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Galapagos NV

(GLPG-NASDAQ)

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Initiation of Coverage

Rating

Strong Buy 1

Current and Target Price

Current Price (Nov-13-18)	$102.79
Target Price:	$157.00
52-Week Range	$122.28 - $84.13
Suitability	High Risk/Speculation

Market Data

Shares Out. (mil.)	54.3
Market Cap. (mil.)	$5,582
Avg. Daily Vol. (10 day)	106,378
Dividend/Yield	$0.00/0.0%
BVPS (Sep-18)	$25.42
ROE %	-7%

Earnings & Valuation Metrics

	2017A	2018E	2019E
GAAP EPS	$(2.34)	$(2.00)	$(4.00)

Initiating at Strong Buy ($157 Price Target): Filgotinib Emerging as Best-in-Class

Recommendation: We initiate coverage of Galapagos (GLPG) with a Strong Buy rating and a $157 12-month price target. Galapagos is a clinical stage biopharma company with a lead drug, filgotinib, which could be approved as a disease modifying drug for multiple auto-immune disorders, beginning with an U.S. FDA approval for the treatment of rheumatoid arthritis during 2020. Our investment thesis is based upon three key points, **1)** filgotinib has demonstrated a clear path to approval across multiple indications, supporting our forecast for ~$2.9B in global drug sales during 2023E, **2)** clinical data for filgotinib has steadily built evidence that it could be a best-in-class JAK inhibitor, and **3)** the Galapagos pipeline of wholly owned therapeutic candidates is expected to rapidly expand over the next several years.

- **JAK-inhibitors continue to take mind-share within auto-immune disorders:** Overall, we forecast the current class of JAK inhibitors (baricitinib, filgotinib, tofacitinib, upadacitinib) reaching ~$11B in sales during 2023E, which we think is a relatively reasonable market build compared to the current ~$38B in global sales generated by the anti-TNF injectable biologic class, or the ~$12B generated by the current class of Interleukin targeted biologic therapies.

- **Clinical data has steadily built the case for filgotinib as a best-in-class JAK inhibitor during 2018:** FINCH-2 results have provided a first look at cross-comparability to the rest of the JAK class within a pivotal trial setting for rheumatoid arthritis. **Notably, filgotinib recorded a ~28% spread above the placebo group for patients achieving ACR50, and ~15% for ACR70, which were both numerically higher than what was recorded for the other JAK inhibitors across comparable studies. Regarding safety, the compendium of clinical data for filgotinib (patient years' experience) indicates that the drug may have the lowest recorded rate of deep vein thrombosis/pulmonary embolism (DVT/PE) of the current JAK class, potentially attributed to the high selectivity of filgotinib for JAK1 over JAK2.**

- **Expanding pipeline with a removal of the AbbVie cystic fibrosis overhang helps focus attention on new value drivers into 2019:** The results presented during 2018 for GLPG1690 (FLORA study) supported moving the Idiopathic Pulmonary Fibrosis (IPF) program into a Phase 3 study (ISABELA), which commenced during 2H2018. During July 2018, Galapagos announced the PINTA Phase 2 (IPF) trial to evaluate GLPG1205, with enrollment started during 2H2018. **We model conservative IPF market penetration and benchmark pricing to Esbriet and Ofev, which supports GLPG1690 reaching +$800m in annual sales during 2027E.**

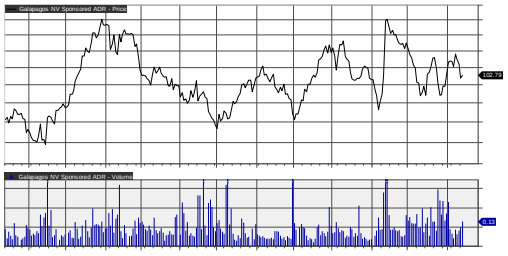
Valuation: Our 12-month forward price target of $157 values GLPG ADR shares at ~6x on a five year forward EV/ Sales basis (2023E) and ~6.6x on a projected 2022 EV/ NTM sales basis. (See pages 5 and 30 for our valuation and bull-bear analysis).

EBITDA (mil.)	Q1 Mar	Q2 Jun	Q3 Sep	Q4 Dec	Full Year	Revenues (mil.)
2017A	$(10)	$(21)	$(29)	$(26)	$(86)	$156
2018E	(31)A	(33)A	(13)A	(54)	(105)	245
2019E	(49)	(49)	(49)	(49)	(196)	160

Rows may not add due to rounding. Figures are based on ADRs/ADSs.

Company Description

Galapagos NV is a clinical-stage biotechnology company that is researching and developing novel small molecules to treat indications such as rheumatoid arthritis and inflammation. It was founded in 1999, and is headquartered in Mechelen, Belgium. Its diverse pipeline consists of multiple programs that are in Phases 1-3, and also has preclinical developments. Its most advanced program is filgotinib, a selective JAK1 inhibitor, which is targeting multiple indications including rheumatoid arthritis, ulcerative colitis, and Crohn's disease. Besides filgotinib, Galapagos has four current primary areas of interest: IPF, atopic dermatitis, OA, and inflammation fibrosis.



Source: FactSet.

Please read domestic and foreign disclosure/risk information beginning on page 39 and Analyst Certification on page 40.

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Link to audio summary.

Investment Thesis

We initiate coverage of Galapagos (GLPG) with a Strong Buy rating and a $157 12-month Price Target. Galapagos is a clinical stage biopharma company with a lead drug, filgotinib (JAK Inhibitor), which could be approved as a disease modifying drug for multiple autoimmune disorders, beginning with a potential U.S. FDA approval for the treatment of rheumatoid arthritis during 2020. Our investment thesis is based upon three key points, **1)** filgotinib has demonstrated a clear path to approval across multiple indications, supporting our forecast for ~$2.9B in global drug sales during 2023E, **2)** clinical data for filgotinib has steadily built evidence that it could be a best-in-class JAK inhibitor, and **3)** the Galapagos pipeline of wholly owned therapeutic candidates is expected to rapidly expand over the next several years.

1) **Filgotinib and the next-generation JAK inhibitor class continue to take mind-share within autoimmune disorders:** We attended the annual American College of Rheumatology (ACR) meeting during October 2018 and also hosted a dinner with the attending management team from Galapagos. Comparing the conversations with key opinion leaders during the ACR 2018 versus the prior year, the mindshare of the JAK inhibitor class has greatly expanded, notably making it into the keynote discussion regarding systemic lupus erythematosus. The genesis of growing JAK mindshare is likely attributable to the oral dosing of small molecule JAK inhibitors, versus the injectable biologic drug axis that currently dominates the autoimmune treatment landscape, and the cadence of data demonstrating comparable effectiveness to the approved biologic drugs broadly (anti-TNF, IL-17, IL-23). **Specifically, we think the presentation of the ORAL-STRATEGY study with tofacitnib set the stage during ACR 2017 for the strong clinical trial read-outs from both filgotinib and upadacitinib during 2018. Overall, we forecast the current class of JAK inhibitors (baricitinib, filgotinib, tofacitinib, upadacitinib) reaching ~$11B in sales during 2023E, which we think is a relatively reasonable market build compared to the current ~$38B in global sales generated by the anti-TNF injectable biologic class, or the ~$12B generated by the current class of Interleukin targeted biologic therapies.**

2) **Clinical data has steadily built the case for filgotinib as a best-in-class JAK inhibitor during 2018:** FINCH-2 results have provided a first look at cross comparability to the rest of the JAK class within a pivotal trial setting. The FINCH-2 study design evaluated filgotinib in Rheumatoid Arthritis (RA) patients that have had an inadequate response to bDMARD therapy, which generally means that the patient population will have been experienced with anti-TNF therapy. **Notably, filgotinib recorded a ~28% spread above the placebo group for patients achieving ACR50, and ~15% for ACR70, which were both numerically higher than what was recorded for the other JAK inhibitors across comparable studies. Regarding safety, the compendium of clinical data for filgotinib (patient years' experience) indicates that the drug may have the lowest recorded rate of deep vein thrombosis/ pulmonary embolism/pulmonary embolism (DVT/ PE) of the current JAK class, which may owe the high selectivity of the drug for JAK1 over JAK2. DVT/PE event rates have been a focus for the new JAK inhibitors since the U.S. FDA limited approval for baricitinib in the treatment of RA to the lower dose level (2mg) as a result of unacceptably high rates of DVT/PE occurred within the 4mg cohort with inadequate added clinical efficacy.**

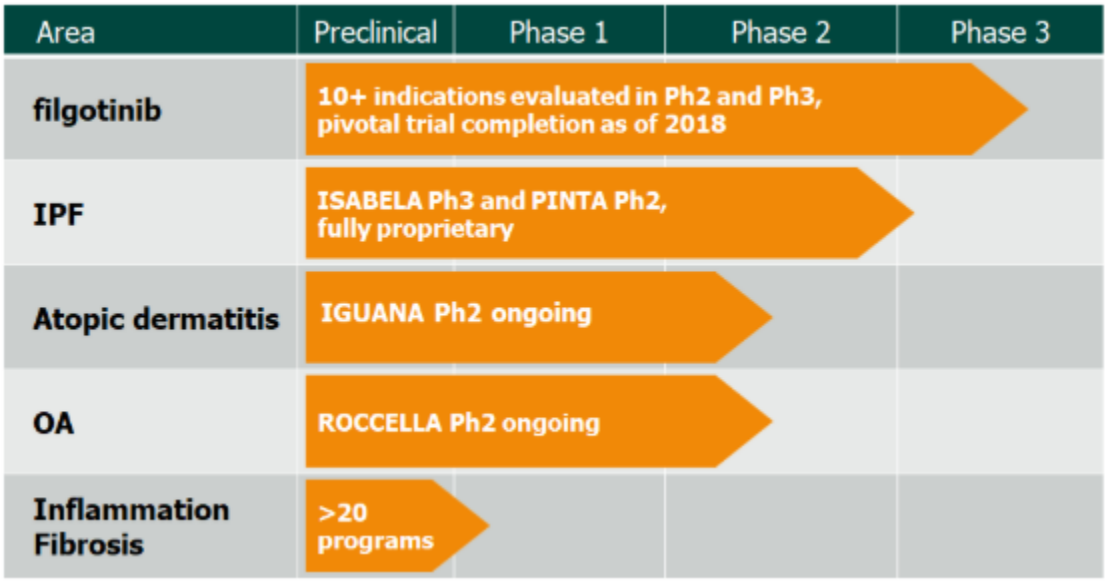
3) **Expanding pipeline with a removal of the AbbVie Cystic Fibrosis overhang helps focus attention on new value drivers into 2019:** We expect a cadence of data regarding the Idiopathic Pulmonary Fibrosis (IPF) program during 2019. The results presented during 2018 for GLPG1690 (FLORA study) supported moving the program into a Phase 3 study (ISABELA), which commenced during 2H2018**.** Galapagos announced the PINTA Phase 2 trial to evaluate GLPG1205 during July 2018 and with enrollment started during 2H2018. **New treatments for IPF are a high priority, as the two most widely used disease modifying drugs on the market (Esbriet and Ofev) only slow disease progression, and the median survival post diagnosis is 3-5 years. Our model currently assumes low single digit market penetration and benchmark pricing to Esbriet and Ofev, which supports GLPG1690 reaching +$800M in annual sales during 2027E.**

Galapagos Background and Key Catalysts

Galapagos NV is a clinical-stage biopharma company that is researching and developing novel small molecules for the treatment of autoimmune (inflammatory) disorders, fibrotic disorders and metabolic diseases. Galapagos originally contracted with large biopharma companies as a unique drug discovery platform that was able to mimic *in vivo* profiles of therapeutic compounds using *in vitro* disease assays. The company was founded in 1999, and is headquartered in Mechelen, Belgium. GLPG shares are listed on Euronext Amsterdam in the Netherlands, as well as American Depository Receipt (ADR) through NASDAQ.

Below are potential stock catalysts through 2019.

Galapagos Drug Pipeline



Source: Galapagos NV

Catalyst Calendar

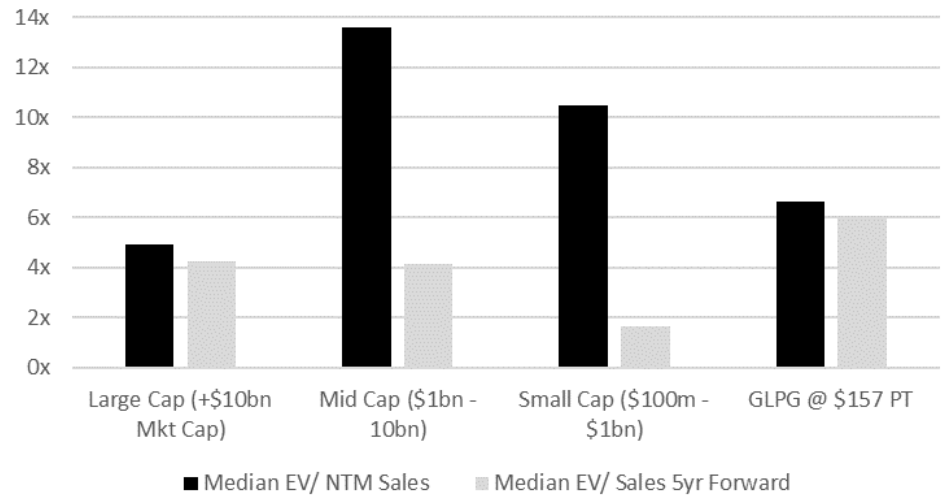
Clinical Program	Study Phase	Catalyst Date	Event	Notes
Filgotinib (Ulcerative Colitis)	Phase 3 (SELECTION study)	4Q18	Complete Enrollment in Phase 3 Selection trial	The SELECTION, Phase 3 study of filgotinib in moderate to severe Ulcerative Colitis patients is expected to complete its enrollment in Q42018.
Filgotinib (testicular safety study)	Phase 2 (MANTA study)	2019	Data-Readout	The MANTA, Phase 2 study of filgotinib is evaluating the testicular safety of filgotinib in patients with moderate to severe ulcerative colitis. After a brief dosage limitation from preclinical trials showing low-sperm count in rodents and dogs, the FDA lifted the limitation following filgotinib in RA being moved to Phase 3. We remain unclear whether the U.S. FDA would require full completion of MANTA ahead of the RA program NDA submission.
Filgotinib (Rheumatoid Arthritis)	Phase 3 (FINCH 1 study)	1H19	Data-Readout	Following FINCH-2's data readout, FINCH-1 is observing filgotinib + methotrexate in patients with moderate to severe active Rheumatoid Arthritis that did not respond to methotrexate alone. Company has said that the expected data readout is in 1H2019 (along with FINCH-3), and we expect the extended study will give more insight of the effectiveness of combining filgotinib with methotrexate.
Filgotinib (Rheumatoid Arthritis)	Phase 3 (FINCH 3 study)	1H19	Data-Readout	In addition to FINCH-1, data from the Phase 3 FINCH-3 study is expected in the first half of 2019. FINCH 3 is testing patients with moderate to severe RA, that are naïve to methotrexate. We believe the additional data readout of FINCH 3 (alongside already in FINCH-2, and the upcoming FINCH-1) will test our thesis that filgotinib has a best-in-class profile for the JAK inhibitors.

Raymond James research, Galapagos

Financial Analysis

Our 12-month forward price target of ~$157 values GLPG ADR shares at ~6x on a five year forward EV/sales basis (2023E) and ~6.6x on a projected 2022 EV/NTM sales basis. Valuation relative to the biopharma universe is benchmarked to the biopharma mid-cap group, and our price target basis is a +40% premium to the group's five year forward multiple but a 50% discount to the current next-twelve-month (NTM) trading multiple (Exhibit 1). The premium multiple we attribute to our five year forward sales forecast is justified by the de-risking of the filgotinib commercial pathway, and our expectation that Galapagos could be a profitable company with a high sales growth rate during 2023. Furthermore, the company platform allows for rapid expansion of therapeutic drug candidates, and as such, we expect the pipeline value of the company to rapidly expand over the next five years.

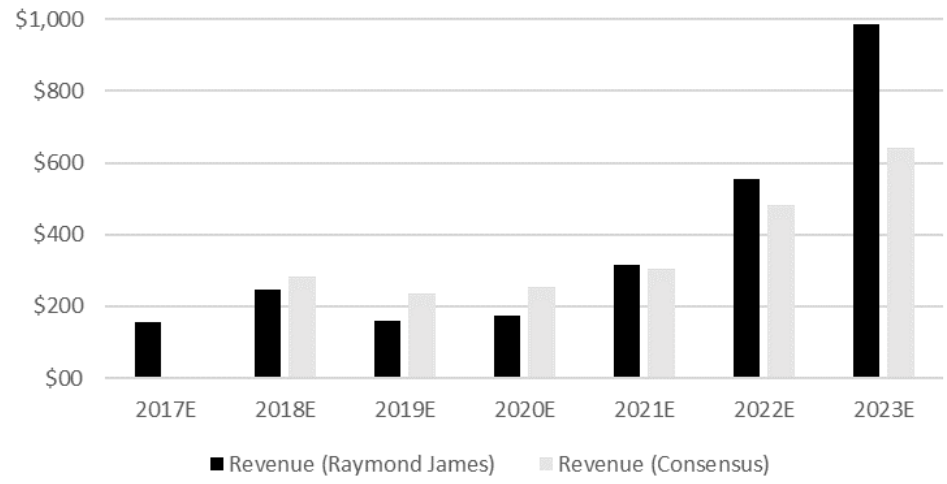
Exhibit 1. GLPG Price Target Valuation Relative to Peer Group



Source: Raymond James research

Our sales estimates for Galapagos are well ahead of the Street during 2023E (Exhibit 2). The basis for our higher estimates is likely attributable to a higher level of conviction for the commercial potential of filgotinib and the JAK-inhibitor class as compared to our peers. We include potential sales of GLPG1690, and note that our 2023E estimate of ~$157M seems to be well below the consensus estimate of ~$431M, although we would think that the consensus estimate is likely of low quality and driven by outliers.

Exhibit 2. Raymond James Estimates for GLPG Relative to Consensus



Source: Raymond James research, FactSet

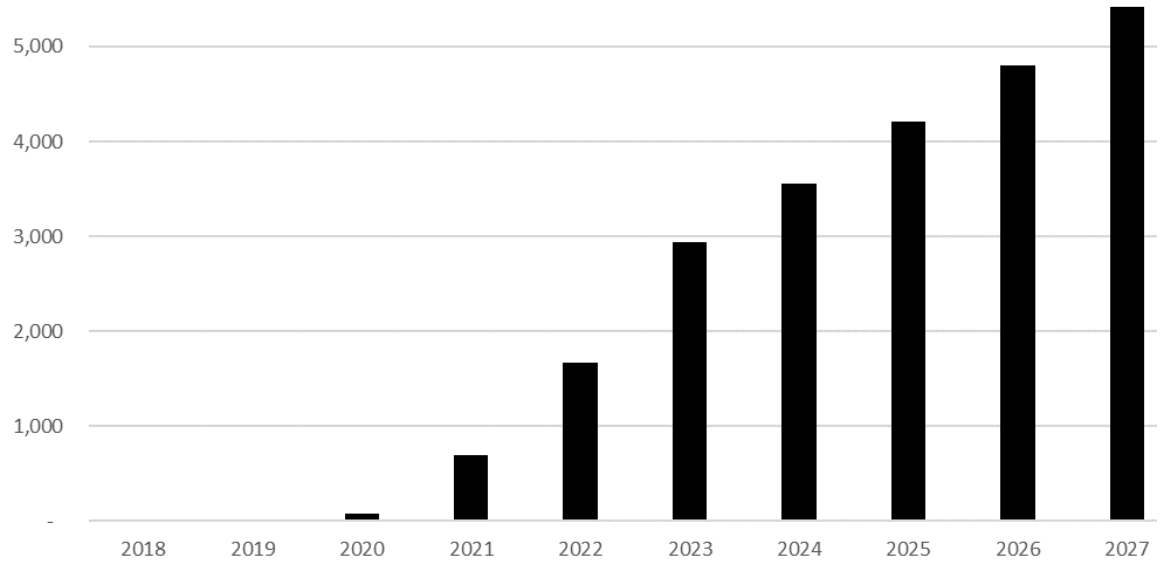
Drug Portfolio Analysis

Filgotinib – Galapagos/ Gilead

Filgotinib is an oral small molecule drug that modulates the immune system by inhibiting signaling through the JAK/STAT pathway. Filgotinib is highly selective for the JAK1/JAK3 kinases and is in direct competition with other small molecule drugs that target the JAK kinases for the treatment of autoimmune disorders. Specifically, the development of filgotinib is on near parallel clinical timeline as upadacitinib from AbbVie, which is also considered to be a leading next-generation JAK inhibitor in development. Filgotinib is currently in clinical testing for Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Crohn's Disease (CD), Ulcerative Colitis (UC), and several other related diseases. Filgotinib was developed by Galapagos and originally partnered with AbbVie during 2012, but during 2015, AbbVie returned the rights to filgotinib and moved forward with an internal program, which is now upadacitinib (formerly ABT-494). **Later in 2015, Galapagos re-partnered the filgotinib program with Gilead, which resulted in a high-royalty rate for Galapagos within the U.S. and 50-50 economics within Western Europe.**

Across all indications, we forecast total sales of filgotinib reaching ~$2.9B during 2023E (Figure 3), which may not be comparable to the current consensus estimate of ~$870m (given the revenue split between Galapagos and Gilead). As a reference, our sales estimates for filgotinib of ~$4.2B during 2025 are lower than AbbVie's ~$6.5B sales estimate for upadacitinib during 2025. ***A key difference in our forecasts for filgotinib relative to AbbVie's expectations for upadacitinib is our exclusion of Atopic Dermatitis (AD) from the list of potential indications for filgotinib.***

Exhibit 3. Raymond James Estimates for Filgotinib Sales (US$M)

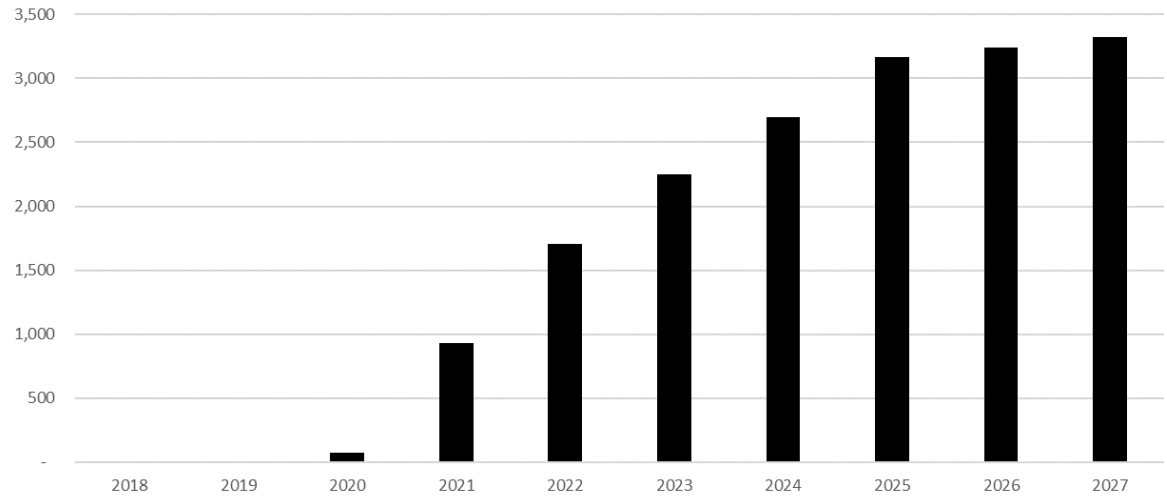


Source: Raymond James research

Filgotinib: Rheumatoid Arthritis

Filgotinib is being evaluated across four different pivotal studies for the treatment of patients with rheumatoid arthritis (RA). From the pivotal program, FINCH Studies 1-4, results of the FINCH-2 study were announced during 3Q2018, and data from the other FINCH studies are expected to read-out during 1H2019. Our current expectation is for Galapagos/Gilead to file for U.S. FDA approval of filgotinib in the treatment of rheumatoid arthritis during 2H2019, with a potential New Drug Approval during 2H2020. That said, Gilead does have a Priority Review Voucher that could be applied to the program, which would reduce the twelve month standard approval clock to eight months or less. We model a solid commercial launch into the crowded field of rheumatoid arthritis disease modifying drugs based upon our views that **1)** filgotinib has an emerging best-in-class profile and **2)** the JAK inhibitor class is poised to gain market share, as cumulative data across JAK inhibitor studies is suggesting advantages over traditional biologic disease modifying anti-rheumatic drugs (bDMARDS). **Our model forecasts sales of filgotinib in rheumatoid arthritis reaching ~$1.68B during 2023E** (Exhibit 4).

Exhibit 4: **Raymond James Estimates for Filgotinib Sales in Rheumatoid Arthritis (US$M)**



Source: Raymond James research

FINCH-2 results have provided a first look at cross comparability to the rest of the JAK class within a pivotal trial setting. The FINCH-2 study design evaluated filgotinib within rheumatoid arthritis patients that have had an inadequate response to bDMARD therapy, which generally means that the patient population will have been experienced with anti-TNF therapy. Evaluation of efficacy for the inadequate bDMARD patient population has been a cornerstone of the clinical study portfolio for the current on-market JAK class, tofacitinib (Xeljanz) and baricitinib (Olumiant), along with next-generation JAK inhibitor upadacitinib (Exhibit 5). Cross trial comparisons of filgotinib to the JAK-class within the bDMARD rheumatoid arthritis setting suggest that filgotinib could be one of the most potent drugs within the class. Across the standard efficacy scoring metrics for rheumatoid arthritis, filgotinib consistently demonstrated leading response rates, relative to the placebo control arm. **Notably, filgotinib recorded a ~28% spread above the placebo group for patients achieving ACR50, and ~15% for ACR70, which were both numerically higher than what was recorded for the other JAK inhibitors.**

Exhibit 5: **Cross Comparison of JAK-inhibitor Clinical Trial Results for RA**

Clinical Comparison of JAK Class (rel. Control) in Rheumatoid Arthritis	ACR20%	ACR50%	ACR70%	DAS28 (CRP) <2.6 (Clinical Remission)	DAS28 (CRP) <3.2 (Low Disease Activity)	Study Notes
Filgotinib FINCH-2 wk12 100mg (PBO)	26%	17%	8%	17%	22%	Inadequate response bDMARD
Filgotinib FINCH-2 wk12 200mg (PBO)	35%	28%	15%	14%	25%	Inadequate response bDMARD
Filgotinib FINCH-2 wk24 100mg (PBO)	20%	16%	12%	14%	17%	Inadequate response bDMARD
Filgotinib FINCH-2 wk24 200mg (PBO)	35%	27%	24%	18%	27%	Inadequate response bDMARD
Upadactinib SELECT-BEYOND wk12 15mg (PBO)	37%	22%	5%		29%	Inadequate response bDMARD
Upadactinib SELECT-BEYOND wk12 30mg (PBO)	28%	24%	11%		28%	Inadequate response bDMARD
Tofacitinib STUDY-V wk12 5mg BID (PBO)	17%	18%	12%			Inadequate response bDMARD
Tofacitinib STUDY-V wk12 10mg BID (PBO)	24%	20%	8%			Inadequate response bDMARD
Baricitinib STUDY-IV wk12 2mg BID (PBO)	22%	12%	11%	7%		Inadequate response bDMARD
Baricitinib STUDY-IV wk24 2mg BID (PBO)	18%	10%	10%	5%		Inadequate response bDMARD

Source: Raymond James research

Xeljanz was the first JAK inhibitor approved for the treatment of rheumatoid arthritis patients during 2012, and in our estimate, currently has a low-teen market share of the U.S. rheumatoid arthritis market. Prior to approval for use in psoriatic arthritis patients during December 2017, Xeljanz was generating +$1B in sales within the U.S. rheumatoid arthritis market. Although Xeljanz offered an oral solution in a market of dominant anti-TNF drugs that required injection or infusion, questions regarding relative effectiveness and safety were a limiting factor in broader adoption, historically. Those historical questions are now being answered, and from emerging datasets, the JAK class looks to be more efficacious and potentially more tolerable compared to the leading anti-TNF biologic therapies (adalimumab). The ORAL-Strategy study comparing tofacitinib (Xeljanz) to adalimumab (Humira) recorded stronger results in the tofacitinib + methotrexate arm (MTX) compared to adalimumab + MTX, but tofacitinib did not reach non-inferiority as a single-agent (Exhibit 6). However, given the relatively close trend between tofacitinib monotherapy compared to adalimumab + MTX, **we do see an opportunity for a potentially more potent JAK-inhibitor to bridge the non-inferiority gap. Supporting this view is the SELECT-COMPARE study of upadacitinib + MTX versus adalimumab + MTX, where the upadacitinib arm dominated across every relevant clinical measure of efficacy.**

Exhibit 6: **Cross Comparison of JAK-Inhibitor RA Clinical Trial Results Against Adalimumab (Anti-TNF)**

JAK Class vs adalimumab in Rheumatoid Arthritis	ACR20%	ACR50%	ACR70%	DAS28 (CRP) <2.6 (Clinical Remission)	DAS28 (CRP) <3.2 (Low Disease Activity)	Study Notes
Tofacitinib monotherapy (ORAL-Strategy) 26wk	65%	38%	18%	21%	41%	4 - 7% anti-TNF exp
Tofacitinib + MTX (ORAL-Strategy) 26wk	73%	46%	25%	31%	46%	4 - 7% anti-TNF exp
Adalimumab + MTX (ORAL-Strategy) 26wk	71%	44%	21%	28%	47%	4 - 7% anti-TNF exp
Tofacitinib monotherapy (ORAL-Strategy) 52wk	62%	39%	21%	24%	41%	4 - 7% anti-TNF exp
Tofacitinib + MTX (ORAL-Strategy) 52wk	70%	48%	29%	30%	47%	4 - 7% anti-TNF exp
Adalimumab + MTX (ORAL-Strategy) 52wk	68%	46%	26%	35%	52%	4 - 7% anti-TNF exp
Upadacitinib 15mg + MTX (SELECT-COMPARE) 12wk	71%	45%	25%	29%	45%	MTX inadequate response
Adalimumab 40mg EOW + MTX (SELECT-COMPARE) 12wk	63%	29%	13%	18%	29%	MTX inadequate response
Placebo + MTX (SELECT-COMPARE) 12wk	36%	15%	5%	6%	14%	MTX inadequate response

Source: Raymond James research, Abbvie, Pfizer

We view a future study of a monotherapy JAK inhibitor reaching non-inferiority to an anti-TNF agent + MTX as a potential disruptor to the anti-TNF dominated axis within rheumatoid arthritis. The rationale for our view is two-fold, **1)** anti-TNF agents are generally dependent on a methotrexate backbone to prevent the development of auto-antibodies that render the drugs useless, and **2)** methotrexate can add toxicity and tolerability issues to the dosing regimen (Exhibit 7). While we have not seen an ORAL-Strategy clinical study design announced for either filgotinib or upadacitinib, we would note that both agents are being tested in the front-line setting for methotrexate naïve patients.

Exhibit 7: **Adverse Event Report From ORAL-Strategy Study**

Adverse Event Report of ORAL-Strategy	Tofacitinib Mono	Tofacitinib + MTX	Adalimumab + MTX
Patients with treatment-related Adverse Events	26%	30%	35%
Patients with serious Adverse Events	9%	7%	6%
Patients with Severe Adverse Events	6%	5%	6%
Patients Discontinuing due to Adverse Events	6%	7%	10%
Serious infections	2%	3%	2%
Herpes Zoster	1%	2%	2%
Opportunistic Infections	1%	1%	1%
Tuberculosis	0%	1%	0%

Source: Raymond James research, Pfizer

Datasets across the FINCH program will be needed for a full assessment of the safety and tolerability of filgotinib, but data taken from the DARWIN studies have not raised any flags regarding adverse events. The DARWIN-2 study was filgotinib monotherapy compared to placebo, which avoided a confounding safety signal from methotrexate usage (DARWIN-1), and filgotinib as a monotherapy agent displayed no concerning imbalances from the summary of adverse events report relative to the placebo control arm (Exhibit 8).

Exhibit 8: **Adverse Event Report From DARWIN-2 Study**

Adverse Event Report of DARWIN-2 (filgotinib mono), 12wk cohort	Placebo	Filgotinib 100mg	Filgotinib 200mg
Treatment Emergent Adverse Event (TEAE)	39%	33%	44%
Serious TEAE	1%	0%	4%
Serious TE Infection	0%	0%	1%
Death	0%	0%	0%
Permanent Discontinuation of Study due to TEAE	6%	0%	1%

Source: Raymond James research, Galapagos

Concerns regarding a JAK-class safety affect around deep vein thrombosis and pulmonary embolism have been a focal point of conversation as the datasets evolve. In our view, these concerns have been primarily driven by the U.S. FDA review of DVT/ PE event rates with baricitinib, which prompted the U.S. FDA to deny baricitinib approval of the higher 4mg dose that was submitted. We will not have conclusive data until we have the full FINCH program datasets, but our underlying thesis is that inhibition of JAK-2 is the root cause of DVT/ PE events, and the selectivity of filgotinib for JAK-1 and JAK-3 has prevented this safety signal from emerging within the current datasets. Safety data from the DARWIN-3 108 week Open Label Study supports our view, as there were no DVT/ PE events within the filgotinib monotherapy arm, and only one DVT leading to PE event within the 100mg BID filgotinib + MTX cohort (Exhibit 9).

Exhibit 9: **Adverse Event report from DARWIN-3 study**

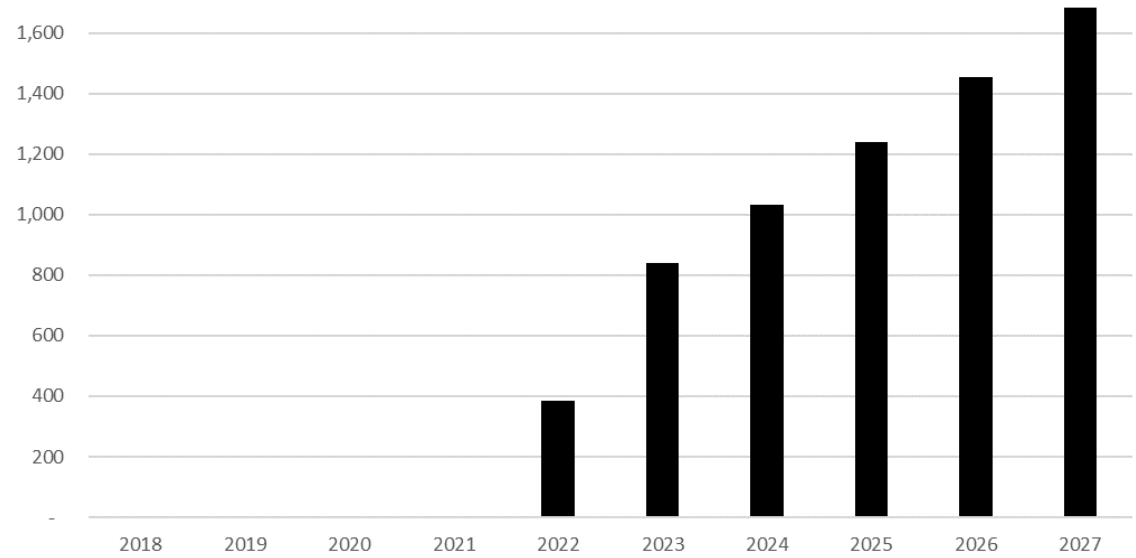
Adverse Event Report of DARWIN-3 (filgotinib), 108wk Open Label Extension, Events per 100 PYE	Filgotinib 100mg BID + MTX	Filgotinib 200mg QD + MTX	Filgotinib 200mg QD
Serious TEAEs for Infections	1.2	0.6	2.2
Malignancy (ex NMSC)	0.8	0.4	0.7
Herpes Zoster	1.2	1.5	1.1
Deep Vein Thrombosis	0.2	0	0
Pulmonary Embolism	0.2	0	0
Active Tuberculosis	0	0	0

Source: Raymond James research, Galapagos

Filgotinib: Inflammatory Bowel Disease (IBD), Crohn's Disease and Ulcerative Colitis

Filgotinib is currently being tested across a number of active Phase 3 studies for inflammatory bowel disease (DIVERSITY and SELECTION programs) that are expected to support a commercial launch in both Crohn's disease and ulcerative colitis during 2022. Xeljanz was approved during May 2018 as the first oral immunomodulatory medication for chronic use in the treatment of moderate to severe ulcerative colitis. While it is too early to predict the market dynamics for Xeljanz within IBD, and implications for the JAK class broadly, we view the entrance several years ahead of filgotinib as a positive for changing the current axis of treatment with biologic therapies. Specifically, we see the JAK class as 'maintenance' medication, versus the approved biologic therapies that will likely remain as the choice for 'induction' treatment when a patient presents with a disease flare. Data for filgotinib within the IBD space is currently limited to the Phase 2 FITZROY study, which was published during December 2016. We are optimistic that the JAK inhibitor class can find utilization within the IBD treatment paradigm, but take a conservative approach to modeling the market opportunity until we have a more robust dataset. **Our model forecasts sales of filgotinib in IBD reaching ~$839M by 2023 (Exhibit 10). We think this is reasonable given that Entyvio is expected to surpass +$2B in IBD sales during 2018 after being launched during 2016.**

Exhibit 10: **Raymond James Estimates for Filgotinib Sales in IBD (US$M)**



Source: Raymond James research

The primary Phase 3 studies for filgotinib in the treatment of Crohn's disease (DIVERSITY) and ulcerative colitis (SELECTION) are both expected to be completed during December 2019, with long term extension studies for both programs scheduled to finish during 2022. The Phase 2 FITZROY study evaluated filgotinib 200mg QD dosing in both anti-TNF naïve and anti-TNF experienced Crohn's disease patients. Comparing the dataset on the standard Clinical Response (100pt reduction in CDAI) and Clinical Remission (CDAI below <150pts), the percentage of patients achieving meaningful clinical outcomes relative to placebo looks generally in line with that of the IL-23 class (risankizumab and Stelara) and JAK-peer upadacitinib (Exhibit 11). **Our current expectation is that when full datasets are available, the IL-23 biologic class may be superior at induction therapy versus the JAK-class, but at this time-point, we cannot say that with certainty.**

Exhibit 11: **Cross comparison of JAK-inhibitor CD clinical trial results against IL-targeted biologic drugs**

Responses vs Placebo	Risankizumab (anti-TNF exp.) 200mg	Risankizumab (anti-TNF exp.) 600mg	Stelara CD-1 (anti-TNF exp.) 6mg/kg	Stelara CD-2 (anti-TNF naïve) 6mg/kg	Upadacitinib (anti-TNF exp.) 12mg BID	Upadacitinib (anti-TNF exp.) 24mg BID	Filgotinib (anti-TNF naïve) 200mg QD	Filgotinib (anti-TNF exp.) 200mg QD
Clinical Response (100pt CDAI Chg.) wk8			18%	26%				
Clinical Remission (<150pt CDAI) wk8			14%	20%				
Clinical Response (100pt CDAI Chg.) wk10							23%	15%
Clinical Remission (<150pt CDAI) wk10							47%	8%
Clinical Response (100pt CDAI Chg.) wk12	16%	21%						
Clinical Remission (<150pt CDAI) wk12	9%	22%						
Clinical Response (100pt CDAI Chg.) wk16					17%	29%		
Clinical Remission (<150pt CDAI) wk16					23%	15%		

Source: Raymond James research

The 20 week assessment of adverse events from the FITZROY study does not contain any unexpected events, and generally seems consistent with the totality of filgotinib's current safety profile (Exhibit 12). The one notable signal within the report is the relatively high rate of discontinuations, ~29%, within the 200mg arm up to 20 weeks, although it is unclear what percentage of discontinuations occurred between weeks 10-20. During the first 10 week leg of the study, ~13% of patients discontinued the filgotinib 200mg arm versus ~16% in the placebo arm. Discontinuations due to safety in the first 10 week analysis was ~3% for the filgotinib 200mg arm versus ~7% for placebo.

Exhibit 12: **FITZROY Adverse Event Summary**

Adverse Event Report of FITZROY (filgotinib), 20wk (re-assignment at wk10)	Filgotinib 200mg QD <> 100mg QD	Filgotinib 200mg QD	Placebo
Serious TEAEs	3%	16%	14%
Severe TEAEs	3%	18%	23%
Serious TEAEs for Infections	0%	5%	0%
TEAE leading to Discontinuation	13%	29%	27%
Herpes Zoster	3%	0%	0%
Pneumonia	0%	1%	0%

Source: Raymond James research

Xeljanz is the only current available dataset to use as a proxy for the JAK-Class in UC, and Entyvio is one of the few non-TNF blocker biologic therapies currently available for the treatment of ulcerative colitis. The results of both studies look quite similar for the induction (six weeks/eight weeks) and maintenance (52 week) time points (Exhibit 13). Overall, we would give an edge to the Xeljanz studies, given that they enrolled a higher percentage of patients that had previously failed an anti-TNF therapy.

Exhibit 13:

Cross Comparison of Xeljanz UC Clinical Trial Results Against Entyvio

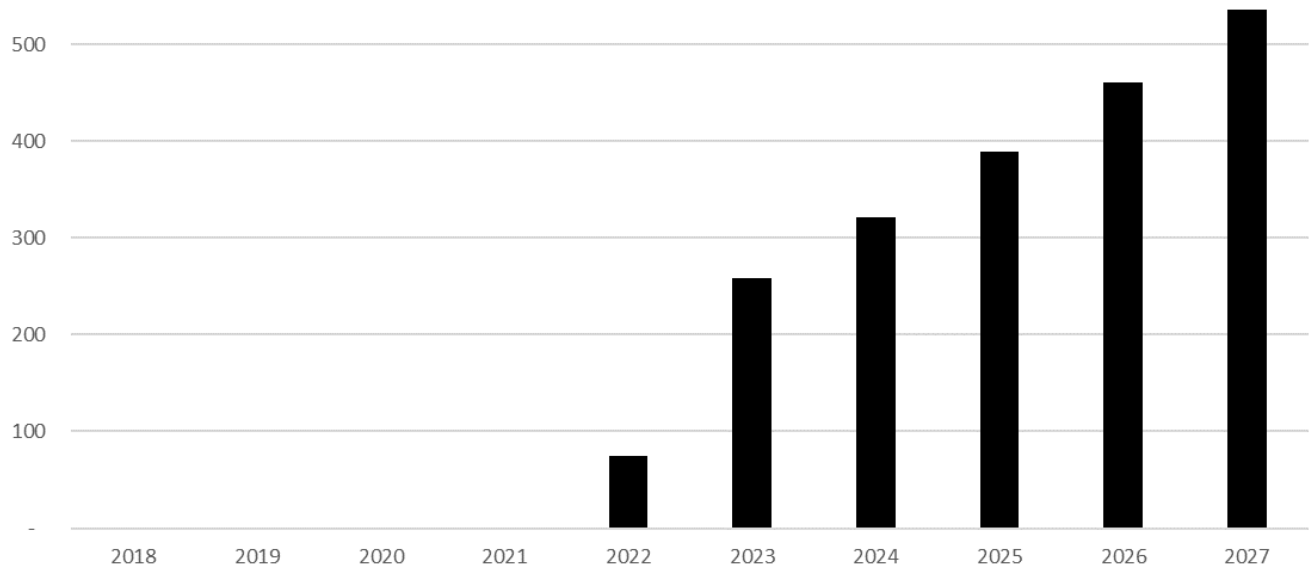
Ulcerative Colitis Phase 3 Study Results: Responses vs Placebo	Xeljanz 10mg BID (~51 - 52% prior anti-TNF)	Entyvio 300mg (~32 - 39% prior anti-TNF)
Remission at Week 6		12%
Remission at Week 8	11%	
Remission at Week 52	30%	26%

Source: Raymond James research, Pfizer, Takeda

Filgotinib: Psoriatic Arthritis (PsA)

The Phase 2 EQUATOR study evaluating filgotinib for the treatment of moderate to severe psoriatic arthritis patients announced positive results during May 2018. The results were generally supportive of moving into a pivotal program, and we tentatively benchmark a commercial launch during 2H2022 based upon a 12-month lag on upadacitinib, which started a pivotal program for psoriatic arthritis during April 2017 (SELECT-PsA 1 and SELECT-PsA 2). Given the uncertainty around time-to-market and a more robust dataset for filgotinib in psoriatic arthritis, we take a conservative approach to our modelling assumptions for sales of filgotinib. **We currently forecast filgotinib surpassing +$500M in revenues within the psoriatic arthritis market during 2027.**

Exhibit 14: **Raymond James Estimates for Filgotinib Sales in Psoriatic Arthritis (PsA) (US$M)**



Source: Raymond James research

The EQUATOR study results seem comparable to the pivotal studies evaluating Xeljanz in both anti-TNF naïve and experienced patients with active moderate to severe psoriatic arthritis (Exhibit 15). **At this juncture, we cannot posit whether one dataset looks better than the other, but can say the results of the filgotinib arm relative to placebo look more akin to the Xeljanz anti-TNF naïve cohort.** The EQUATOR study design allowed for anti-TNF experienced patients to enroll, but the patient mix is currently unreported. Regarding the limited safety data of EQUATOR provided by company communication, there was one case of fatal pneumonia (1-2%) within the filgotinib cohort and one case of herpes zoster (1-2%), but importantly there were no reported cases of thromboembolism.

Exhibit 15: **Cross Comparison of Filgotinib PsA Clinical Trial Results Against Xeljanz**

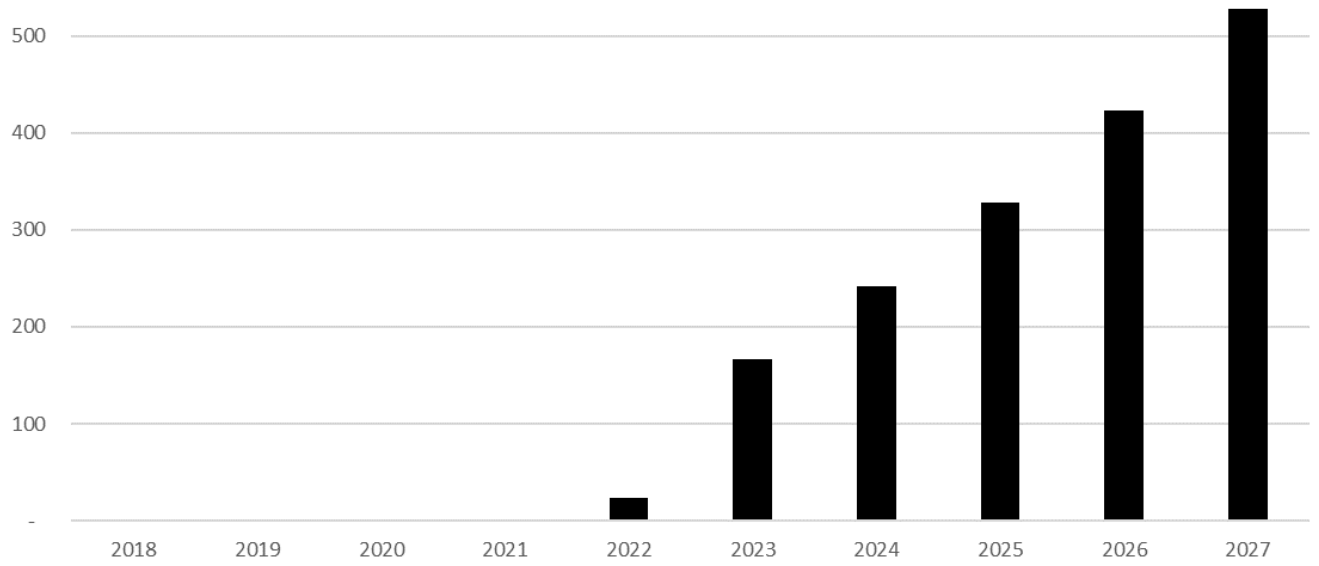
Psoriatic Arthritis Clinical Response vs Placebo	Filgotinib	Xeljanz 10mg BID (anti-TNF naïve)	Xeljanz 10mg BID (anti-TNF exp)
ACR20% wk12		28%	23%
ACR50% wk12		30%	13%
ACR70% wk12		9%	4%
ACR20% wk16	47%		
ACR50% wk16	33%		
ACR70% wk16	17%		

Source: Raymond James research, Galapagos, Pfizer

Filgotinib: Ankylosing Spondylitis (AS)

Positive results from the Phase 2 TORTUGA study evaluating filgotinib in patients with Ankylosing Spondylitis were reported during September 2018. No drugs within the JAK-class are currently approved for the treatment of Ankylosing Spondylitis, although upadactinib is also being tested in an active Phase 2 study (SELECT-Axis was started roughly six months after TORTUGA during 2017). Our current assumption that filgotinib could reach commercialization in Ankylosing Spondylitis during 2022 is predicated on the timeline for upadacitinib set-forth by AbbVie, for the same year in the same indication, and also taking into account that the upadacitinib program may be roughly six months behind filgotinib. **We use conservative estimates given the limited dataset, and forecast sales of filgotinib in Ankylosing Spondylitis reaching over $500M during 2027** (Exhibit 16).

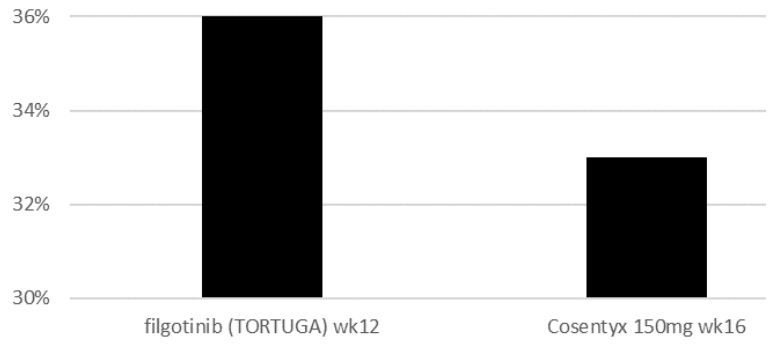
Exhibit 16: **Raymond James Estimates for Filgotinib Sales in Ankylosing Spondylitis (AS) (US$M)**



Source: Raymond James research

We hesitate to draw conclusions from the currently limited dataset of the TORTUGA study, but can say that on the basis of the ASAS20 response measure, the relative percentage of patients achieving ASAS20 response at 12 weeks looks relatively in line with the 16 week cohort from the Phase 3 study of Cosentyx for the treatment of Ankylosing Spondylitis (Exhibit 17). Regarding safety, only highlights currently available from the TORTUGA study are that one patient experienced a non-serious deep venous thrombotic event and one patient was hospitalized for pneumonia.

Exhibit 17:
Cross Comparison of Filgotinib AS Clinical Trial Results Against Cosentyx



Source: Raymond James research, Galapagos, Novartis

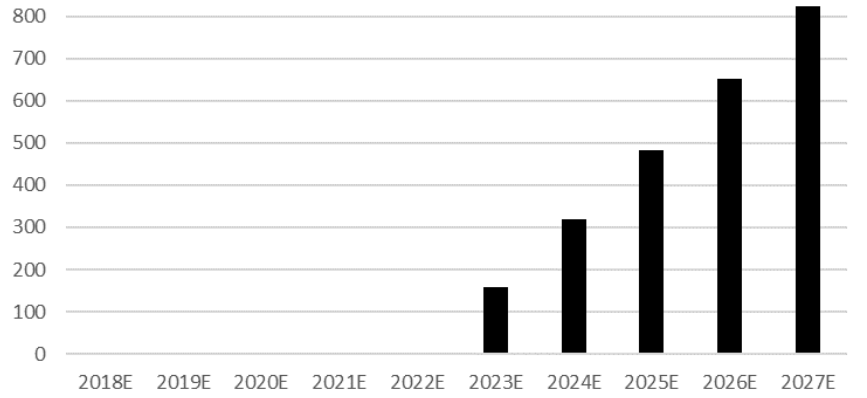
GLPG1690: Idiopathic Pulmonary Fibrosis (IPF)

GLPG1690 is an oral small molecule drug that inhibits autotaxin for the treatment of idiopathic pulmonary fibrosis (IPF). Autotaxin is a secreted lysophospholipase D that mediates production of lysophosphatidic acid (LPA), which effects cellular signaling through LPA Receptors 1-6. Signaling through the LPA receptors is widely functional across tissue types and dysregulation has been linked to a wide range of diseases including cancer and autoimmunity. Increased concentrations of both autotaxin and LPA have been recorded within the lung tissue of people diagnosed with IPF. **Results from the Phase 2 FLORA study of GLPG1690 for the treatment of IPF were published in the Lancet Respiratory Medicine journal during August 2018. The FLORA study results supported the advancement of GLPG1690 into a potentially pivotal Phase 3 study, named ISABELA, which commenced during 2H2018. New treatments for IPF are a high priority, as the two most widely used disease modifying drugs on the market (Esbriet and Ofev) only slow disease progression, and the median survival post diagnosis is 3-5 years.**

Given that the ISABELA program started during October 2018 and is not expected to complete evaluation of the ~750 patient enrollment target until YE2021, we do not forecast a U.S. FDA approval until 2023. Modeling the revenue opportunity for GLPG1690 is difficult given the limited current dataset and a likelihood that other drugs targeting IPF are approved within the interim. **For example, Fibrogen's pamrevlumab (FG-3019) that targets connective tissue growth factor (CTGF) reported strong results within the Phase 2 PRAISE study, and subsequently gained Fast Track Designation from the U.S. FDA during September 2018.**

Our model currently assumes low single digit market penetration and benchmark pricing to Esbriet and Ofev, which supports GLPG1690 reaching over $800M in annual sales during 2027E (Exhibit 18).

Exhibit 18: **Raymond James Estimates for GLPG1690 Sales in IPF (US$m)**



Source: Raymond James research