

Arcellx, Inc.

AdCom a positive read to ACLX: de-risk path to 2L MM, possible late-mover adv

Maintain Rating: BUY | PO: 84.00 USD | Price: 70.94 USD

AdCom voted in favor of CAR-T competitor as expected

Today, an FDA AdCom panel for key BCMA CAR-T competitor (Carvykti) voting 11:0 in favor of risk/benefit assessment for Carvykti in earlier line (2L+) multiple myeloma (MM) indication. The outcome was consistent with our [KOL feedback](#) (see report) which pointed to a favorable vote supporting risk/benefit. We suspect FDA approval and labeling for early-line use will mirror the panel vote, while safety concerns around early OS detriment could be addressed through labeling. Ultimately, future maturation of longer-term OS benefit (+ supply) will be needed to drive CAR-T adoption into earlier lines of MM. From an ACLX perspective, we don't see late-mover status as a major impediment as anito cel can incorporate learnings from Cart4 into upcoming pivotal trial design (better bridging therapy access) + faster CAR-T delivery time may mitigate early OS detriment + combined with anito's other points of differentiation. Maintain Buy.

FDA took issue at CAR-T logistics linked to early deaths

The FDA asked the AdCom to weigh in on risk/benefit of Carvykti in 2L+ MM given early deaths imbalance for which the Agency views as a safety signal. While the FDA cautioned around concluding the drug benefit based on current immature OS data, the AdCom panel ultimately viewed the widening of OS curve separation (after early deaths) as an indicator of long-term benefit potential which outweighed the risk of small imbalance in early deaths (similar frontloaded risk as bone marrow transplant).

CAR-T delay, bridging tx possible factors for early deaths

Cause of early deaths observed in the Cartitude-4 (C-4) trial remains a debate, but AdCom discussions indicate delayed CAR-T delivery and suboptimal bridging therapies as factors that may have contributed to the early death imbalance. The drug sponsor and its invited KOL speaker framed current practice as having better bridging therapies than those used in C-4, which we'd expect to be accessible in future 2L+ trials to be conducted ACLX/Gilead. At the Gilead/Kite's cell therapy event yesterday, Gilead indicated it expects to rapidly bring down anito cel turnaround time closer to Yescarta levels (~14d median) post-tech transfer this year (see report for [our takeaways from the site visit](#)), which compares to 79d median vein-to-vein time reported in C-4.

Early CAR-T use may require market build in 2L MM

Per our prior KOL checks, the market building efforts for CAR-T to penetrate in earlier lines should provide some cushion for anito cel to catch-up to Carvykti in earlier line MM. Given vast majority of AdCom panelists were solid tumor oncologists (vs 1 MM expert), we do not see today's endorsement as reflective community MM doctors.

Labeling was not a key discussion at AdCom

Overall, the AdCom largely did not discuss label considerations around line of therapy or risks of early deaths outside of a couple of panelists. On poor OS benefit seen from Carvykti in 2L relative 3-4L subgroups, the FDA downplayed the conclusiveness of the sub-group data citing the analysis was post-hoc/exploratory. On risk of early deaths, the panel believes the cause of early deaths warrant further investigations but ultimately relegates the decision of whether/when to use CAR-T to physicians and patients.

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15 March 2024

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Stock Data

Price	70.94 USD
Price Objective	84.00 USD
Date Established	8-Mar-2024
Investment Opinion	C-1-9
52-Week Range	27.28 USD - 75.10 USD
Mkt Val (mn) / Shares Out (mn)	3,745 USD / 52.8
Free Float	73.9%
Average Daily Value (mn)	31.99 USD
BofA Ticker / Exchange	ACLX / NAS
Bloomberg / Reuters	ACLX US / ACLX.OQ
ROE (2024E)	-10.6%
Net Dbt to Eqty (Dec-2023A)	-82.8%
ESGMeter™	N/A

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L: line of therapy
AdCom: advisory committee
CAR-T: cell therapy, BCMA: antigen
OS: overall survival
KOL: expert
Tx: therapy
FDA: US Food and Drug Administration

Price objective basis & risk

Arcellx, Inc. (ACLX)

Our \$84 per share price objective is based on a risk-adjusted, sum-of-the-parts DCF. We assume 1) a discount rate of 10% for a pivotal clinical-stage company, 2) a Probability of Success of 80% for ddBCMA program given that it will soon enter pivotal testing. 3) terminal value with terminal growth rate of 0% to reflect a durable market position for ddBCMA given high capital barriers to competitor entry

Downside risks are: 1) ddBCMA trial failure, 2) worse-than-expected ddBCMA clinical data

Upside risks are: 1) better-than-expected ddBCMA clinical data and 2) acquisition at a premium.

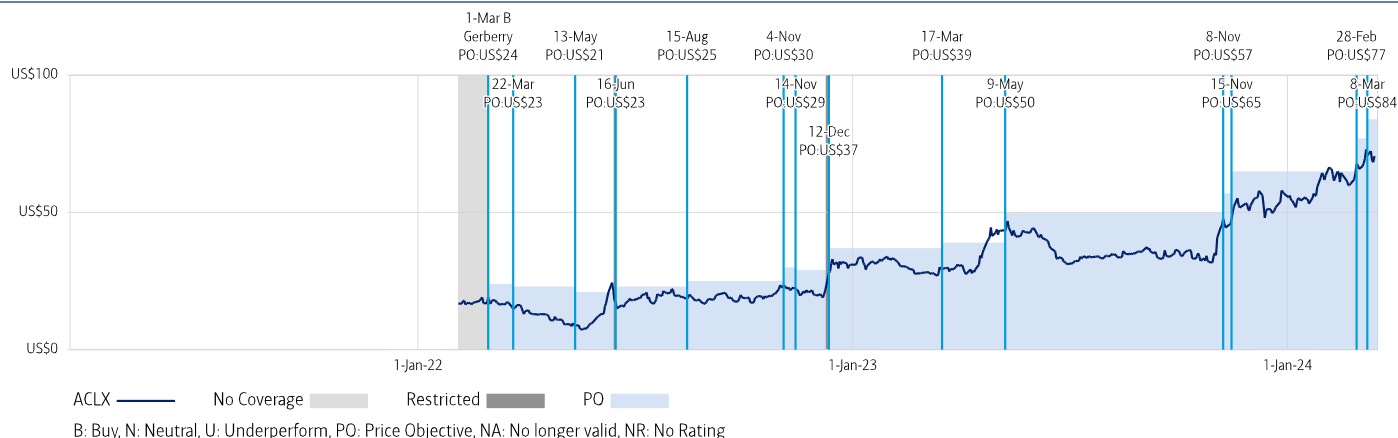
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Arcellx (ACLX) Price Chart



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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%
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Sell	807	22.84%	Sell	383	47.46%

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