
Total exposure, patient years	2996	515	365
Patients with thrombotic events, n	16	2	0
Thrombotic events per 100 Patient years	0.5	0.4	0

Source: FDA briefing materials

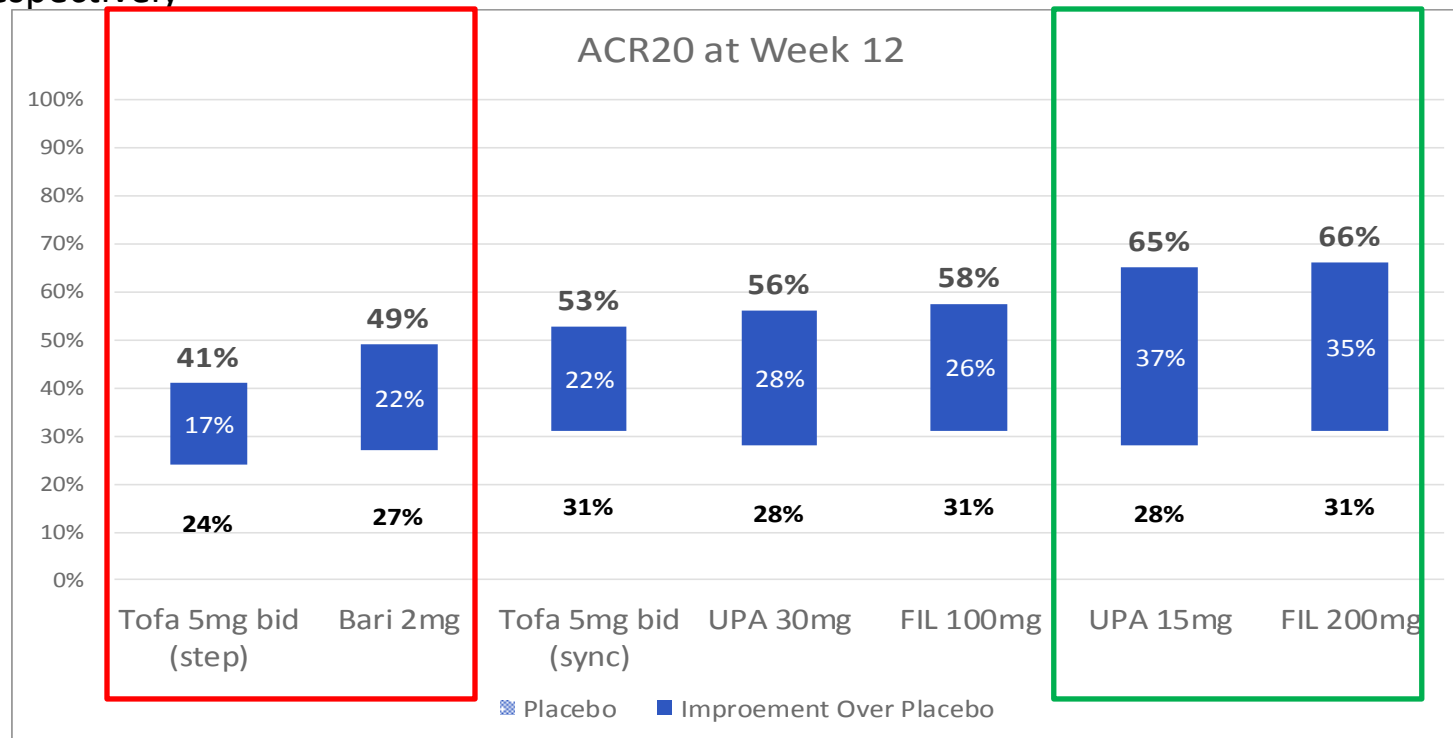
Note: This data has been compiled and rates calculated by Cantor Fitzgerald not company reports

Review of FINCH 2 data (top-lined in September '18)

We think FINCH 2 sets a high bar in terms of efficacy and safety for filgotinib. But we think it also bodes well for what we could see in FINCH 1 & 3.

On a placebo-adjusted basis at week 12, filgotinib and upadacitinib both led to much-higher response rates in the biologic refractory RA population relative to Xeljanz and Olumiant

- ACR20 is the primary endpoint in most RA studies. At week 12, the proportion of patients who achieved ACR20 (improvement of 20% or more) was:
 - 66% and 65%** with filgotinib (200mg) and upadacitinib (15mg), respectively; vs.:
 - 49% and 41-53%** with Olumiant (baricitinib 2mg, U.S. approved dose) and Xeljanz (tofacitinib), respectively



We think upadacitinib and filgotinib have meaningful efficacy improvements over Xeljanz and Olumiant at the approved doses

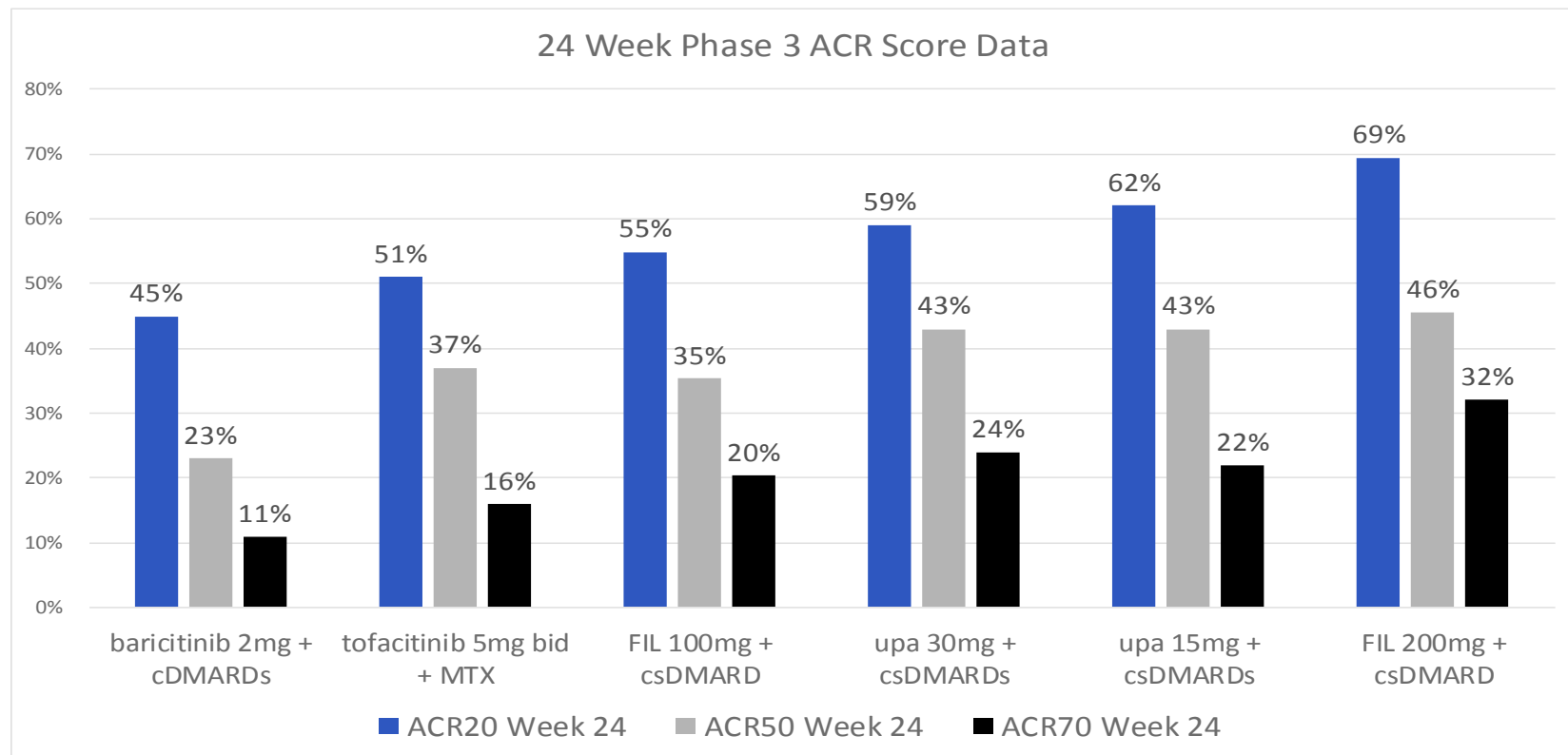
Source: Company Data, Cantor Fitzgerald Equity Research

In FINCH 2, a severely refractory RA population, we think filgotinib and upadacitinib significantly improve on the efficacy of earlier JAKs

A key caveat is that there are many limitations of cross-trial comparisons

- ACR scores are the key measure of efficacy and the standard primary endpoint in RA studies
 - ACR 20/50/70 Score = An improvement in the American College of Rheumatology (ACR) criteria by 20%/50%/70%, respectively

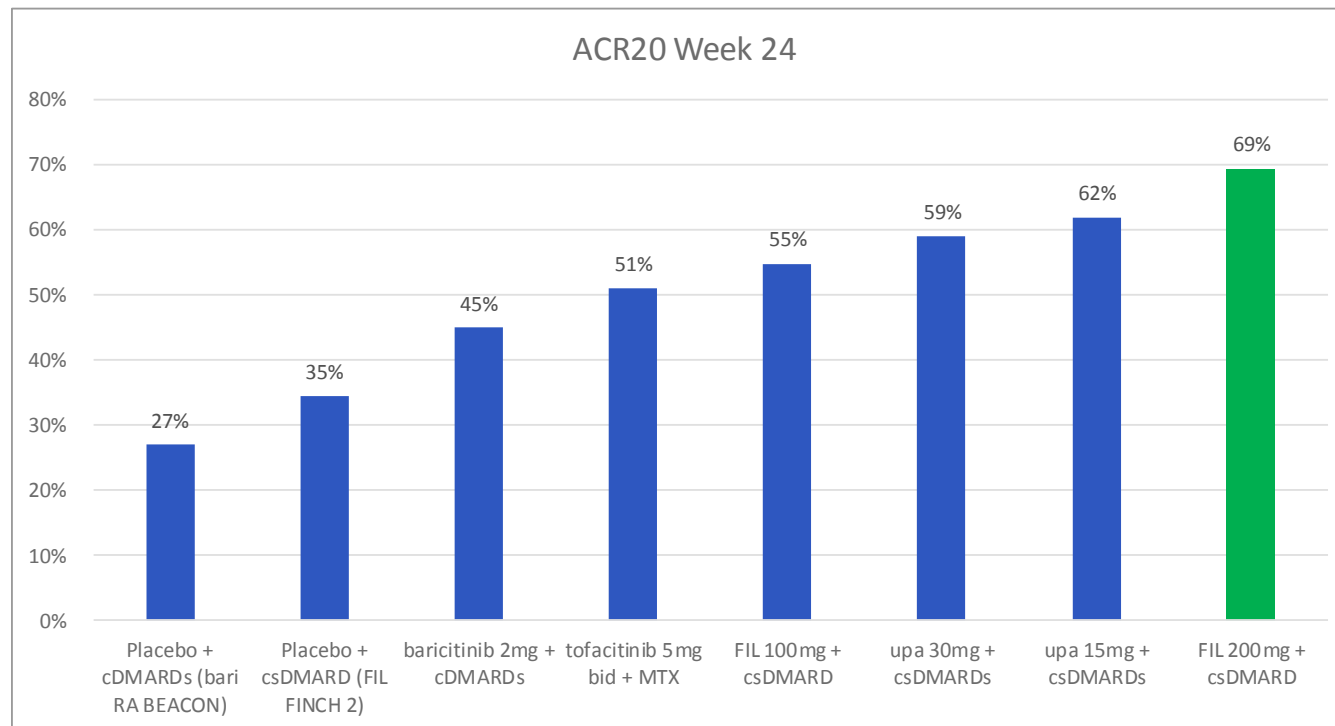
- In FINCH 2, filgotinib (200mg) achieved similar or better responses across all the ACR (American College of Rheumatology) scores at both 12 and 24 weeks



Source: Company Data, Cantor Fitzgerald Equity Research

We think filgotinib's response rates from FINCH 2 compare favorably with those of the other JAK inhibitors in the biologic refractory population

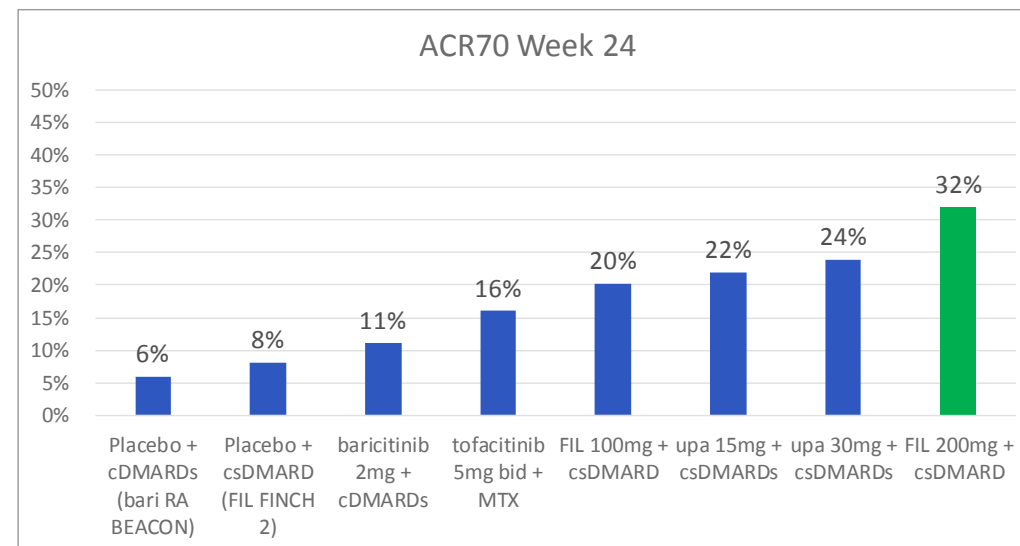
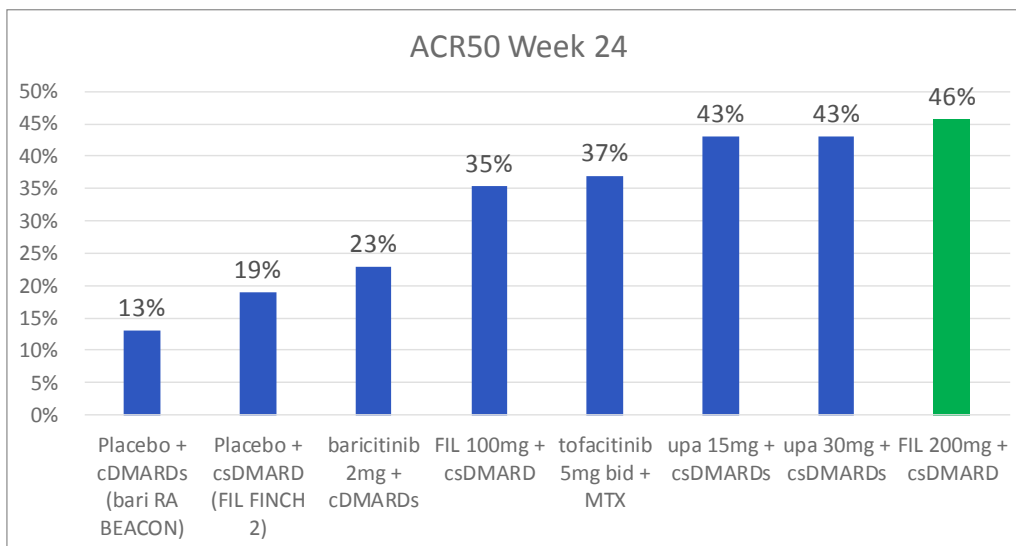
- We compared the rates from the FINCH 2 study to upadacitinib's SELECT BEYOND, tofacitinib's ORAL Step and ORAL Sync and baricitinib's RA BEACON
- These were all studies done in biologic refractory populations and studied in combination with conventional systemic DMARDs (disease modifying anti-rheumatic drugs), e.g., methotrexate
- At week 24, we think the filgotinib efficacy compares favorably with the other agents on ACR20, which is the most-frequently used primary endpoint in RA studies



Source: Company Data, Cantor Fitzgerald Equity Research

At week 24, ACR50 and ACR70 rates continue to favor filgotinib and upadacitinib

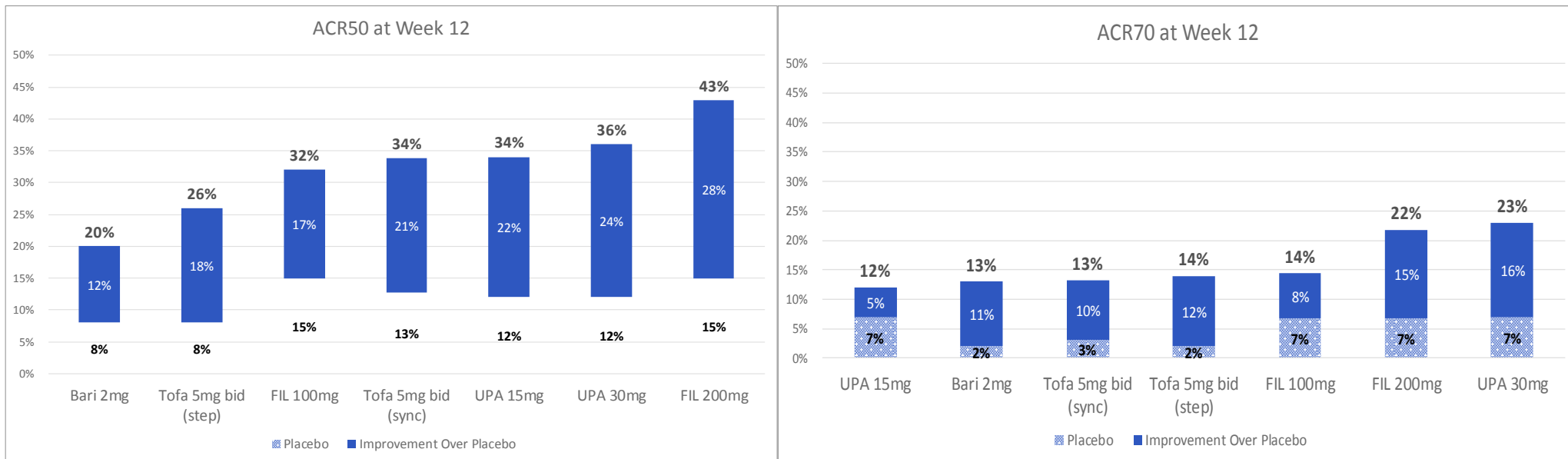
- We note that filgotinib’s efficacy improvement between the 100mg and 200mg dose is clear
- However, with upadacitinib in the biologic refractory population, the efficacy is relatively similar in both the 15mg and 30mg dose



Source: Company Data, Cantor Fitzgerald Equity Research

We think the efficacy improvements from filgotinib and upadacitinb are even-more striking when looking at the ACR50 and ACR70, which are much harder endpoints to achieve

- ACR50 and ACR70 correspond to the proportion of patients who saw a 50% or 70% improvement in the RA disease criteria – *thus, these endpoints represent a much-higher hurdle*
- Typically, these rates are fairly low, even among therapies with wide usage in RA
- In the biologic refractory population, both filgotinib and upadacitinb were able to achieve higher ACR50 and ACR70 response rates vs. existing JAK inhibitors



Source: Company Data, Cantor Fitzgerald Equity Research

Company Description

Galapagos is a clinical-stage biotechnology company. The company's lead asset, filgotinib, is partnered with Gilead (covered by A. Young) and is in development for a variety of diseases in the inflammation and immunology (I&I) space such as rheumatoid arthritis, ulcerative colitis, and Crohn's amongst many others. Other programs in development include the wholly owned idiopathic pulmonary disease (IPF) franchise, which has entered Phase 3.

Disclosures Appendix

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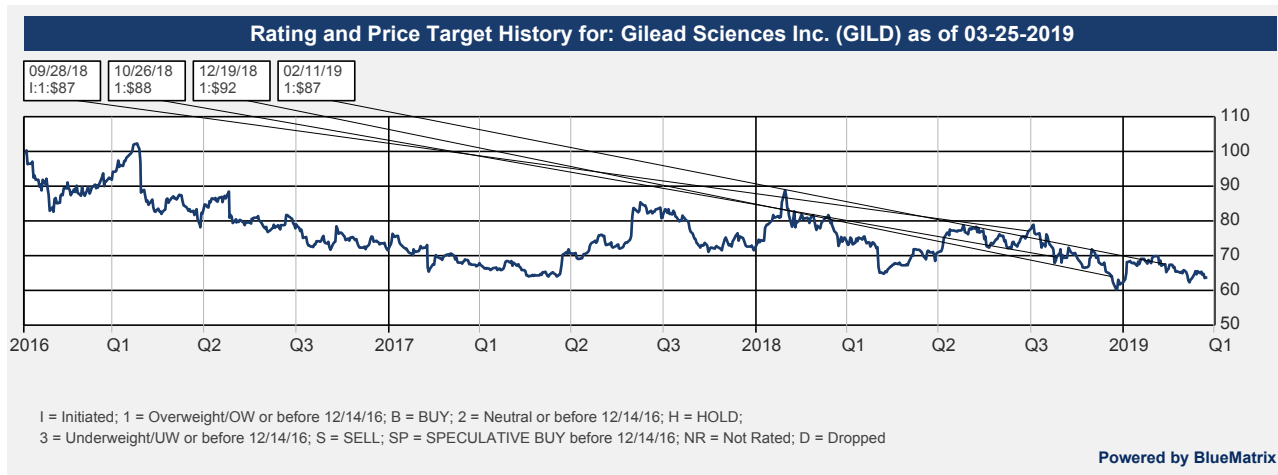
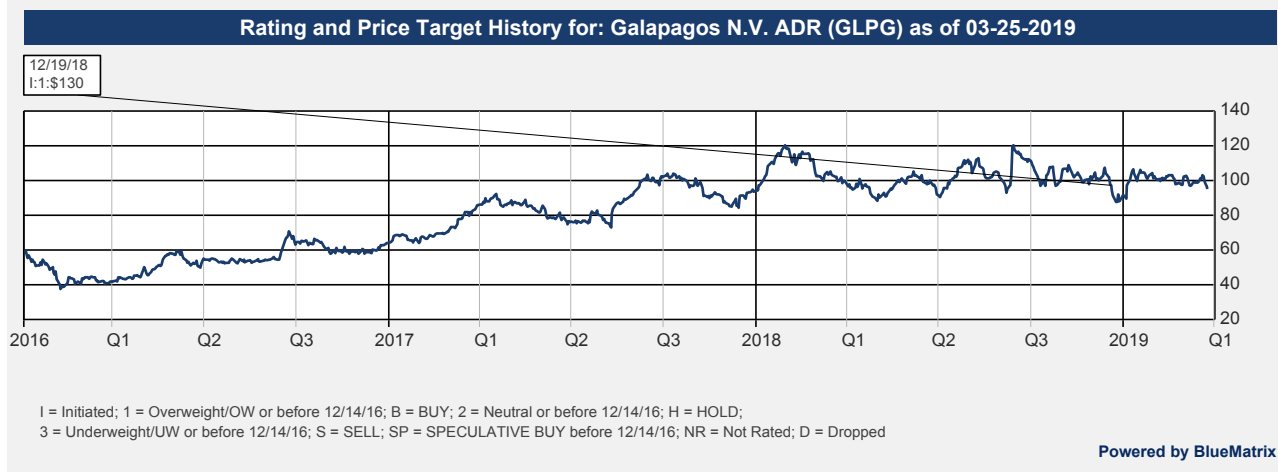
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Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
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