

US Biopharmaceuticals

PBM-biosimilar expert call: discussion topics in advance of call

Industry Overview

US biosimilar Humira launches: what have we learned?

Below, we summarize key topics we aim to address on our (Friday) expert call with generics sourcing expert Vinod Melvani. The focus of the call will be on issues that have limited adoption of biosimilar Humira and the role of channel (pharmacy vs. medical benefit). We believe the topic is relevant for branded biologics suppliers, biosimilar developers and PBMs.

What's happened in US b-Humira market + read-through

- **First biosimilar managed by PBMs tracking well below biosimilars managed under medical benefit:** We look for further clarity on key issues that have limited b-Humira adoption, the first US biosimilar where reimbursement/access has been managed by PBMs. Since the first b-Humira launched (Jan 2023), a total of nine biosimilar versions of Humira have become commercially available but have only captured a combined for ~3% unit share vs. 20-40% share (at similar timepoints) for biosimilars reimbursed under medical benefit (Exhibit 1). On the call, we plan to focus on: (1) the role access has played in biosimilar adoption. So far, branded Humira appears to have parity access with biosimilars on most major plans, although that appears to be changing with CVS (more below); (2) do biosimilar pricing strategies matter, e.g., low vs. high WAC products; and (3) the importance of interchangeability and whether there are any relevant lessons from BI's Cyltezo, which is interchangeable with the less common low concentrate form (LCF).
- **What to expect from b-Humira in '24E and read-across to future biosimilar launches:** Teva recently secured approval for an interchangeable, high concentrate form (HCF) of Humira (the most dispensed form) and plans to launch imminently. Key topics for the call: (1) PBM contracting cycles – when the TEVA biosimilar can be listed on most formularies. Teva is hopeful its product will be listed on formularies by mid-2024, subject to “active [payer] discussions”; (2) how will payers leverage an interchangeable biosimilar and could the brand see diminished access; and (3) framing dynamics of a steadier state biosimilar market (2025-2026). Of note, the biggest US biosimilar supplier (Sandoz) has achieved the broadest b-Humira payer coverage (albeit low market share), which may speak to the importance of having a deep biosimilar portfolio or possibly because Sandoz is the only provider to have a dual high/low WAC pricing strategy for the HCF b-Humira (Exhibit 5).
- **ABBV's Humira outlook implies \$2-3bn biosimilar opportunity—which has yet to materialize:** Key elements of Abbvie's recent (4Q23) US Humira outlook call for >80% US net sales erosion (\$1.7bn vs. \$12.2bn FY23), which appears largely price-driven, but the company indicated there would be a greater degree of volume erosion. Exiting '23, we estimate Abbvie's net price per unit has compressed by 37% Y/Y (average for full year). On the call, we look to understand better the read-across to biosimilars from brand-led price contraction to defend market share. **See remainder of report on page 2...**

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Equity
United States
Biopharmaceuticals

Jason M. Gerberry
Research Analyst
BofAS
+1 646 743 0180
jason.gerberry@bofa.com

Allen Lutz, CFA
Research Analyst
BofAS
+1 646 855 4380
allen.lutz@bofa.com

Pavan R. Patel
Research Analyst
BofAS
+1 646 855 5825
pavan.r.patel@bofa.com

Hanna Lee
Research Analyst
BofAS
+1 646 855 3682
hanna.y.lee@bofa.com

Chi M. Fong
Research Analyst
BofAS
+1 646 855 5264
chi.fong@bofa.com

Dina Ramadane
Research Analyst
BofAS
+1 646 556 0492
dina.ramadane@bofa.com

Dev Weerasuriya
Research Analyst
BofAS
+1 646 855 5707
dev.weerasuriya@bofa.com

Acronyms:

WAC: Wholesale Acquisition Cost
LCF: low concentrate form
HCF: high concentrate form
PBM: pharmacy benefit manager
b-Humira: biosimilar Humira
BI: Boehringer Ingelheim
CI: Cigna
UNH: United Healthcare

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- **CVS Cordavis presents a unique model but the endgame is unclear:** In Aug. 2023, CVS announced the launch of Cordavis, a wholly owned subsidiary that will work directly with manufacturers to commercialize and/or co-produce biosimilar products for the US market. Cordavis plans to market a private label b-Humira in 1Q24 with Sandoz supply contracts for its b-Humira (Hyrimoz), as well as a co-branded version of Humira in 2Q24 with committed volume from Abbvie. It remains unclear to what degree the entity will move market share following April 1, when CVS Caremark will remove branded Humira from its national commercial template formularies. More recently, Sandoz has disclosed that as of April 1, 2024, Hyrimoz will have preferred access to 65% of CVS Caremark's commercial lives. On the call, we look to understand better: (1) incentives for employer plans to work with Cordavis; (2) factors that will drive use of the biosimilar vs. Abbvie's cobranded version of Humira; and (3) whether other major PBMs might adopt similar mechanisms to spur biosimilar adoption.

Appendix

Exhibit 1: Sandoz has achieved the broadest payer coverage since biosimilar Humira launch

Per last PR, UnitedHealthcare is only payer to cover branded Humira at parity to biosimilars

Payer coverage of biosimilars Humira	CVS	CI	UNH
% of 320m covered lives	33%	24%	22%
SDZNY's Hyrimoz (branded and unbranded)	yes	yes	yes
BI's Cyltezo	--	yes	yes
AMGN's Amjevita	--	--	yes
OGN's Hadlima	yes	--	--
branded Humira covered at parity to biosimilars?	no	no	yes

Source: Company reports

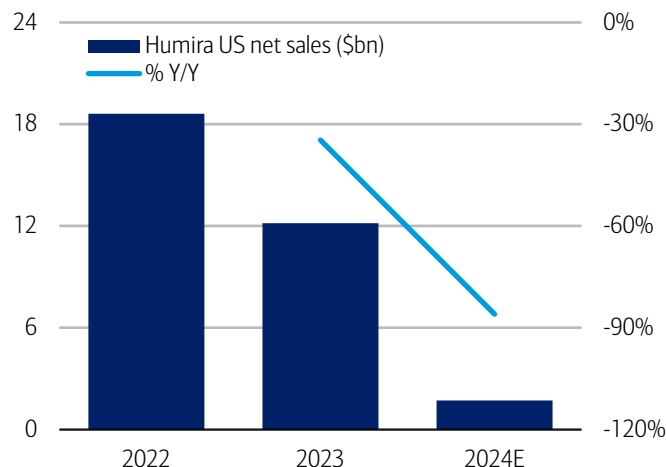
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"In the US, we have once again secured broad formulary access for Humira in 2024. While there will be some step-down in coverage year-over-year, we will still have **parity access to biosimilars for the vast majority of US patient lives.**"

– ABBV Chief Commercial Officer (Feb 2024)

Exhibit 2: ABBV's 2024 guide implies steep branded Humira erosion

Given early-stages of biosimilar launch, price likely large component

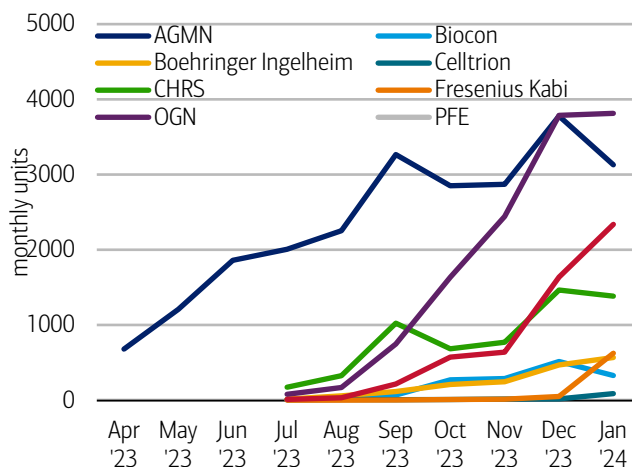


Source: Company reports

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Exhibit 3: Top 3 b-Humira unit share: 1) OGN, 2) AMGN, 3) Sandoz

With payer dynamics, Sandoz appears positioned for unit share gains



Source: IQVIA

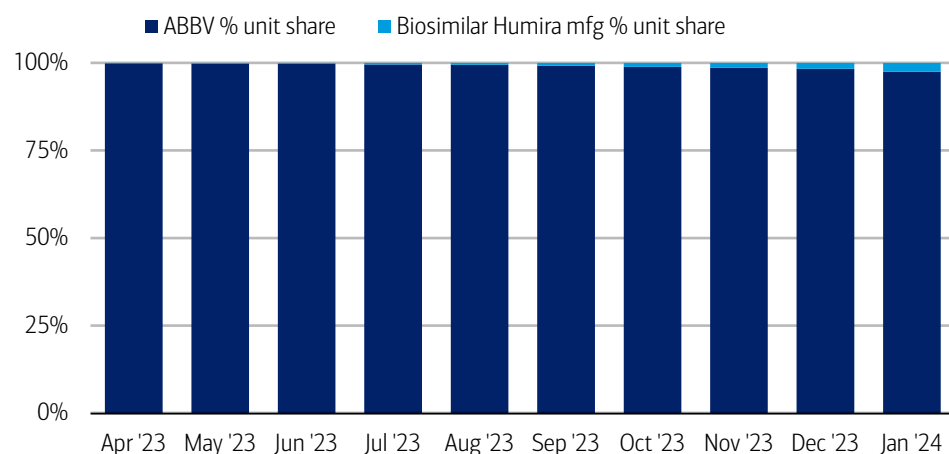
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"We do expect in the US the tail [of branded Humira] to emerge in 2025-2026 timeframe...We'll have to see what happens with **volume uptake** this year and also where **interchangeability** lands. And ultimately what does **contracting** look like next year. So, I wouldn't expect us to quantify the tail this year...either in 2025 or 2026."

– ABBV Chief Commercial Officer (February 2024)

Exhibit 4: Biosimilar Humira has captured 3% unit share as of Jan 2024

Biosimilar manufacturers have captured limited market share



Source: IQVIA

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Exhibit 5: Nearly half of manufacturers launched branded + unbranded versions of b-Humira

Sandoz + BI have achieved broad payer coverage with high/low WAC marketing strategy

Brand/unbranded/both	Company
brand only	AMGN
	Celltrion
	CHRS
	OGN
	PFE
branded and unbranded versions	Biocon
	Boehringer Ingelheim
	Fresenius Kabi
	Sandoz

Source: Company reports, FDA.gov

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Exhibit 6: ABBV's 2024 commentary suggests the biosimilar Humira opportunity is likely ~\$1.6-3.0bn

Based on OGN CEO commentary, we'd expect ~80% price erosion in 2024, suggesting

	FY24 -- Humira market share -- originator (ABBV) as % of total units					
	FY22	FY23	75%	50%	35%	25%
Units (m)	7	7	5	3	2	2
Net sales (\$m)	18619	12160	1700	1700	1700	1700
Price/unit	2793	1773	330	496	708	991
% discount vs. pre-biosimilar		-37%	-88%	-82%	-75%	-64%
Implied biosimilar market net sales (\$m)			503	1605	3022	4910
Total Humira market (\$m)			2203	3305	4722	6610

Source: BofA Global Research estimate, company reports

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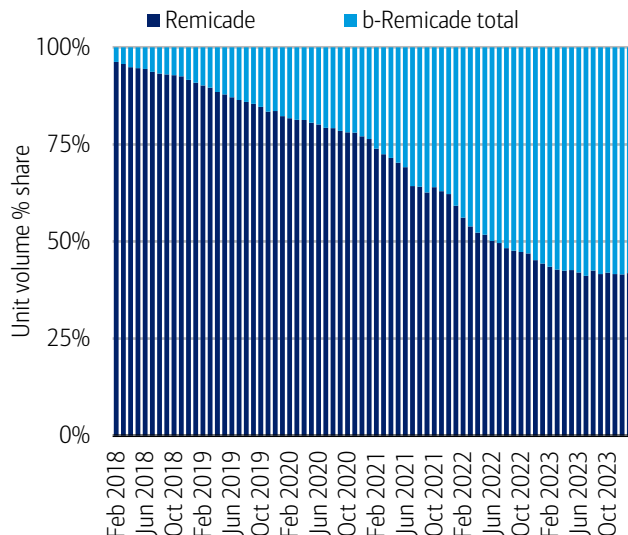
Pharmacy and medical benefit biosimilar uptake

Pharmacy benefit biosimilars typically drive up to 50-60% uptake of market

Below, we examine uptake of pharmacy benefit biosimilars from Feb 2018+ or launch. This subset includes Remicade and Lantus.

Exhibit 7: b-Remicade has achieved ~60% of the total market

Remicade has favorable pharmacy benefit uptake

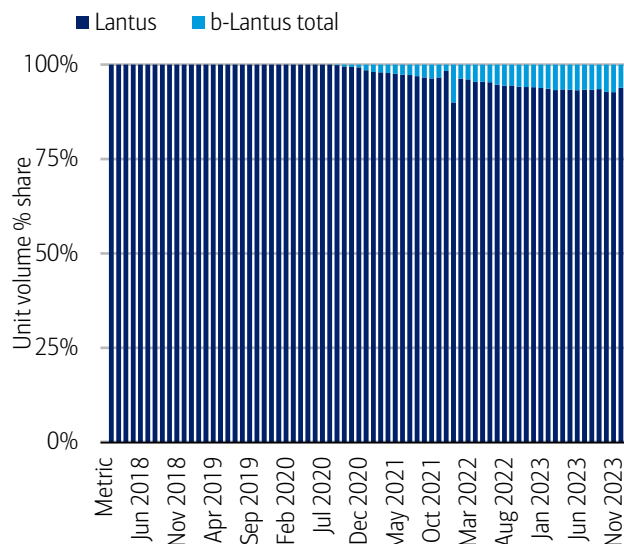


Source: IQVIA

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Exhibit 8: b-Lantus has achieved nearly <10% of the total market

Lantus has favorable pharmacy benefit uptake



Source: IQVIA

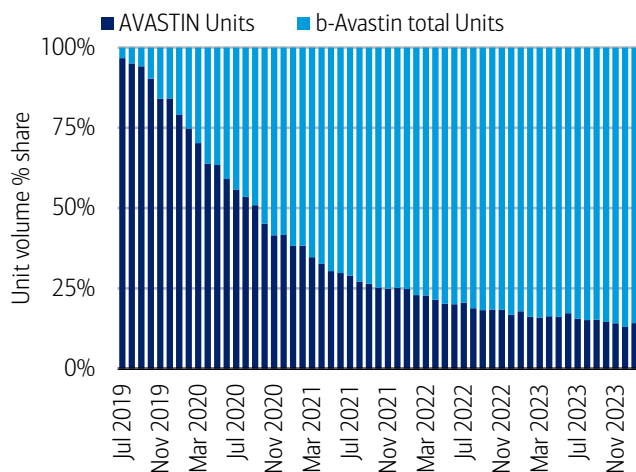
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Medical benefit biosimilars can capture up to 70-90%+ of the total market

Below, we examine uptake of medical benefit biosimilars from Feb 2018+ or launch. This subset includes Avastin, Rituxan, Herceptin, Neupogen, Neulasta, Epogen, and Xgeva

Exhibit 9: b-Avastin has achieved ~85% of the total market

b-Avastin has favorable medical benefit uptake

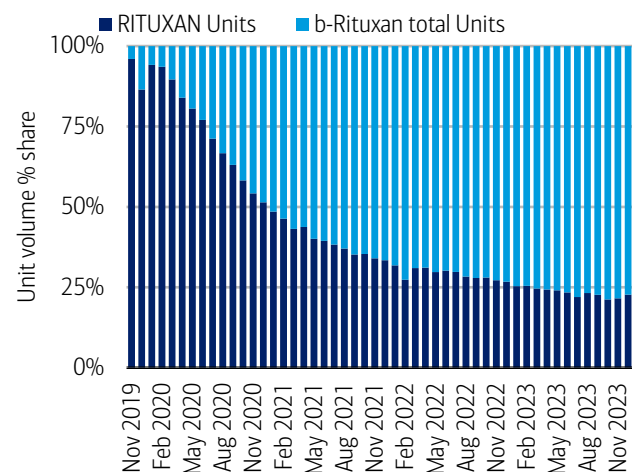


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Exhibit 10: b-Rituxan has achieved ~80% of the total market

b-Rituxan has favorable medical benefit uptake

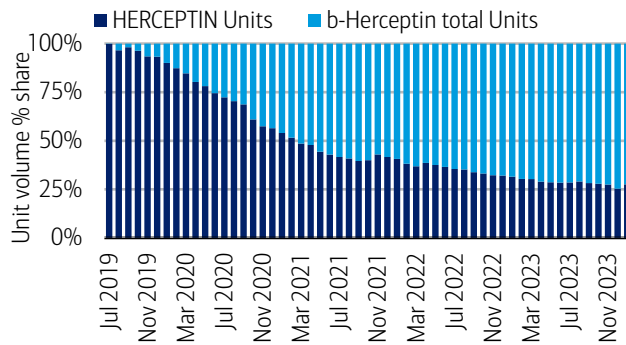


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Exhibit 11: b-Herceptin has achieved ~70% of the total market

b-Herceptin has favorable medical benefit uptake

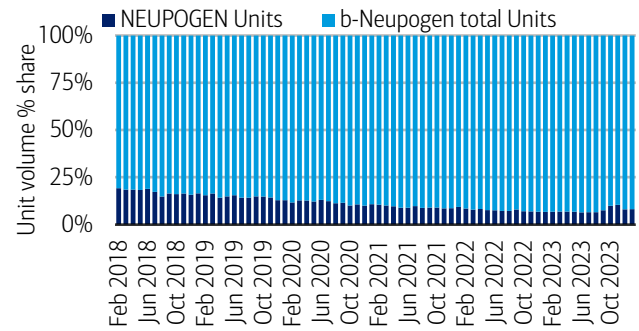


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Exhibit 12: b-Neupogen has achieved >90% of the total market

b-Neupogen has favorable medical benefit uptake

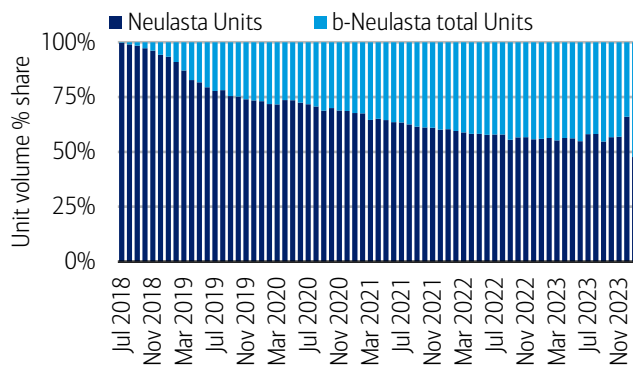


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Exhibit 13: b-Neulasta has achieved ~50% of the total market

b-Neulasta has favorable medical benefit uptake

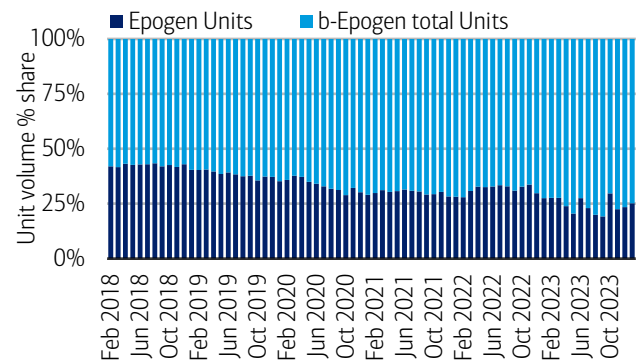


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Exhibit 14: b-Epogen has achieved 75% of the total market

b-Epogen has favorable medical benefit uptake

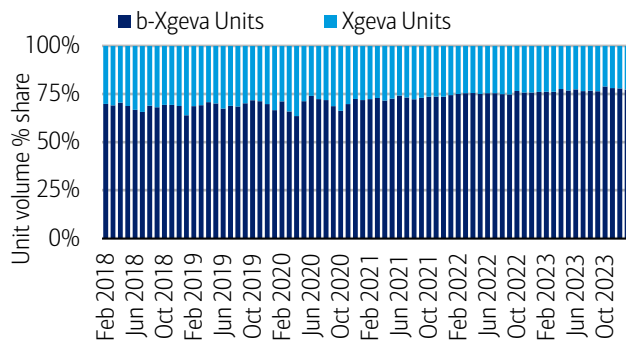


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Exhibit 15: b-Xgeva has achieved nearly 80% of the total market

b-Xgeva has favorable medical benefit uptake



Source: IQVIA

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