August 18, 2019

OUTPERFORM

Reason for report:

COMPANY UPDATE

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SVBLEERINK

ABBVIE INC.

Upa Gets Class, but Not Product Thrombosis Labelling; P/T $91

• **Bottom Line:** On Friday, August 16, the FDA approved AbbVie's JAK inhibitor, Rinvoq (upadacitinib) with a 15mg dose, for the treatment of adult patients with moderate to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate (MTX). The approval was widely anticipated and based on positive results of 5 Phase 3 studies (~2800 upa patients treated in RA pivotal studies). Rinvoq's label is consistent with the clinical trial results, but does not include methotrexate naïve disease, and the labeled safety liabilities are consistent with two other approved JAKs (tofacitinib and baricitinib). Rinvoq has a black box warning for increased risk of serious infections, malignancy, and thrombosis, despite having a better safety profile in its pivotal trials. However, the safety language excludes specific mention of upadacitinib being associated with thrombosis events, despite their inclusion in the label. This suggests that the FDA now regards these events as class liabilities, regardless of what is reported from pivotal trials. This standard could be negative for Gilead's (MP) filgotinib which is depending on greater JAK1 specificity, and lower adverse event liabilities, for its long term positioning. We are increasing our probability of success (PoS) for upadicitinib (Rinvoq) from 65% to 100% and our long term risk-adjusted peak sales forecast for upa increases from ~$3bn to ~$5bn. Our new upa forecast is 18% below consensus for 2019 but 11-25% higher from 2020-2024E. Based on these changes, we increased our price target for AbbVie to $91 (from $88) and reiterate our Outperform rating for AbbVie's stock.

Key Stats:	**(NYSE: ABBV)**
Sector:	**Biotechnology**
S&P 500 Health Care Index:	**1,045.87**
Price:	**$64.43**
Price Target:	$91.00 from $88.00
Methodology:	Average of DCF, P/E, P/Sales
52 Week High:	$100.23
52 Week Low:	$62.66
Shares Outstanding (mil):	1,488.0
Market Capitalization (mil):	95,871.8
Cash Per Share:	$(18.00)
Net Debt to Total Capital:	(1)%
Dividend (ann):	$4.28
Dividend Yield:	6.6%
Est LT EPS Growth:	6%
P/E to LT EPS Growth (FY20):	1.19

Completion: August 18, 2019, 4:13PM EDT.
Distribution: August 18, 2019, 4:13PM EDT.
Cash Per Share: 2019E net cash
Price: Intra-day price
Est LT EPS Growth: '19E-'22E

Dec Yr	1Q	2Q	3Q	4Q	FY Rev	1Q	2Q	3Q	4Q	FY EPS	P/E
2018A	$7,934.0	$8,258.0	$8,236.0	$8,305.0	$32,733.0	$1.88	$2.01	$2.15	$1.91	$7.94	8.1x
2019E - New	**$7,828.0A**	**$8,255.0A**	**$8,315.0**	**$8,559.0**	**$32,957.0**	**$2.15A**	**$2.27A**	**$2.18**	**$2.20**	**$8.81**	**7.3x**
2019E - Old	$7,828.0A	$8,255.0A	$8,313.0	$8,547.0	$32,943.0	$2.15A	$2.26A	$2.18	$2.20	$8.80	NM
2020E - New	**--**	**--**	**--**	**--**	**$35,069.0**	**--**	**--**	**--**	**--**	**$9.01**	**7.2x**
2020E - Old	--	--	--	--	$34,956.0	--	--	--	--	$8.97	NM

Source: Company Information and SVB Leerink LLC Research.
Revenues in $MM; Diluted EPS including Option Expense Presented

INVESTMENT THESIS

Our price target for AbbVie (ABBV) is $91 per share and the stock is rated Outperform. Having established itself as an independent pharmaceutical company, AbbVie has transitioned to a new phase in terms of scale and operating efficiency with the planned acquisition of Allergan in early 2020. Allergan brings $16bn in new revenue, from markets and categories outside AbbVie's current product portfolio. Allergan's esthetics business is one of the most enduring franchises in the industry, and is unlikely to be adversely affected by many of the risks facing the traditional branded drug business (patents, pricing, reimbursement, importation, etc.).

While we are not necessarily fans of consolidation for its own sake, we see AbbVie bringing discipline and decisiveness to Allergan's portfolio, and are confident that AbbVie can maximize the value of the Allergan esthetics business, and its cash flows, without disrupting the effectiveness of the business unit and its innovative culture and commercial effectiveness. Adding Allergan dilutes AbbVie's exposure to Humira from 46% to ~30%, which is positive, and offers the company significant opportunities for operating efficiencies over and above the $2bn in synergies already disclosed. AbbVie faces many challenges to their Humira franchise (rebate reform, patent challenges, biosimilar pathway changes, patent reform) but the product's cash flows through 2023 seem relatively secure. Beyond these two cornerstones, AbbVie's hematology business should grow strongly for several years at least, and the emerging combined neuroscience portfolio should generate significant revenue, and positive cash flow, by the early 2020's. The most important pipeline programs for the combined company come from AbbVie (Skyrizi, Venclexta, Imbruvica new indications), but the most significant incremental opportunity is probably from Allergan's neurology (migraine) and psychiatry (schizophrenia) programs, which should boost AbbVie back into indications that the company has long since abandoned. We see the combined company delivering mid-single digit revenue growth through 2023, and high single digit EPS growth, and offering investors attractive low double digit dividend growth from a dividend yield of more than 6.5% today. We do not regard AbbVie's portfolio as particularly innovative today, and view the stock as a compelling trading vehicle from the mid $60's to a more reasonable post deal valuation in the $85-90 range.

Better efficacy, marginally better safety and less alarming warnings for upa label

As expected, Rinvoq received a class label with a similar black box warning to Pfizer's Xeljanz and Lilly's Olumiant (serious infections, malignancy and thrombosis) but managed to avoid more alarming wording such as fatal events and higher rate of all-cause mortality which are specifically described in the Xeljanz and Olumiant labels (Exhibit 1).

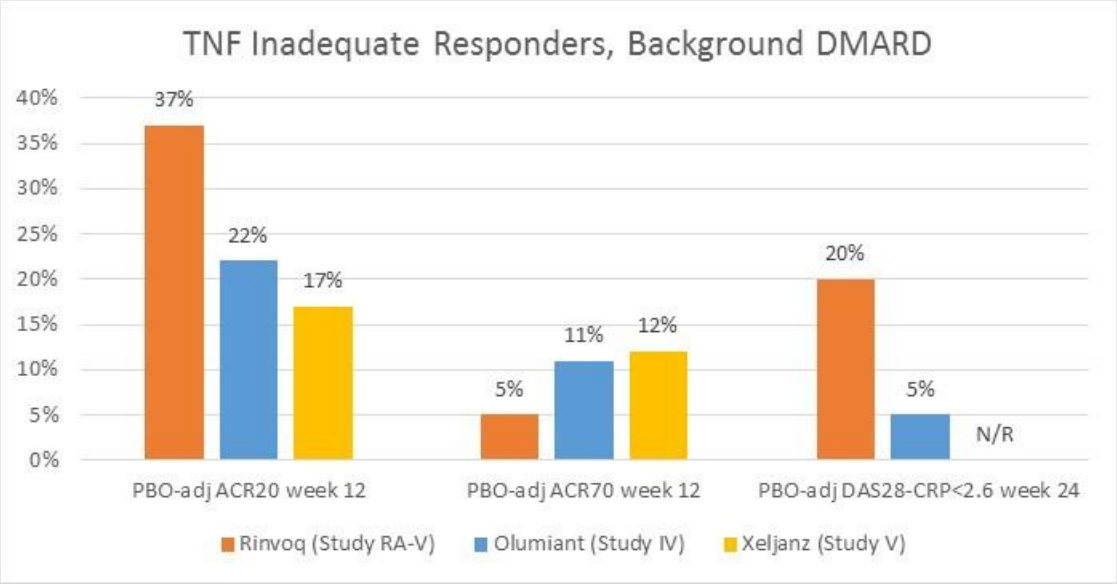
Exhibit 1: Comparison of Black Box Warnings

	Xeljanz	Olumiant	RINVOQ
Black Box Warning Headline	Serious infections, mortality, malignancy and thrombosis	Serious infections, malignancy and thrombosis	Serious infections, malignancy and thrombosis
Thrombosis Related Warnings	Rheumatoid arthritis patients with at least one cardiovascular (CV) risk factor had a higher rate of all-cause mortality and thrombosis with XELJANZ 10 mg twice daily vs. 5 mg twice daily or TNF blockers	Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with OLUMIANT. Patients with symptoms of thrombosis should be evaluated promptly.	Thrombosis, including deep vein thrombosis, pulmonary embolism, and arterial thrombosis, have occurred in patients treated with Janus kinase inhibitors used to treat inflammatory conditions

Source: Xeljanz, Olumiant and Rinvoq Prescribing Information

Although every trial is different, comparing the pivotal trials for Xeljanz, Olumiant and Rinvoq, in TNF inadequate responders, Rinvoq had a higher percentage of patients reaching placebo-adjusted ACR20 (American College of Rheumatology score), a slightly lower percentage reaching ACR70, and much better results on disease remission measured by Disease Activity Score (DAS28-CRP<2.6) (Exhibit 2).

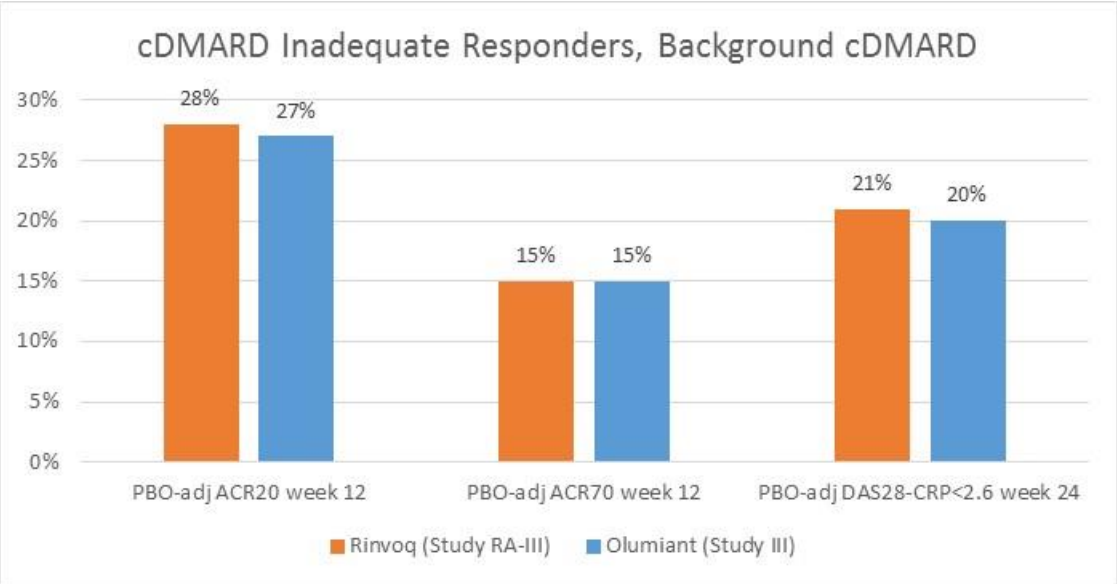
Exhibit 2 Comparison of Placebo-Adjusted Efficacy Data for TNF Inadequate Responders



Source: Xeljanz, Olumiant and Rinvoq Prescribing Information

For cDMARD (conventional disease-modifying anti-rheumatic drugs) inadequate responders, Rinvoq is largely comparable to Olumiant with PBO-adj. ACR20, PBO-adj. ACR70 and PBO-adj. DAS28-CRP<26 virtually the same. (Exhibit 3)

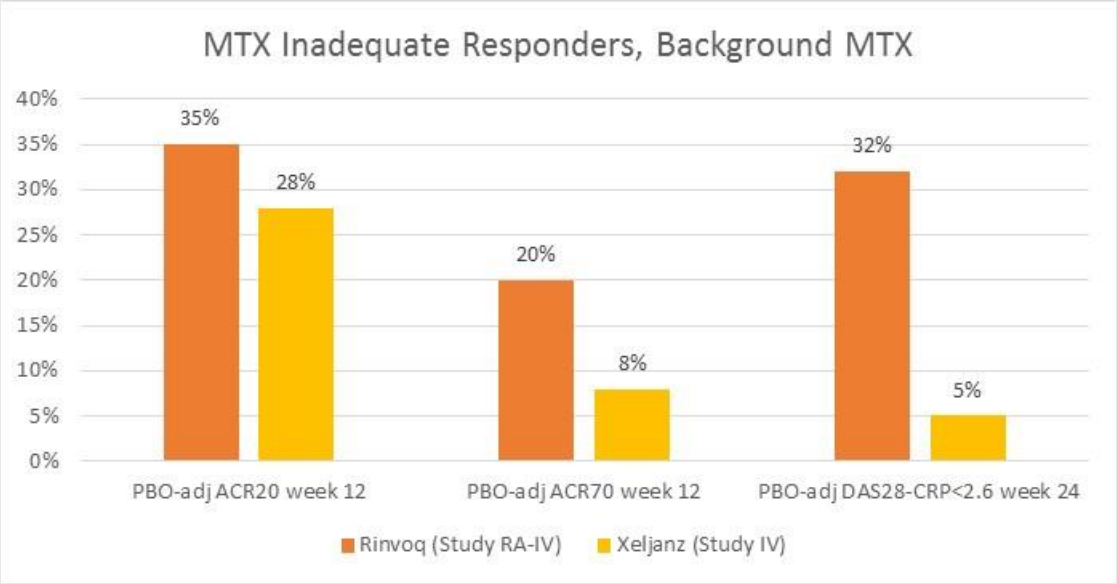
Exhibit 3 Comparison of Placebo-Adjusted Efficacy Data for cDMARD Inadequate Responders



Source: Xeljanz, Olumiant and Rinvoq Prescribing Information

Rinvoq's label looks better than Xeljanz in MTX inadequate responders, with a higher percentage of patients reaching PBO-adj ACR 20 response (35% vs. 28%), a higher percentage reaching ACR 70 response (20% vs. 8%) and much higher percentage reaching disease remission (DAS28-CRP<26) (32% vs. 5%). (Exhibit 4)

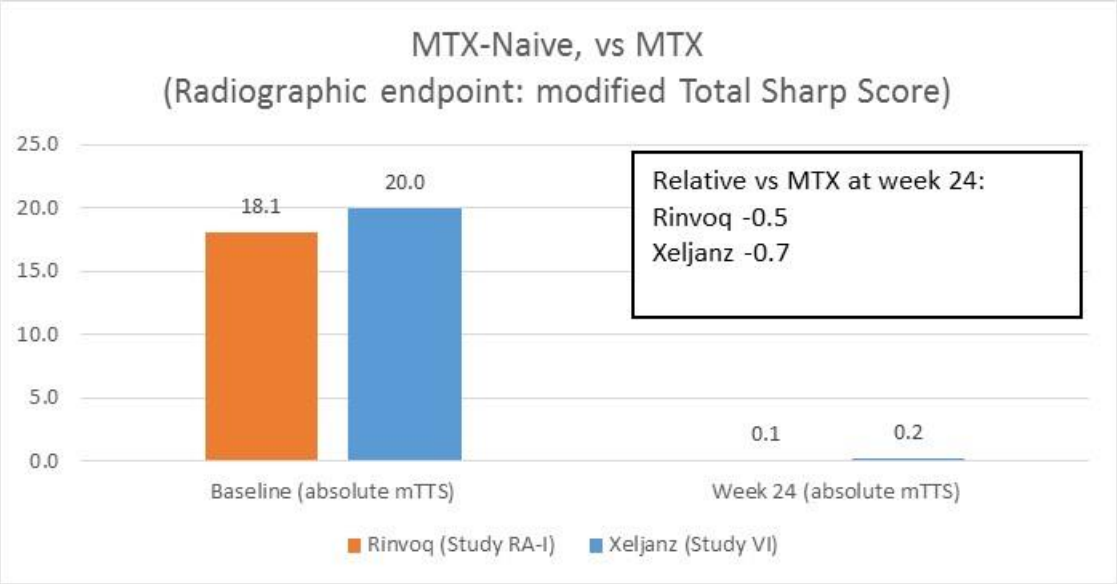
Exhibit 4 Comparison of Placebo-Adjusted Efficacy Data for MTX Inadequate Responders



Source: Xeljanz, Olumiant and Rinvoq Prescribing Information

Lastly on the efficacy side, Rinvoq showed similar effectiveness to Xeljanz in terms of changes in modified total sharp score based on the radiographic endpoint (Exhibit 5).

Exhibit 5 Comparison of Changes in Modified Total Sharp Score



Source: Xeljanz, Olumiant and Rinvoq Prescribing Information

Upadacitinib gets class labelling for major risks, filgotinib seems likely to as well

Although Rinvoq demonstrated better safety in its pivotal trials, with a lower venous thromboembolic event (VTEs) rate compared to placebo and Humira, the FDA has still insisted on applying class labelling for risk, giving the product a black box warning for thrombosis risk based on the occurrence of such events with tofacitinib and baricitinib. While such class labelling does limit Rinvoq's commercial opportunity, we now expect the whole JAK class, including the much-anticipated "safer JAK inhibitor" filgotinib, to receive similar labelling. With AbbVie's best-in-class commercial capability, we expect Rinvoq to outperform other JAKs, including filgotinib, as the multiple indications in development (RA, IBD, PsA) are ultimately commercialized.

Rinvoq to launch for RA in 1-2 weeks, derm and IBD label expansions on the way

AbbVie indicated that Rinvoq will be available in late August for second line treatment for RA after methotrexate (MTX). AbbeVie set the annual list price for Rinvoq at $59,000, which is largely in line with other JAKs. AbbVie also submitted the European Medicines Agency (EMA) application for upadacitinib late last year and should be approved there later this year. Upadacitinib is currently being studied in late stage trials for multiple diseases in dermatology and inflammatory bowel disease (IBD). Based on clinicaltrails.gov, we may expect Phase 3 readouts in atopic dermatitis (AD), Crohn's disease (CD) and psoriatic arthritis (PsA) in the first half of 2020.

Safety overview from the label

According to the label, out of 1,035 patients treated with Rinvoq 15mg in the pivotal study, 13.5% experienced upper respiratory tract infection (URTI), 4% higher than the placebo arm. Small differences (~+1%) were observed for other common adverse events including nausea, cough and pyrexia. In three placebo-controlled studies RA-II, IV, and V, the serious infection rate was twice as high in the Rinvoq 15mg group vs. placebo (4.6/100 pt years vs. 2.3/100 pt years). No major difference in serious infection rate was seen between the high dose group 30mg and the low dose group 15mg according to the 12-month exposure dataset. In terms of malignancy risk, low dose Rinvoq group appeared to be largely the same as placebo (1.1/100 pt year vs. 0.4), while high dose Rinvoq group showed higher risk compared to placebo (3.5 vs. 0.4). Conversely in the MTX-controlled studies, the malignancy rate is three time higher in low dose group vs. MTX-controlled arm (2.4 vs. 0.8) whereas high dose group had zero malignancy cases. Both Rinvoq and placebo group had 1 venous thrombosis event in the placebo-controlled studies. In the MTX-controlled studies, Rinvoq group had 1 venous thrombosis event (low dose), 1 venous thrombosis event (high dose), 1 arterial thrombosis event (high dose), compared to MTX group with 1 venous thrombosis event. Based on 12-month exposure dataset, high dose and low dose Rinvoq groups appeared to have a similar low venous and arterial thrombosis event rate.

Increase risk adjusted revenue; PT to $91 (from $88)

Based on the approval, we are increasing our PoS from 65% to 100% for upadacitinib/Rinvoq, and our peak global revenue forecast for upa increases from $3bn to $5bn, and our risk adjusted upa revenue forecast is largely in-line with AbbVie's guidance. Our new upa forecast is 18% below consensus for 2019 but 11-25% higher from 2020-2024E. Based on these changes, we increased our price target to $91 (from $88) and reiterate our Outperform rating for AbbVie's stock.

VALUATION

Our price target for AbbVie (ABBV) is based on a simple average of three approaches that we believe are a reasonable basis for valuing the stock today. These approaches are simple price to earnings multiples for comparable large biopharmaceutical companies; price to sales multiples for large cap peer companies' stocks; and discounted cash flow (DCF). We apply peer EPS and revenue multiples using an average for large cap, large molecule therapeutic companies with mid-term growth and tail risk (CELG, GILD, BIIB, AMGN, AGN, BMY). Their average 2019 consensus EPS multiple of 10.0x applied to our current 2020 EPS estimate for ABBV of $9.01, gives a value of $90 in 2019. Using a 2019E revenue multiple for similar companies of 3.7x 2019E consensus sales, and applied to our 2020 revenue estimate for ABBV of $35bn, gives a 2019 value of $88. Lastly, our DCF valuation given a 6.9% WACC and a terminal cash flow growth rate of 0% beginning 2029E (after Humira biosimilar entry) gives a present value of $97. The average of these three methods is our current price target of $91. Upon completion of our analysis of quarterly results, we will revisit our price targets and at present they remain unchanged.

RISKS TO VALUATION

The risks to our view, outlook, and valuation for AbbVie include any major change in the price outlook, reimbursement coverage, labeling, or competitive position for Humira, the company's main product. Other risks include commercial or development disappointments for the company's follow-on programs in inflammatory diseases, for Imbruvica and Venclexta in expanded hematological malignancies, as well as the competitive positioning of the company's next-generation HCV therapy. Also, the company remains highly levered and committed to a growing dividend, and any reduction to forecasted EBITDA due to negative business trends would place the company's capital allocation strategy and dividend growth at risk. Opportunities for upside from our expectations include stronger-than-expected pricing, volume and share for Humira and emergence of more tangible demand for underappreciated elements of the company's early-to-mid stage pipeline assets, and potential label expansion opportunities to late stage opportunities.