September 13, 2016

Biotechnology

UEGW Preview: Feedback from CELG and GLPG Prior to Data Release

Bottom Line: We expect endoscopy data for CELG's mongersen, GILD/GLPG's filgotinib, and potentially ABBV's ABT-494 in Crohn's disease to be presented at the upcoming United European Gastroenterology Week conference (October 15-19). Management enthusiasm suggests good data for mongersen and filgotinib and "similar" enrollment criteria that should allow cross-trial comparisons. We expect abstracts (exp. Sept 23; late-breakers later, timing TBA) to benefit GILD/GLPG shares, as we expect data to provide evidence of mucosal healing. Conversely, we believe cross-trial comparisons represent another hurdle for CELG shares. We believe benefit in TNF-refractory population, especially one with prior surgery, will help de-risk ongoing Phase III trials and enable CELG shares to begin to reflect mongersen's $4bn potential in Crohn's disease alone ($2.4bn 50% risk-adjusted).

Key Points

TNF-naive data should enable best cross-trial filgotinib/mongersen comparisons. We believe similar patient inclusion criteria (CDAI range, active CD endoscopic evidence, similar TNF-naive/refractory ratio) should facilitate cross-trial mongersen to filgotinib comparisons. We believe that TNF-naive patients should provide a better "apples-to-apples" comparison group to assess drug benefit, as TNF-refractory patients have greater variability due to the number of prior treatments and surgeries, and disease severity. We expect similar distribution of TNF-naive/failure patients across trials, as the ~60% TNF-refractory population in filgotinib's P2 trial is in line with CELG management's comments that the majority of CD-001 patients were TNF-refractory.

Lack of placebo control for mongersen represents biggest challenge. We believe the CD-001 trials' lack of a placebo control arm may make drug benefit determination challenging. During our call with mgmt, CELG noted that with the high SES-CD cutoff (>=7), the potential for a placebo endoscopic response is quite low. However, we note that high placebo clinical response rates in filgotinib's trial may make cross-trial comparisons difficult. We believe that clear evidence of a relationship between duration of mongersen dosing and response will be key to increasing confidence in mongersen's clinical benefit. CELG has noted that benefit was observed in all 3 dosing schedules, but we look to the data presentation to clarify the duration-response relationship.

Keep endoscopic response definitions in mind. While all 3 drugs will report endoscopic remission data, CELG's CD-001 trial defines it as SES-CD<2 while GLPG's FITZROY defines it as SES-CD<4, a more liberal definition of response (ABBV has not specified which cutoff will be used). Both mongersen and filgotinib will report change in SES-CD from baseline, including endoscopic response analyses (mongersen: % patients >25% change; filgotinib: % patients > 50% change).

What would be considered successful endoscopic data? We believe orals will need to show endoscopic improvements on par with biologics to be considered successful. Based on our literature review, we believe endoscopic response and remission rates of ~25% and ~20% (pbo-adjusted), respectively, would constitute success (Exhibit 7). However, we note these prior studies did not screen patients based on active disease endoscopic evidence. CELG has guided to "good data" as a 25% improvement in SES-CD from baseline at 12wks, 50% reduction by 26wks, and reduction to SES-CD<2 at 52wks.

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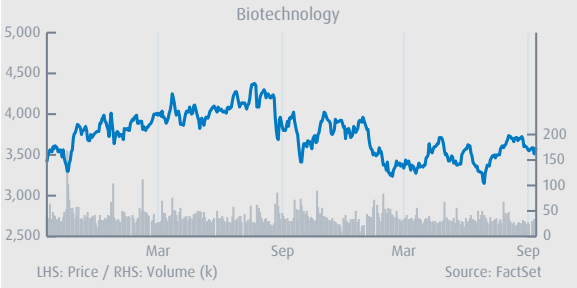

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Safety Data To Confirm Well-Tolerated Profiles to Date

Filgotinib has shown a similar safety profile with data observed in its rheumatoid arthritis studies. Only one serious infection was observed in the 10 week induction period of the FITZROY study across both arms, similar to the low infection rate observed in the DARWIN RA studies (Exhibit 1). Rates of infections and infestations, GI disorders, and nervous system disorders did not differ between groups. Similar changes in hemoglobin, lymphocytes, ALT between groups were observed. There was a slight decrease in neutrophils (+0.1 vs. -0.2), higher creatinine (+6 vs. +4), and a better artherogenic index. Should the 20 week data confirm the safety profile to date, we believe this represents a better safety profile than existing biologics, which have black box warnings for serious infections and malignancies.

Despite its new MOA targeting Smad7, data to date have shown that mongersen has been safe and well-tolerated, with drug-related adverse events similar to placebo. We believe its limited systemic distribution lowers infection risk, in contrast to anti-TNF biologics and JAK inhibitors. A theoretical concern of fibrosis or stenosis of the bowel has been suggested based on the mechanism of action of mongersen to increase TGF-β1 levels, which induces the synthesis of collagen and fibronectin and promotes fibrosis. We believe demonstration of a safety profile that avoids mechanism-related fibrosis, combined with endoscopic benefit is key to achieving our $4bn peak sales estimate.

Exhibit 1: Filgotinib Safety at 10 weeks

	Placebo	200mg
N	44	130
TE AE	61.4%	66.2%
Serious TEAE	6.8%	4.6%
Serious TE infections	0.6%	
SAE leading to death	0.0%	0.0%
Severe TEAE	9.1%	8.5%
TEAE leading to stop	11.4%	11.5%

Source: Company data, BMO Capital Markets research

Different MOAs Should Enable Combination Approach in CD

We believe success of these compounds could lead to combination approaches for treating Crohn's disease. We believe these combinations could involve proprietary combinations such as CELG's ozanimod (S1P1R modulator) along with mongersen (Smad7) or GILD/GLPG's filgotinib (JAK1) in combination with GS-5745 (MMP-9 mAb). In addition, success could also support combination of filgotinib and mongersen themselves given their differing mechanisms of action.

Filgotinib and Mongersen Trials Have Similar Design & Patient Populations

Based on information from clintrials.gov and our conversation with both companies, we believe that the patient populations in the filgotinib and mongersen trials are most similar (Exhibit 2), as both trials require patients to have a CDAI score between 220 and 450 as well as a Simplified Endoscopic Score in Crohn's Disease (SES-CD) greater than or equal to 7 at screening. We note that use of the SES-CD≥7 criteria selects for patients who are sicker at baseline, which should reduce the potential for a high placebo response. Filgotinib further requires patients to demonstrate evidence of ulceration (a score of 2 or 3 in at least 5 of the ileocolonic segments). While ABBV's ABT-494 also requires patients to have CDAI great than or equal to 220 or less than or equal to 450, there is no explicit mention of endoscopic inclusion criteria. We believe evidence for active inflammation using endoscopic confirmation of disease will be needed to best perform cross-trial comparisons of ABT-494 with filgotinib and mongersen.

All drugs are also evaluating different dose levels of their respective drugs in Crohn's disease, which should enable determination of dose-response relationships (Exhibit 2). However, while ABT-494 and filgotinib both include placebo control arms in their studies, CELG's mongersen lacks a control arm, making the evaluation of response from the drug more difficult. We believe that clear evidence of a relationship between duration of mongersen dosing and clinical endpoints will be important to increasing confidence in mongersen's clinical benefit.

Exhibit 2: Overview of Design and Patient Inclusion Criteria for ABT-494, Filgotinib, and Mongersen Phase 2 Trials

Drug	Trial Arms	Dosing Frequency	N	Placebo Control?	TNF Naives	TNF Failures	Induction Period	CDAI Inclusion Criteria	Clinical Trial Sites	Notes
ABT-494	Low Dose 2x daily Low/Medium Dose 2x daily Medium/High Dose 2x daily High dose 1x daily	1-2x daily	210	YES	YES	YES	16 weeks	220≤CDAI≤450	Global	-
Filgotinib	Filgotinib 200mg Filgotinib 100mg (Week 10-20 only) Placebo	1x daily	175	YES	YES	YES	10 weeks	220≤CDAI≤450	EU only	SES-CD≥7 at screening, and evidence of ulceration (score of 2 or 3 in at least 5 of the ileocolonic segments)
Mongersen	Mongersen 4 weeks, Placebo 8 weeks Mongersen 8 weeks, Placebo 4 weeks Mongersen 12 weeks	1x daily	64	NO	YES	YES	12 weeks	220≤CDAI≤450	80-85% USA	SES-CD≥7 at screening (ileitis only require SES-CD≥4)

Source: clintrials.gov, BMO Capital Markets research

Population Composition Key to Efficacy Comparisons

Filgotinib has previously reported data at 10 weeks from its FITZROY Phase 2 study, detailing the patient population (Exhibit 3). Approximately 60% of patients were TNF-experienced non-responders in the trial, and population had a mean CDAI of ~290. Based on our discussions with CELG management, the mongersen trial primary enrolled TNF refractory patients, with a large population of these patients having had prior surgery, indicating the severity of disease in these patients. Management also indicated that the CDAI scores were higher than those in the IGON-1 trial (median of 248 in the IGON-1 trial), potentially more in line with the mean CDAI in the filgotinib trial. We believe the best cross-trial comparisons will be made by comparing responses in the TNF-naïve subgroups, as TNF-refractory patients are likely more heterogeneous due to prior treatment and surgical history.

Exhibit 3: Baseline Patient Characteristics in Filgotinib FITZROY Phase 2 Study

	Placebo (N=44)	200 mg (N=130)	p-value
Age, mean, years	35.1	37.4	0.2472
Female	59%	55%	0.6054
Duration of CD, mean, years	6.8	8.8	0.1349
CDAI, mean	299	291	0.4417
SES-CD, mean	15.9	14.2	0.1504
CRP, mean, mg/L	19.8	14.2	0.1125
CRP > 10mg/L	41%	42%	0.9418
Concomitant oral corticosteroids	52%	48%	0.6621
mean daily dose, mg	23.6	23.1	0.8679
Anti-TNF naive	36%	44%	NA
Anti-TNF experienced non-responders	64%	56%	NA

Source: Company data

Filgotinib and Mongersen have Shown High Clinical Benefit

Two-week dosing of mongersen in mild-to-moderate patients in the IGON-1 trial demonstrated high rates of clinical remission by week 4 that was sustained through week 12 (Exhibit 4). Patients receiving two weeks of treatment with mongersen showed significantly higher rates of clinical remission versus placebo at the week 4 primary assessment (55.0% and 65.1% vs. 9.5%), which was sustained out to 7 weeks after trial start (62.5% and 67.4% vs. 21.4%). These improvements were similar across low (≤260) and high (>260) CDAI subgroups in the high dose (160mg) cohort, suggesting efficacy is similar regardless of disease severity (Exhibit 5). The placebo-adjusted clinical remission rate (46.0%) was on par with data reported from GILD/GLPG at week 10 for filgotinib in TNF-naïve patients (48%). These data compare favorably to the historical time to and rates of clinical remission with those observed in pivotal trials of approved biologics, but those trials were conducted in moderate-to-severe CD (Exhibit 4). Despite the more modest efficacy in TNF refractory patients, we believe the filgotinib data are encouraging given the difficulty of treating these patients. We look for mongersen clinical remission and response data in the CD-001 trial to

be consistent with that observed in the IGON-1 trial to confirm mongersen's competitive profile, while we look for durability of clinical response for filgotinib in the 20 week dataset.

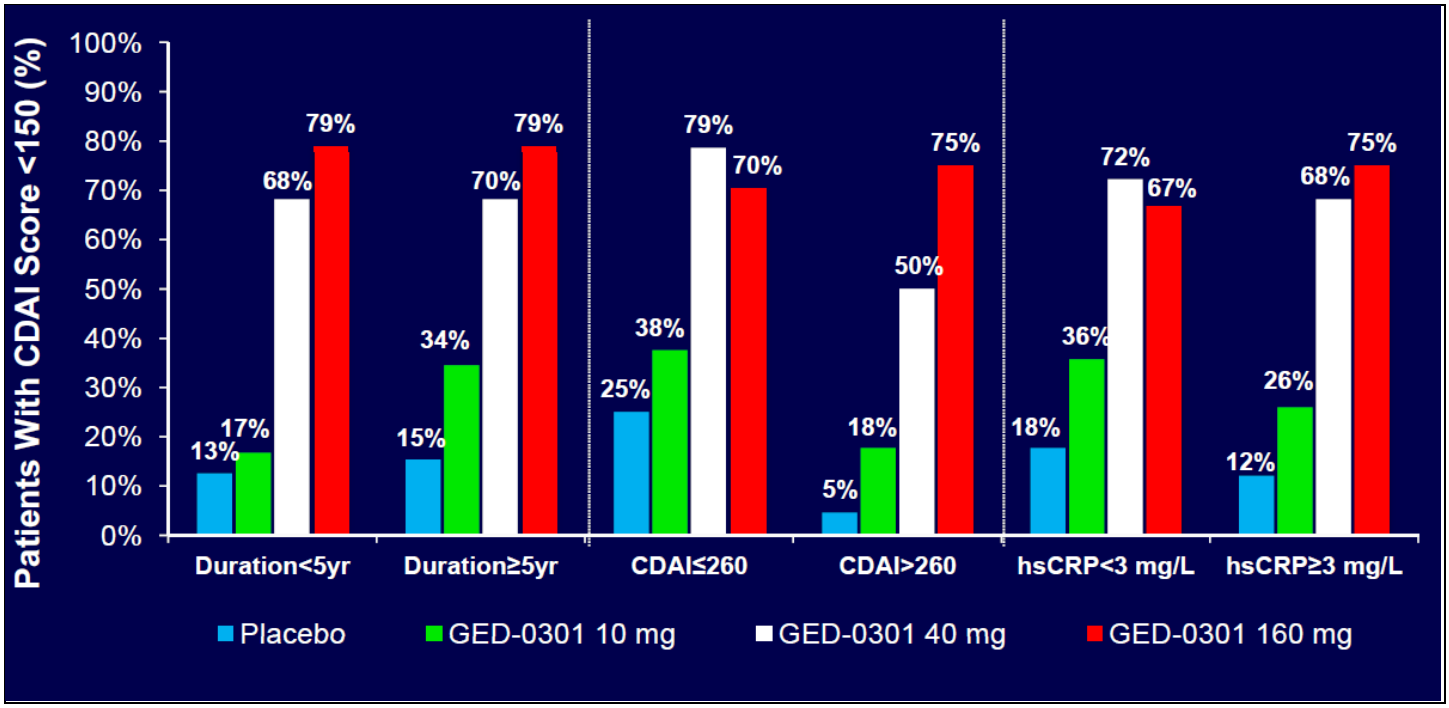
Exhibit 4: Clinical Remission and Response Rates in Crohn's Disease Trials

Anti-TNF Naives								
Drug	Dose	Clinical Remission			Clinical Response			Week
		PBO	Drug	PBO-Adjusted	PBO	Drug	PBO-Adjusted	
Filgotinib	**200mg**	**13%**	**61%**	**48%**	**44%**	**68%**	**24%**	**10**
Xeljanz	5mg	21%	24%	3%	47%	58%	11%	4
Cimzia	400mg	17%	22%	5%	27%	35%	8%	6
Entyvio	300mg	16%	35%	19%	22%	51%	29%	10
Humira	160mg	12%	36%	24%	25%	50%	25%	4
Remicade	5mg/kg	4%	33%	29%	17%	81%	64%	4
Tysabri	300mg	35%	39%	4%	57%	58%	1%	10
Mongersen^	**160mg**	**21%**	**67%**	**46%**	**17%**	**72%**	**55%**	**7***
TNF Failures								
Drug	Dose	Clinical Remission			Clinical Response			Week
		PBO	Drug	PBO-Adjusted	PBO	Drug	PBO-Adjusted	
Filgotinib	**200mg**	**29%**	**37%**	**8%**	**39%**	**54%**	**15%**	**10**
Entyvio	300mg	12%	27%	15%	25%	47%	22%	10
Humira	160mg	7%	21%	14%	25%	38%	14%	4
Stelara	6mg/kg	11%	18%	8%	17%	44%	26%	8
Tysabri	300mg	22%	33%	11%	35%	55%	20%	10
PF-00547659	225mg	23%	29%	6%	59%	58%	-1%	12
Risankizumab**	600mg	15%	37%	21%	21%	42%	21%	12

Clinical response for Xeljanz, PF-00547659, Remicade, Tysabri - CDAI decrease of 70
*Clinical response for mongersen measured at Week 4
**Overall population (94.2% patients exposed to ≥1 TNF antagonist)
^Patients could have failed 1 prior biologic therapy

Source: Company data, BMO Capital Markets research

Exhibit 5: Severity of Disease or Level of Inflammation Did Not Impact Efficacy of Mongersen 160mg Dose



Source: Company data, BMO Capital Markets research

Endoscopic Endpoint Definitions Vary Across Trials

While the Phase 2 trials for ABT-494, filgotinib, and mongersen all include endoscopic endpoints (Exhibit 6), the specific endpoint data reported may vary across trials. Data for all 3 drugs will report the proportion of subjects who achieve endoscopic remission, with filgotinib's trial specifically defining endoscopic remission as SES-CD≤4 at week 10 and CELG defining endoscopic remission as SES-CD≤2. In our discussion with CELG management, they noted that use of a cutoff of SES-CD≤4 represents a more liberal definition of remission. Both GILD/GLPG and CELG will report at the UEGW the change in SES-CD score from baseline (i.e., endoscopic response), as well as responder analyses on change in SES-CD. For responder analysis, GILD/GLPG will report the percentage of patients achieving at least a 50% reduction in SES-CD at week 10, while CELG will report the percentage of patients achieving at least a 25% reduction in SES-CD at week 12. GILD/GLPG will also detail the percentage of subjects achieving mucosal healing at week 10 (SES-CD = 0).

Exhibit 6: Comparison of Primary and Secondary Endpoints in ABT-494, Filgotinib, and Mongersen Phase 2 Trials

Endpoint	ABT-494	Filgotinib	Mongersen
Primary Endpoint(s)	--Proportion of subjects who achieve endoscopic remission (determined using SES-CD) --Proportion of subjects who achieve clinical remission	--% subjects achieving clinical remission at Week 10 --% subjects achieving clinical remission (defined by CDAI<150 points)	--Change in SES-CD score
Secondary Endpoint(s)	--Proportion of subjects who achieve CDAI<150 --Proportion of subjects with decrease in CDAI ≥70 points --Proportion of subjects who achieve remission at Week 52	--% subjects achieving clinical remission (up to week 20) --% subjects achieving clinical response (CDAI decrease ≥100 points) --% subjects achieving endoscopic remission at week 10 (SES-CD≤4, ulcerated surface subscore ≤1 at week 10) --% subjects achieving endoscopic response (reduction of SES-CD by at least 50% from screening at Week 10) --% subjects achieving mucosal healing at Week 10 (SES-CD = 0 at week 10) --Change from baseline CDAI index score --Change from screening endoscopic score --Change from screening histopathology biopsy score --Change from baseline QoL (BDQ questionnaire) --Number of subjects with adverse events --Number of subjects with abnormal lab tests --Number of subjects with abnormal vital signs --Number of subjects with abnormal ECG --Plasma levels of filgotinib + metabolite --Change vs. baseline in levels of immune / inflammation parameters in whole blood & serum --Change vs. baseline levels of faecal calprotectin --Change vs. baseline in microbial communities in stool samples	--Proportion of subjects achieving clinical remission (CDAI score<150 at induction week 4) --Adverse events

Source: clintrials.gov, BMO Capital Markets research

Exhibit 7: Endoscopic improvement data at weeks 10-12 in Crohn's disease

adalimumab vs placebo

Trial	Drug	Schedule/Dose	Week	Mucosal Healing			Endoscopic Response			Endoscopic Remission			Deep Remission		
Trial				PBO	Drug	PBO-Adj	PBO	Drug	PBO-Adj	PBO	Drug	PBO-Adj	PBO	Drug	PBO-Adj
EXTEND	adalimumab	Induction	12	13%	27%	14%				28%	52%	24%			

Mucosal Healing ("absence of mucosal ulceration")
Endoscopic remission (CDEIS ≤4)

Clinical response CR-70=ΔCDAI≥70; CR-100=ΔCDAI≥100
Clinical remission CDAI <150

infliximab vs placebo

Trial	Drug	Schedule/Dose	Week	Mucosal Healing			Endoscopic Response			Endoscopic Remission			Deep Remission		
Trial				PBO	Drug	PBO-Adj	PBO	Drug	PBO-Adj	PBO	Drug	PBO-Adj	PBO	Drug	PBO-Adj
ACCENT I (MH substudy)	infliximab	induction	10	4%	30%	26%									

Mucosal Healing absence of mucosal ulceration, including aphthoid ulceration, superficial or shallow ulceration, deep ulceration, or ulcerated stenosis. mucosal ulceration must have been present at baseline (Week 0) and absent at follow-up.

risankizumab vs placebo

Trial	Drug	Schedule/Dose	Week	Mucosal Healing			Endoscopic Response			Endoscopic Remission			Deep Remission		
Trial				PBO	Drug	PBO-Adj	PBO	Drug	PBO-Adj	PBO	Drug	PBO-Adj	PBO	Drug	PBO-Adj
NCT02031276 (Phase 2)	risankizumab	Induction/600mg	12				13%	37%	24%	3%	20%	17%	0%	12%	12%

Endoscopic response (CDEIS ≤7; >50% improvement in the lining of the bowel from before treatment started, as seen during an endoscopy)
Endoscopic remission (CDEIS ≤4, normalization of the lining of bowel as seen during an endoscopy)
Clinical remission (CDAI <150)
Deep remission (patients achieving clinical and endoscopic remission at the same time)

Source: clintrials.gov, BMO Capital Markets research

Coverage Universe

Company Name	Ticker	Analyst	Rating	Sep-12 Price	Target	Annual Div.	Yield	Book	Mkt/Bk	Total Return	Mkt Cap. (mm)
Aeglea Biotherapeutics	AGLE	MS	OP	$7.77	$19.00	$0.00		$5.51	1.4x	144.5%	104
Alexion Pharmaceuticals	ALXN	MS	OP	$126.79	$165.00	$0.00	0.0%	$36.57	3.5x	30.1%	28,432
Amgen	AMGN	MS	OP	$169.30	$190.00	$4.00	2.4%	$40.24	4.2x	14.6%	126,698
AveXis	AVXS	MS	OP	$35.95	$52.00	$0.00	0.0%	$5.84	6.2x	44.6%	827
Biogen	BIIB	MS	Mkt	$297.41	$304.00	$0.00	0.0%	$52.04	5.7x	2.2%	65,169
BioMarin Pharmaceutical	BMRN	MS	OP	$93.88	$123.00	$0.00	0.0%	$11.74	8.0x	31.0%	16,033
Celgene	CELG	MS	OP	$104.53	$141.00	$0.00	0.0%	$7.16	14.6x	34.9%	81,023
Five Prime Therapeutics	FPRX	MS	Mkt	$47.74	$53.00	$0.00	0.0%	$15.05	3.2x	11.0%	1,353
Gilead Sciences	GILD	MS	Mkt	$78.06	$98.00	$1.88	2.4%	$11.67	6.7x	28.0%	103,012
Incyte Corporation	INCY	MS	OP	$79.21	$100.00	$0.00	0.0%	$1.58	50.1x	26.2%	14,892
Intercept Pharmaceuticals	ICPT	MS	OP	$146.89	$218.00	$0.00	0.0%	$16.89	8.7x	48.4%	3,632
MyoKardia	MYOK	MS	OP	$19.33	$28.00	$0.00		$2.85	6.8x	44.9%	522
Neurocrine Biosciences	NBIX	MS	OP	$50.27	$66.00	$0.00	0.0%	$4.39	11.4x	31.3%	4,361
OncoMed Pharmaceuticals	OMED	MS	OP	$11.91	$19.00	$0.00	0.0%	($1.43)	-8.3x	59.5%	365
Protagonist Therapeutics	PTGX	MS	OP	$12.88	$21.00	$0.00		$6.19	2.1x	63.0%	210
Tetraphase Pharmaceuticals	TTPH	MS	Mkt	$3.74	$6.00	$0.00	0.0%	$4.84	0.8x	60.4%	137

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Hold	Market Perform	55.9%	11.0%	40.5%	54.9%	44.4%	39.8%
Sell	Underperform	3.8%	14.3%	3.6%	3.5%	1.8%	5.5%

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