

BridgeBio Pharma

Positive clinical data further support anticipated approval of acoramidis

Maintain Rating: BUY | PO: 52.00 USD | Price: 33.31 USD

No mortality seen in 30 months supports clinical impact

BridgeBio announced positive phase 3 results evaluating acoramidis in Japanese patients conducted by licensing partner, Alexion, AstraZeneca Rare Disease, where notably no mortality was reported over the 30-month treatment period and acoramidis was overall well tolerated. While we note that the focus for the acoramidis program remains on the anticipated FDA acceptance of the recent NDA submission for the approval of acoramidis in the US, we believe that the data update today further strengthens the acoramidis clinical profile and builds upon [previous positive readouts \(see report\)](#). Looking at the US ATTR-CM opportunity, we think that acoramidis could have broad usage in the space and currently model \$4.4B risk-adjusted peak sales (95% PoS) and a launch in 2024. As one of [our top picks for 2024 \(see our Year Ahead report\)](#), we think that BridgeBio is showing encouraging progress across a broad product pipeline, including the anticipated launch of acoramidis. We maintain our Buy rating and \$52 PO.

Data details

The phase 3 open-label, single-arm study was conducted in Japan by licensing partner Alexion, AstraZeneca Rare Disease. The results were consistent with the ATTRIBUTE-CM phase 3 trial, which achieved the primary endpoint (Win ratio 1.8; $p < 0.0001$) along with other endpoints (81% survival rate at 30 months; 0.29 annualized cardiovascular hospitalization rate). The Japan-based trial had no mortality reported and no safety signals of potential clinical concern reported. BridgeBio noted that the full dataset will be presented at an upcoming medical meeting.

Global commercialization in view for acoramidis program

Alexion, AstraZeneca Rare Disease, maintains an exclusive license with Eidos Therapeutics to develop and commercialize acoramidis in Japan. Under the terms of license agreement, Eidos has the potential for a one-time payment of \$30M upon the achievement of a regulatory milestone and will be entitled to receive royalties in the low double digits on net sales by Alexion of acoramidis in Japan. The royalty rate is subject to reduction if Alexion is required to obtain intellectual property rights from third parties or upon the introduction of generic competition. Beyond showing further positive data of acoramidis treatment in ATTR-CM, the phase 3 update supports regulatory submission in Japan. BridgeBio is also looking to commercialize acoramidis ex-US and is planning to file global marketing authorization applications in 2024.

See our catalyst calendar below (Exhibit 1):

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Stock Data

Price	33.31 USD
Price Objective	52.00 USD
Date Established	18-Jan-2024
Investment Opinion	C-1-9
52-Week Range	9.88 USD - 44.32 USD
Mkt Val (mn) / Shares Out (mn)	4,670 USD / 140.2
Free Float	73.1%
Average Daily Value (mn)	66.42 USD
BofA Ticker / Exchange	BBIO / NAS
Bloomberg / Reuters	BBIO US / BBIO.OQ
ROE (2023E)	NA
Net Dbt to Eqty (Dec-2022A)	NA
ESGMeter™	Low

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ATTR-CM: transthyretin amyloidosis cardiomyopathy

FDA: Food and Drug Administration

NDA: new drug application

PO: price objective

PoS: probability of success

Exhibit 1: BridgeBio Catalyst Calendar

We also expect FDA acceptance of the NDA filing for the approval of acoramidis in ATTR-CM over the next few days.

Company	Asset	Indication	Event	Timing	Importance
BridgeBio	Acoramidis	ATTR-CM	Global marketing authorization applications	2024	Moderate
BridgeBio	Acoramidis	ATTR-CM	Anticipated FDA approval and launch	2H24	High
BridgeBio	low-dose infigratinib	Achon.	Last patient enrolled	1H24	Moderate
BridgeBio	low-dose infigratinib	Achon.	Study completion	2025	High
BridgeBio	low-dose infigratinib	hypochondroplasia	Clinical program initiation	2024	High
BridgeBio	BBP-418	LGMD2i	Complete enrollment	2024	Moderate
BridgeBio	Encaleret	ADH1	Phase 3 readout	early 2025	Moderate
BridgeBio	Gene therapy	CAH	Phase 2 data readout	3Q24	High
BridgeBio	BBP-418	LGMD2i	FORTIFY topline data	1H25	High
BridgeBio	BBO-8520	Oncology	IND filing	2024	Low

Source: BofA Global Research, company reports

BofA GLOBAL RESEARCH

Price objective basis & risk

BridgeBio Pharma (BBIO)

Our net present value (NPV) sum-of-the-parts valuation gives a price objective of \$52/share for BridgeBio, which includes \$32/share for acoramidis, \$3/share for ribitol in LGMD2i, \$11/share for infigratinib in achondroplasia, \$6/share for encaleret, \$5/share for CAH gene therapy, and -\$4/share in net cash. We assume a weighted-average cost of capital (WACC) of 15% and terminal growth rates ranging from -50% to 0%.

Downside risks to our price objective are 1) clinical trial failures, 2) inability to raise capital to fund development programs, and 3) superior data from competitors.

Upside risks to our price objective are 1) stronger-than-expected uptake in infigratinib, 2) unexpected de-risking data for early programs, and 3) clinical trial failures from competing companies.

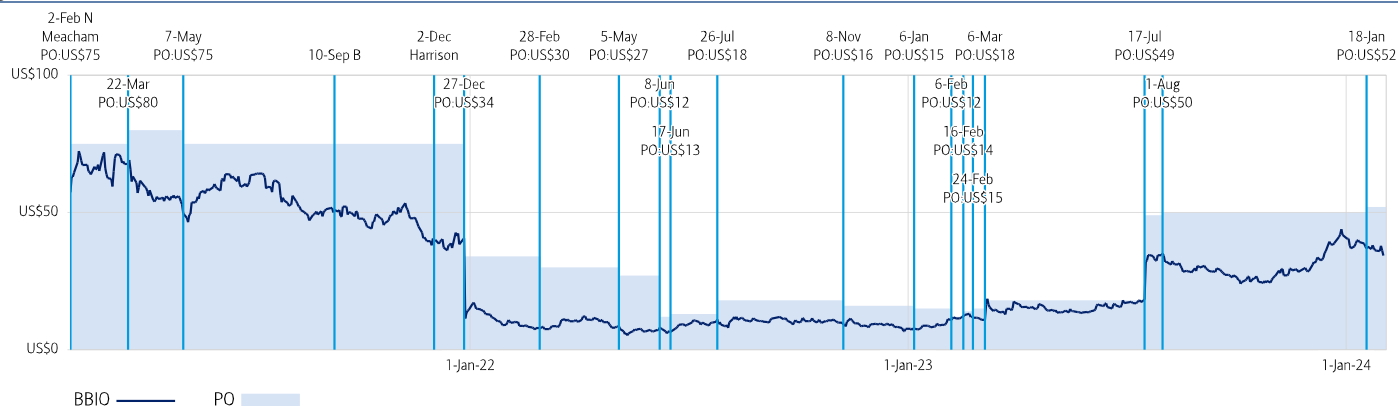
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BridgeBio Pharma (BBIO) Price Chart



B: Buy, N: Neutral, U: Underperform, PO: Price Objective, NA: No longer valid, NR: No Rating

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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%

^{R1} Issuers that were investment banking clients of BofA Securities or one of its affiliates within the past 12 months. For purposes of this Investment Rating Distribution, the coverage universe includes only stocks. A stock rated Neutral is included as a Hold, and a stock rated Underperform is included as a Sell.

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Underperform	N/A	≥ 20%

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