

US Biopharmaceuticals

AdComm favors Cartitude-4 & KarMMa-3,
clearing path for approval

Industry Overview

AdComm support focusing on PFS benefit

Today FDA AdComm voted 11-0 in favor of J&J's Carvykti Cartitude-4 and 8-3 in favor of Bristol's Abecma KarMMa-3 based on their superior progression-free survival (PFS) vs. standard of care, despite FDA's focus on early deaths and pre-specified survival endpoints. Notably, the AdComm largely attributed the risk of earlier deaths to CAR-T treatment delay and bridging therapy rather than the treatment itself. Overall, while there were some concerns initially on the approval timing/ approvability for Carvykti/ Abecma, respectively, given FDA's criticism in the briefing document (see report: [our briefing doc takeaways](#)), today's outcome should clear the path for approval for both therapies and provide next leg of growth. That said, supply constraint and competition from other cell therapies/ bispecifics will likely limit their growth in the near-term. Maintain Neutral rating for JNJ, \$180 PO and maintain Neutral rating for BMY, \$60 PO.

Cartitude-4: prolonged PFS benefit & OS curve separation

Despite FDA's focus on early deaths and the use of OS as a safety endpoint, the AdComm sided with J&J on interpreting Cartitude-4 OS data and adverse events across time points based on both pre-specified and descriptive analyses. Notably, the committee was overwhelmingly impressed with Carvykti's PFS benefit and durability as well as continued improvement of OS benefit. Notably, the committee sees early deaths between the two arms as either insignificant or due to lack of efficacy with bridging therapy and Carvykti treatment delay.

KarMMA-3 crossover complicates OS interpretation

On the other hand, the AdComm had more concerns with regard to Abecma's survival benefit, despite a nearly 50% crossover from the standard treatment arm. Specifically, some members believe that there should still be an OS separation despite a high crossover rate, which was further exacerbated by the lack of PFS plateauing. Importantly, it's unclear whether treating with Abecma earlier could provide benefit given the OS curves cross at different timepoints. That said, the AdComm still believes the trial met its primary endpoint, which showed meaningful PFS improvement vs standard of care based on pre-specified analysis.

15 March 2024

Equity
United States
Biopharmaceuticals

Geoff Meacham
Research Analyst
BofAS
+1 646 855 1004
geoff.meacham@bofa.com

Charlie Yang
Research Analyst
BofAS
+1 646 855 5732
charlie.yang@bofa.com

Susan Chor
Research Analyst
BofAS
+1 646 855 0102
susan.chor@bofa.com

Alexandria Hammond
Research Analyst
BofAS
+1 646 855 1654
alexandria.hammond@bofa.com

John Joy
Research Analyst
BofAS
+1 646 855 1136
john.joy@bofa.com

Abbreviation:

SOC: standard of care

PDUFA: Prescription Drug User Fee Act

FDA: Food and Drug Administration

AdComm: Advisory committee

OS: overall survival

PFS: progression-free survival

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Refer to important disclosures on page 4 to 7. Analyst Certification on page 2. Price Objective Basis/Risk on page 2.

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Timestamp: 15 March 2024 09:07PM EDT

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Exhibit 1: Stock mentioned

Stock prices and ratings mentioned in this report

BofA Ticker	Bloomberg ticker	Company name	Price	Rating
BMJ	BMJ US	Bristol-Myers Squibb	US\$ 52.34	B-2-7
JNJ	JNJ US	Johnson & Johnson	US\$ 158.18	A-2-7

Source: BofA Global Research

BofA GLOBAL RESEARCH

Price objective basis & risk

Bristol-Myers Squibb (BMJ)

Our \$60 price objective (PO) is based on a 50/50 blended average of our risk-adjusted discounted cash flow (DCF) and P/E multiple applied to 2024E EPS. Our DCF assumes 7% WACC and -4% terminal growth rate, and we assume an approximate 8x 2024 P/E multiple given an impending patent cliff and risks associated with later-stage pipeline.

Risks to our PO are 1) uninspiring readouts from late-stage trials in key I/O indications, 2) more rapid deceleration of Revlimid erosion than expected, 3) negative outcomes from the company's later-stage pipeline assets in development, 4) pressures from headline risks facing the sector (including drug pricing reform), and 5) negative patent rulings.

Johnson & Johnson (JNJ)

Our price objective of \$180/share is based on a sum of the parts (SOTP) of roughly 18x MedTech multiple, and 14x pharma '24 multiple, slightly below peers given looming loss of exclusivity (LOE) and talc uncertainty, yielding \$57/share, and \$123/share, respectively.

The downside risks to our PO are slower growth in MedTech due to competitive pressure and faster-than-expected erosion from biosimilars to the pharma business.

Upside risks to our PO are better-than-expected launch of new products, better-than-expected clinical data for the pharma pipeline, quick resolution of talc litigation, and constructive M&A.

Analyst Certification

I, Geoff Meacham, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or view expressed in this research report.

US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	89bio, Inc	ETNB	ETNB US	Geoff Meacham
	Acumen Pharma	ABOS	ABOS US	Geoff Meacham
	Agios Pharmaceuticals	AGIO	AGIO US	Greg Harrison, CFA
	BioMarin	BMRN	BMRN US	Geoff Meacham
	BioXcel Therapeutics	BTAI	BTAI US	Greg Harrison, CFA
	BridgeBio Pharma	BBIO	BBIO US	Greg Harrison, CFA
	Caribou	CRBU	CRBU US	Geoff Meacham
	CRISPR Therapeutics	CRSP	CRSP US	Geoff Meacham
	Eli Lilly and Company	LLY	LLY US	Geoff Meacham
	Gilead Sciences Inc.	GILD	GILD US	Geoff Meacham
	HUTCHMED	HCM	HCM US	Alec W. Stranahan
	Immatics	IMTX	IMTX US	Alec W. Stranahan
	Insmed Incorporated	INSM	INSM US	Jason Zemansky
	Intellia Therapeutics	NTLA	NTLA US	Greg Harrison, CFA
	Janux Therapeutics	JANX	JANX US	Alec W. Stranahan
	Keros	KROS	KROS US	Greg Harrison, CFA
	Kiniksa Pharmaceuticals, Ltd.	KNSA	KNSA US	Geoff Meacham
	Krystal Biotech	KRYS	KRYS US	Alec W. Stranahan
	Kura Oncology	KURA	KURA US	Jason Zemansky
	Liquidia Corporation	LQDA	LQDA US	Greg Harrison, CFA
	Lyell Immunopharma	LYEL	LYEL US	Geoff Meacham
	MeiraGTx	MGTX	MGTX US	Alec W. Stranahan
	Merck & Co.	MRK	MRK US	Geoff Meacham
	Mineralys Therapeutics	MLYS	MLYS US	Greg Harrison, CFA
	Neumora Therapeutics	NMRA	NMRA US	Geoff Meacham
	Regenxbio, Inc.	RGNX	RGNX US	Alec W. Stranahan
	Revolution Medicines	RVMD	RVMD US	Alec W. Stranahan
	Rocket Pharmaceuticals, Inc.	RCKT	RCKT US	Greg Harrison, CFA
	Royalty Pharma	RPRX	RPRX US	Geoff Meacham
	Sana Biotechnology	SANA	SANA US	Geoff Meacham
	SpringWorks	SWTX	SWTX US	Alec W. Stranahan
	Syndax Pharmaceuticals	SNDX	SNDX US	Jason Zemansky
	Traverse Therapeutics Inc	TVTX	TVTX US	Greg Harrison, CFA
	Turnstone Biologics	TSBX	TSBX US	Geoff Meacham
	Vertex Pharmaceuticals Inc.	VRTX	VRTX US	Geoff Meacham
	Werewolf Therapeutics	HOWL	HOWL US	Jason Zemansky
	Xencor	XNCR	XNCR US	Alec W. Stranahan
NEUTRAL				
	AbbVie	ABBV	ABBV US	Geoff Meacham
	Alector, Inc	ALEC	ALEC US	Greg Harrison, CFA
	Amgen Inc.	AMGN	AMGN US	Geoff Meacham
	Amylyx Pharmaceuticals	AMLX	AMLX US	Geoff Meacham
	Arcus Biosciences	RCUS	RCUS US	Jason Zemansky
	Beam Therapeutics	BEAM	BEAM US	Greg Harrison, CFA
	Biogen Inc.	BIIB	BIIB US	Geoff Meacham
	Bristol-Myers Squibb	BMJ	BMJ US	Geoff Meacham
	Cytokinetics, Incorporated	CYTK	CYTK US	Jason Zemansky
	Editas Medicine	EDIT	EDIT US	Greg Harrison, CFA
	Erasca	ERAS	ERAS US	Alec W. Stranahan
	Esperion	ESPR	ESPR US	Jason Zemansky
	Exscientia	EXAI	EXAI US	Alec W. Stranahan
	IGM Biosciences	IGMS	IGMS US	Greg Harrison, CFA
	Johnson & Johnson	JNJ	JNJ US	Geoff Meacham
	Kymera Therapeutics	KYMR	KYMR US	Geoff Meacham
	Moderna	MRNA	MRNA US	Geoff Meacham
	Pfizer	PFE	PFE US	Geoff Meacham
	Recursion Pharmaceuticals, Inc.	RXR	RXR US	Alec W. Stranahan
	Tyra Biosciences	TYRA	TYRA US	Greg Harrison, CFA
	Vir	VIR	VIR US	Alec W. Stranahan
	Y-mAbs Therapeutics, Inc	YMAB	YMAB US	Alec W. Stranahan
UNDERPERFORM				
	AlloVir, Inc.	ALVR	ALVR US	Jason Zemansky
	CureVac	CVAC	CVAC US	Geoff Meacham



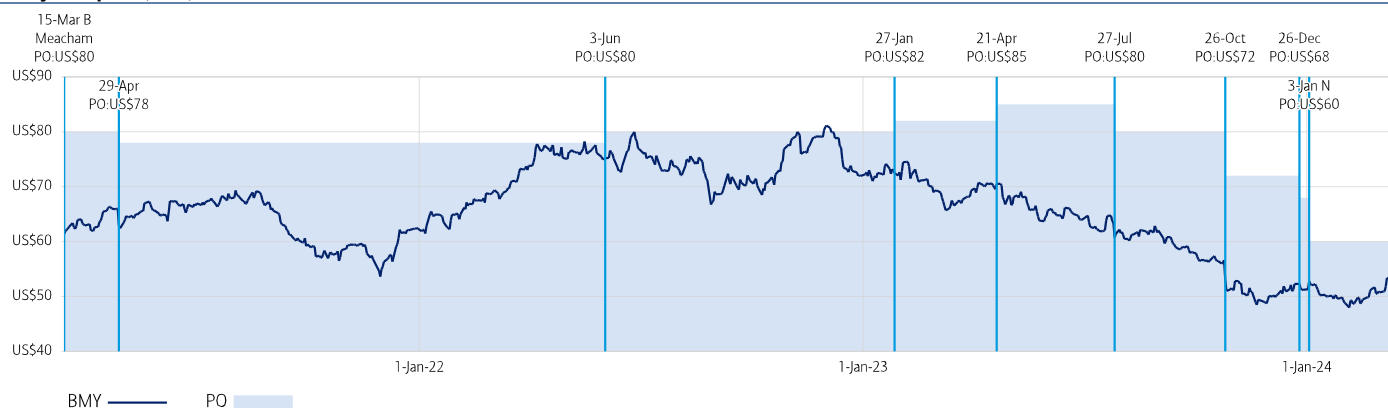
US - Biopharmaceuticals Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
	Day One Biopharmaceuticals	DAWN	DAWN US	Alec W. Stranahan
	Novavax	NVAX	NVAX US	Alec W. Stranahan
	Regeneron Pharmaceuticals Inc.	REGN	REGN US	Geoff Meacham
	Reneo Pharmaceuticals	RPHM	RPHM US	Jason Zemansky
	TG Therapeutics	TGTX	TGTX US	Alec W. Stranahan
	United Therapeutics Corporation	UTHR	UTHR US	Greg Harrison, CFA

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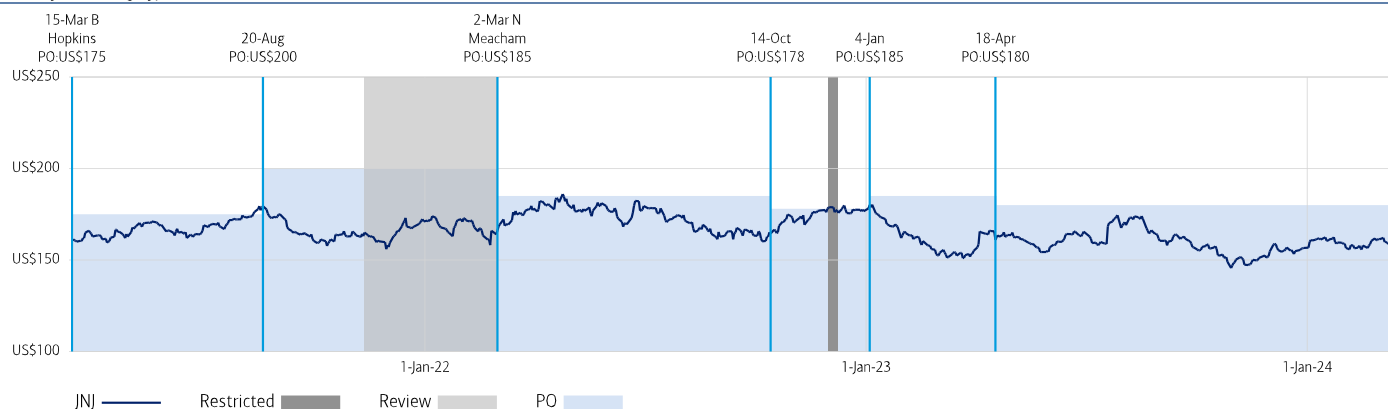
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Bristol-Myers Squibb (BMY) Price Chart



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Johnson & Johnson (JNJ) Price Chart



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Equity Investment Rating Distribution: Health Care Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	234	60.94%	Buy	115	49.15%
Hold	80	20.83%	Hold	36	45.00%
Sell	70	18.23%	Sell	29	41.43%

Equity Investment Rating Distribution: Global Group (as of 31 Dec 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships ^{R1}	Count	Percent
Buy	1895	53.62%	Buy	1083	57.15%
Hold	832	23.54%	Hold	454	54.57%
Sell	807	22.84%	Sell	383	47.46%

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Investment rating	Total return expectation (within 12-month period of date of initial rating)	Ratings dispersion guidelines for coverage cluster ^{R2}
Buy	≥ 10%	≤ 70%
Neutral	≥ 0%	≤ 30%
Underperform	N/A	≥ 20%

^{R2} Ratings dispersions may vary from time to time where BofA Global Research believes it better reflects the investment prospects of stocks in a Coverage Cluster.

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