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Bari Briefing Docs Ominous Approval Unlikely

Quick Note

This morning, the FDA released a briefing document ahead of the baricitinib ADCOM on April 23rd. Recall, the original NDA submission resulted in a CRL raising safety concerns on the risk of thrombosis and the overall risk/benefit of the drug. The issues were addressed with a re-submission on Dec. 4, 2017. We were expecting new clinical data on the lower dose (2mg) to better assess the risk/*benefit* of that dose. According to the briefing doc's, LLY's resubmission lacked sufficient safety on the 2mg dose. LLY also suggested a new dosing strategy for the label as part of the re-submission, which was not well received (start patients on 4mg, and taper to 2mg pending improvement). Overall, the briefing docs had a negative tone, especially in considering data LLY put together on rates of VTE in the RA population (see below, **Fig. 2**). Given the FDA response to the paucity of 2mg safety data, the availability of an equally efficacious drug (tofacitinib), and upcoming competitors (filgotinib and upadacitinib), we are increasingly pessimistic on the April 23rd ADCOM vote and the June 2018 PDUFA date.

We view a June 2018 approval as unlikely and note that US baricitinib is worth $3/share in our $102 target price. Additional studies are likely to be required prior to baricitinib approval in the US.

Further Delays Bode Well for PFE's Xeljanz, ABBV's Upadacitinib, and GLPG/GILD's Filgotinib--the Safer JAK Inhibitor. Filgotinib in cross-trial comparisons has the lowest rate of DVT and PE (**Fig. 1**) and a positive reduction in platelets. We maintain that filgotinib has a safety advantage over upadacitinib (ABBV); note here.

Initial NDA Positions of FDA Reviewers

- **Janet Maynard, Cross Discipline Team Leader Review**: *Recommended approval* but with long-term active-controlled safety study to better understand thromboses.
- **Badrul Chowdhury, Division Director at FDA**: Originally supported the 2mg dose, as he saw a favorable risk-benefit in this dose only—*in an amendment, he now views the safety database of the 2mg to not be large enough*. Claims that tofacitinib serves the same population without thrombosis risk. *"…it would be reasonable to not approve any of the doses of baricitinib at this time and have Lilly assess efficacy of a dose or doses lower than 2 mg…."*
- **Mary Tran Thanh Hai, Office Deputy Director**: *Does not see advantage of baricitinib over tofacitinib. "…the applicant will need to explore whether a lower dose can provide efficacy without this safety concern [thrombosis]."*

LLY's Resubmission Package and FDA Critiques

- **Lilly's Major Argument Is That the Thrombosis Risk Is Not Different from the Thrombosis Risk in the RA Population (Fig. 2),** and that the total number of events in all the studies was low. The FDA did not find this convincing, outlining four major reasons for why VTE rates in the bari trial

Instinet, LLC, Equity Research

19 April 2018

Rating Remains	**Buy**
Target Price Remains	USD 102.00
Closing price 19 April 2018	USD 69.05

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should not be compared: 1) data collection methods and baseline drug exposures differed, 2) inclusion/exclusion criteria differed, 3) crude VTE rates differ by Western/Eastern countries, and 4) patients in some trials included use of anticoagulants at baseline.

- **Proposed Dosing Change—4mg to Start, Taper to 2mg. Not Well-Received.** The FDA notes that LLY's rationale for the proposed dosing change was based on post-hoc analyses, and did not provide evidence that the relative benefit of the two doses differ.
- **Provided Accumulated Safety Info on 2mg and 4mg, and Data from 4mg Trial.** The FDA seems unmoved by the additional 4mg safety data and remains skeptical that enough information is available to make a fair assessment of risk/benefit of the 2mg dose.

Approval Appears Unlikely - Factors That May Lead to Approval

- **Baricitinib Is Approved in the EU for RA.** We note approval and use in the EU (Olumiant) may provide evidence of a favorable outcome; however, we believe that the approval may be further delayed.
- **Platelet Count and Thrombosis Risk Does Not Appear to Be Linked**: we note that thrombotic events occurred in patients without elevated platelet counts, and many patients with elevated platelet counts did not have a thrombotic event. The relationship between platelet counts and thrombosis risk is not clear or conclusive in this setting.

Fig. 1: Safety Comparison of RA JAK inhibtiors (and Adalimumab)

Event Per 100 PYE	filgotinib (50-)200mg daily DARWIN 3 Wk 84	upadacitinib 6 and 12mg BID	baricitinib 2 and 4mg QD	tofacitinib 5mg bid	tocilizumab 4 and 8 mg / kg	adalimumab
	Genovese, ACR2017	Genovese *et al.*, ACR2017	Genovese *et al.*, ACR2017	Wollenhaupt *et al.*, ACR2017	Genovese *et al.*, ACR2012	Burmester *et al.*, 2011
Patient year exposure	1,708	725	6,637	5,891	14,994	23,943
Serious infection	1.5	2.3	2.9	2.2	4.5	4.6
Herpes Zoster	1.2	3.7	3.2	3.6	NR	NR
DVT / PEs	2 / 1,708	5 / 725	31 / 6,754	3 / 1,849(1)	–	–
N cases / 100PY	0.1	0.7	0.5	0.2		

Note: data from separate RA studies not conducted by the Company.
(1) DVT / PE data on tofacitinib from Mease et al, ACR 2017, 5mg bid

Source: GLPG Annual Report

Fig. 2: Incidence Rates per 100 Patient Years by Study Groups
Baricitinib does not appear to have a higher Incidence rate compared to the RA population

Study Groups (Data Source)	VTE	DVT	PE
	IR (95% CI)	IR (95% CI)	IR (95% CI)
Baricitinib (ALL BARI RA)	0.53 (0.38, 0.71)	0.38 (0.25, 0.54)	0.24 (0.14, 0.37)
DMARDs (IMEDS)	1.34 (1.24, 1.44)	1.97 (1.85, 2.09)	0.77 (0.70, 0.84)
DMARDs (Truven – Def. 1)	0.68 (0.65, 0.71)	0.55 (0.52, 0.58)	0.26 (0.24, 0.28)
DMARDs (Truven – Def. 2)	1.05 (1.01, 1.09)	0.84 (0.80, 0.87)	0.38 (0.36, 0.41)
DMARDs (Truven – Def. 3)	1.63 (1.58, 1.69)	1.36 (1.31, 1.40)	0.46 (0.43, 0.49)

Source: Reproduced form FDA Briefing Document

Appendix A-1

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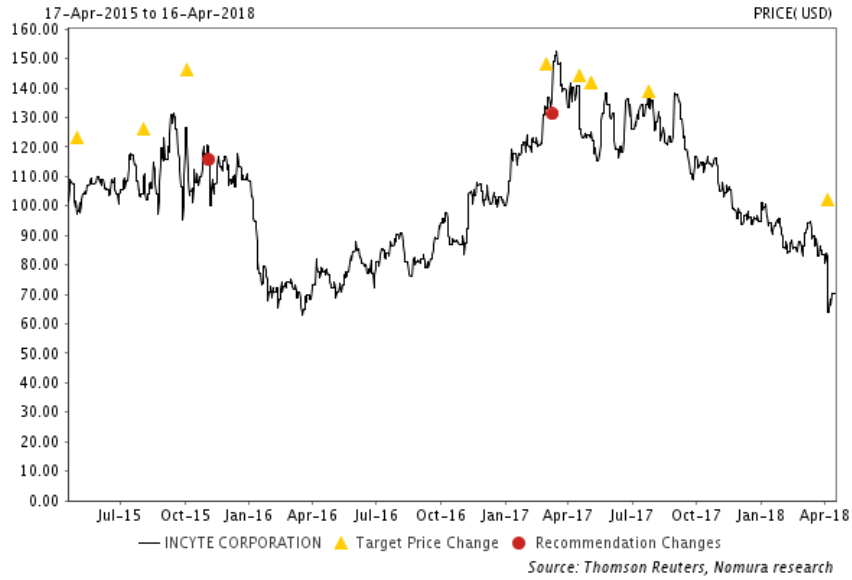
Materially mentioned issuers

Issuer	Ticker	Price	Price date	Stock rating	Sector rating	Disclosures
Incyte Corporation	INCY US	USD 69.05	19-Apr-2018	Buy	Not rated	

Incyte Corporation (INCY US) **USD 69.05 (19-Apr-2018)** Buy (Sector rating: Not rated)

Rating and target price chart (three year history)



Date	Rating	Target price	Closing price
06-Apr-18		102.00	64.02
25-Jul-17		139.00	133.56
04-May-17		142.00	125.00
17-Apr-17		144.00	126.07
01-Mar-17	Buy		133.22
01-Mar-17		148.00	133.22
27-Oct-15	Not Rated		117.64
05-Oct-15		146.00	120.83
04-Aug-15		126.00	109.74
30-Apr-15		123.00	97.16

For explanation of ratings refer to the stock rating keys located after chart(s)

Valuation Methodology We derive our $102 target price for Incyte Corporation (INCY) through an SOTP analysis of the company's therapeutic pipeline. Each asset derives its value from the net present value of our Incyte revenue estimates through 2030. Following the failure of ECHO-301 trial, we no longer include epacadostat estimates in our TP. The benchmark for this stock is the Nasdaq Biotechnology Index.

Risks that may impede the achievement of the target price (1) Development delays or discontinuations of clinical JAK and other TKI pipeline programs. (2) Slowing and/or below-consensus Jakafi or Jakavi sales. (3) Slower-than-anticipated baricitinib launch in EU and longer-than-anticipated delays in the US. (4) Manufacturing issues. (5) Competition outperforming Incyte products. (6) Larger-than-anticipated drug pricing pressure.

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