

Arcellx, Inc.

Previewing '24 catalysts + case for late-mover advantage in BCMA CAR-T

Reiterate Rating: BUY | PO: 84.00 USD | Price: 70.77 USD

Reit Buy on 2024 setup ahead of key data update in 2H

Here, we preview the '24 Arcellx (ACLX) setup highlighted by anito-cel (BCMA CAR-T) pivotal data in late-line RRMM and read-through from a competitor FDA AdCom/labeling decision. Ahead of YE24 anito-cel pivotal data, we are mainly looking for confirmation of the profile established in prior Ph1/2 with delayed neuro-tox a key point of focus / differentiation. On competitor BCMA CAR-T FDA AdCom – we think the base case is for a contentious panel discussion around CAR-T OS benefit in early vs. late-line use but an ultimate vote supporting risk/benefit. Practically, KOL feedback around competitor CART safety + OS debates likely relegates CAR-T to 3L+ (for now) but we don't see negative read-across to ACLX as 3L+ is still a big market / future studies can drive push into earlier lines. We see ACLX having second-mover advantage as lead BCMA approaches continue to struggle with supply and incur the heavy/slow-lift to drive early-line adoption (see CD19 CAR-T analog). We reiterate Buy on ACLX; PO to \$84 (vs \$77 prior) on higher anito cel revenue after rebasing price assumption based on pricing for approved CAR-Ts.

2H pivotal data offer a venue for profile strengthening

We believe Arcellx/Gilead's anito-cel has established a highly competitive BCMA CAR-T profile (see report for detailed discussion). Heading into a pivotal Ph2 study update in 5L+ MM, we see further corroboration from a larger study as an important milestone both confirming anito-cel's safety differentiation + lack of efficacy trade-offs (vs. Carvykti) + improved line of sight on BLA filing/time-to-market. We believe anito-cel's delayed neurotox/parkinsonism data will be the most nuanced point: zero cases would be unequivocal, but 2+ would stir debate on differentiation vs Carvykti given variability in frequencies reported for competitor CAR-Ts. Importantly, we'd like to see near perfect manufacturing success rates vs. ~80% clinical rate for Carvykti. ACLX has not committed to when/where it will offer a Ph1/2 anito-cel updated data-cut (prior PFS within the 24-30 median PFS range vs est. of 28mo mPFS) which KOLs we have spoken with believe comfortably puts anito-cel in range to infer comparability to Carvykti.

Moving to earlier line MM: comp AdCom, ACLX's strategy

On March 15, the FDA will host an AdCom to discuss the potential label expansion of competitor CAR-Ts (Abecma, Carvykti) into earlier line MM. KOL framed line of therapy and risk/benefit of early CAR-T use vs late as possible discussion topics and flagged regulatory risk of getting 3L+ label. ACLX plans to start an earlier line MM trial in 2024 and reveal trial design in near future. See detailed AdCom preview starting on page 3.

Estimates (Dec) (US\$)	2022A	2023A	2024E	2025E	2026E
EPS	(5.19)	(1.46)	(1.63)	1.35	0.10
GAAP EPS	(5.19)	(1.48)	(1.63)	1.35	0.10
EPS Change (YoY)	96.4%	71.9%	-11.6%	NM	-92.6%
Consensus EPS (Bloomberg)			(1.94)	(1.96)	(2.60)
DPS	0	0	0	0	0
Valuation (Dec)					
P/E	NM	NM	NM	52.4x	707.7x
EV / EBITDA*	NM	NM	NM	44.1x	310.1x
Free Cash Flow Yield*	-2.7%	-0.9%	-1.4%	2.4%	0.5%

* For full definitions of *IQmethod*SM measures, see page 17.

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12668409

Timestamp: 08 March 2024 06:00AM EST

08 March 2024

Equity

Key Changes

(US\$)	Previous	Current
Price Obj.	77.00	84.00
2026E Rev (m)	194.1	163.6
2026E EPS	0.70	0.10

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Stock Data

Price	70.77 USD
Price Objective	84.00 USD
Date Established	7-Mar-2024
Investment Opinion	C-1-9
52-Week Range	26.32 USD - 73.30 USD
Mkt Val (mn) / Shares Out (mn)	3,736 USD / 52.8
Free Float	73.9%
Average Daily Value (mn)	31.89 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™	NLA

ESGMeter is not indicative of a company's future stock price performance and is not an investment recommendation or rating. ESGMeter is independent of BofA Global Research's equity investment rating, volatility risk rating, income rating, and price objective for that company. For full details, refer to ["BofA ESGMeter Methodology"](#).

BCMA, CD19: antigen; CAR-T: cell therapy
GILD: Gilead (covered by Geoff Meacham)
RR MM: relapsed/refractory multiple myeloma
L: line of therapy; BLA: biologic drug application
mPFS: median progression free survival
KOL: expert; AdCom: Advisory Committee
FDA: US Food and Drug Administration

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iQprofileSM Arcellx, Inc.

iQmethodSM – Bus Performance*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Return on Capital Employed	-92.8%	-15.0%	-8.9%	7.5%	0.5%
Return on Equity	-119.1%	-14.4%	-10.6%	8.8%	0.6%
Operating Margin	NA	-81.5%	-62.1%	25.9%	9.1%
Free Cash Flow	(102)	(35)	(54)	90	18

iQmethodSM – Quality of Earnings*

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash Realization Ratio	NM	NM	NM	1.4x	4.5x
Asset Replacement Ratio	1.7x	1.6x	1.3x	1.0x	0.8x
Tax Rate	NM	NM	NM	1.0%	1.0%
Net Debt-to-Equity Ratio	-31.3%	-82.8%	-89.9%	-90.9%	-90.7%
Interest Cover	NA	NA	NA	NA	NA

Income Statement Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Sales	0	110	126	280	164
% Change	NA	NA	14.6%	121.2%	-41.5%
Gross Profit	0	110	126	280	164
% Change	NA	NA	14.6%	121.2%	-41.5%
EBITDA	(190)	(88)	(76)	71	10
% Change	-196.9%	53.6%	13.7%	NM	-85.8%
Net Interest & Other Income	3	20	0	0	0
Net Income (Adjusted)	(189)	(70)	(79)	67	5
% Change	-190.3%	62.9%	-12.3%	NM	-92.7%

Free Cash Flow Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Net Income from Cont Operations (GAAP)	(189)	(71)	(79)	67	5
Depreciation & Amortization	1	2	2	4	5
Change in Working Capital	4	10	0	(1)	(5)
Deferred Taxation Charge	NA	NA	NA	NA	NA
Other Adjustments, Net	84	27	25	24	17
Capital Expenditure	(2)	(3)	(3)	(4)	(4)
Free Cash Flow	-102	-35	-54	90	18
% Change	-69.2%	65.8%	-54.7%	NM	-80.2%
Share / Issue Repurchase	260	93	0	0	0
Cost of Dividends Paid	0	0	0	0	0
Change in Debt	0	0	0	0	0

Balance Sheet Data (Dec)

(US\$ Millions)	2022A	2023A	2024E	2025E	2026E
Cash & Equivalents	64	635	641	731	749
Trade Receivables	0	1	1	3	2
Other Current Assets	203	201	141	141	138
Property, Plant & Equipment	11	12	13	13	12
Other Non-Current Assets	36	36	36	36	36
Total Assets	314	885	832	924	936
Short-Term Debt	NA	NA	NA	NA	NA
Other Current Liabilities	57	66	67	67	58
Long-Term Debt	0	0	0	0	0
Other Non-Current Liabilities	52	52	52	52	52
Total Liabilities	109	118	119	119	110
Total Equity	205	767	713	804	826
Total Equity & Liabilities	314	885	832	924	936

* For full definitions of iQmethodSM measures, see page 17.

Company Sector

Biotechnology

Company Description

Arcellx is a clinical stage biopharmaceutical company focused on the development of novel autologous CAR-T cell therapies for the treatment of cancers. The company's lead candidate, ddBCMA, is in clinical-stage for the treatment of relapse/refractory multiple myeloma (R/R MM). The company is also expecting to bring its ARC-SparX CAR-T technology into the clinic in the near term, which offers potential for a unique, differentiated approach to CAR-T treatment.

Investment Rationale

We rate Arcellx Buy and like the company based on 1) encouraging Ph1 clinical data for anito-cel (ddBCMA) which looks competitive relative to more advanced players in the relapsed/refractory multiple myeloma CAR-T space, 2) 2024 data readouts are material catalysts with potential to de-risk anito-cel, and 3) upside optionality with SparX approach (we do not currently include SparX programs [early stage] in model).

Stock Data

Average Daily Volume 450,566

Quarterly Earnings Estimates

	2023	2024
Q1	-0.58A	NA
Q2	-0.51A	NA
Q3	-0.81A	NA
Q4	0.44A	NA

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Executive Summary

Arcellx (ACLX) is in a pivotal Ph2 trial (iMMagine-1) developing lead asset anito-cel (ddBCMA), a BCMA CAR-T, for relapsed and refractory (r/r) or 5L+ multiple myeloma (MM). Trial enrollment is ongoing and preliminary data are expected in 2H24. ACLX's prior Ph1 data indicate anito cel has competitive efficacy profile relative to standard of care, J&J/Legend's Carvykti (BCMA CAR-T), based on cross-trial comparisons of progression free survival (PFS). ACLX's Ph1 data also point to potential anito-cel differentiation vs Carvykti: 1) neuro safety – KOLs have concerns around rare but serious neurotoxicity such as Parkinsonian-like events observed with Carvykti, vs none reported in ACLX's Ph1 trial; 2) efficacy in EMD patients – anito cel appears as effective at treating EMD (extramedullary disease) patients as non-EMD patients; EMD is a subgroup of difficult to treat patients more refractory to Carvykti treatment, 3) manufacturing success rate – 100% for anito cel in ACLX's Ph1 vs 82% reported for Carvykti in clinical trial. In ACLX's 2H pivotal data, we are focused on further support for anito-cel efficacy as measured by complete response (CR) and cleaner neuro safety profile (i.e. lack of delayed neurotox and Parkinsonism) in a larger patient number (Ph2: n~110) vs prior Ph1 data (n=32 on Ph2 dose, n=38 total). In 2024, ACLX also plans to initiate a randomized controlled Ph3 trial for advancing anito cel in earlier line of MM (bigger market) and intends to disclose Ph3 trial design in near future. Prior management commentary suggest that the Ph3 would be aimed at expanding anito cel into 3L/4L plus a targeted segment of 2L. ACLX expects the studied population to be distinct than competitors' trials (KarMMa-3, Cartitude-4) but framed its trial size and corresponding addressable population would be comparable vs competitors' trials.

More near term, on March 15th, we look to FDA AdCom discussions regarding competitor BCMA CART (Carvykti + Abecma) label expansion into earlier lines of MM (2-4L). We expect BCMA CAR-Ts to secure approval in earlier lines of therapy and we believe the bigger questions are what line of therapy the treatments will be approved and where the CAR-Ts will fit into current treatment algorithm based on current data. Furthermore, we look to panelist discussion regarding whether data support the use of Carvykti early (2L) versus later (3-4L) as it remains unclear if using CAR-T earlier will lead to longer overall survival than use in later line settings. Commentary from AdCom panel might serve as a harbinger for BCMA CAR-T use in earlier lines (once supply issues are resolved) or if ongoing/future trials will be needed to drive broader use of BCMA CAR-Ts in 2L MM.

Exhibit 1: ACLX EV as % of (closest comp) LEGN EV over time

ACLX EV gap up vs competitor as ACLX executed company milestones



Source: Bloomberg

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ACLX'24: preliminary pivotal data in focus

Background: treatment algorithm, CAR-T opportunity

Multiple myeloma (MM) is a cancer of plasma cells (white blood cells) in the bone marrow. Each year an est. >30k/>40k new MM cases are diagnosed in the US/EU. For newly diagnosed patients, the US treatment guideline (NCCN) recommends a Revlimid (lenalidomide)-based combo regimen followed by maintenance therapy with Revlimid. In addition to Revlimid (IMiD), a 1L induction regimen typically includes a proteasome inhibitor (PI), dexamethasone (dex), and/or an anti-CD38 antibody (e.g. Darzalex / daratumumab). There has been increased use of Darzalex in 1L based on NCCN preferential guideline recommendation for non-transplant eligible patients (~two-third of 1L MM) and recent positive Ph3 data (Perseus; dara-quadruplet [D-VRd]) in transplant-eligible pts (regulatory submission 2024E). For patients who progress on 1L therapy, a typical 2-4L regimen may include some combination of an alternative IMiD (Pomalyst / pomalidomide) with dexamethasone, a CD38, a PI, and/or other mechanisms. BCMA CAR-Ts (Abecma, Carvykti) and BCMA-directed bi-specific antibodies are approved for use in MM patients 4+ prior lines of therapy (i.e. 5L+), vs NCCN guideline recommending use of CAR-Ts and bi-specifics after 3 prior therapies (i.e. 4L+) (Exhibit 2).

In the US, we estimate the current CAR-T label indication of 5L MM+ has a US incidence of ~4k pts which translates to a US market opportunity of ~\$1.5bn, vs ~\$2.5bn global. If the category is successful in expanding its label indication into earlier line settings, we estimate 2L+ and 3L+ MM carries a \$11bn and \$6bn global market opportunity, respectively, under assumptions laid out in Exhibit 3, though in reality treatment with CARTs is unlikely to be isolated to one line of therapy (meaning practices may vary).

Exhibit 2: US treatment guideline (NCCN) for multiple myeloma (MM)

We summarize guideline-recommended treatment algorithm in MM

Line	Subgroup	Tier	Regimens	Mechanism						
				IMiD	CD38	PI	Steroid	Chemo	CAR-T	Bi-specific
1L	Transplant candidates	Preferred	Bortezomib, lenalidomide, dexamethasone (VRd)	R		V	d			
		Preferred	Carfilzomib, lenalidomide, dexamethasone (KRd)	R		K	d			
		Other recommended	Daratumumab, lenalidomide, bortezomib, dexamethasone (DVRd)	R	D	V	d			
1L	Non-transplant candidates	Preferred	Bortezomib, lenalidomide, dexamethasone (VRd)	R		V	d			
		Preferred	Daratumumab, lenalidomide, dexamethasone (DRd)	R	D		d			
		Other recommended	Daratumumab, bortezomib, melphalan, prednisone (D-VMP)		D	V	P	M		
		Other recommended	Carfilzomib, lenalidomide, dexamethasone (KRd)	R		K	d			
		Other recommended	Daratumumab, cyclophosphamide, bortezomib, dexamethasone (D-VCd)		D	V	d	C		
2-4L	Lenalidomide refractory	Preferred	Daratumumab, bortezomib, dexamethasone (DVd)		D	V	d			
		Preferred	Daratumumab, carfilzomib, dexamethasone (DKd)		D	K	d			
		Preferred	Isatuximab, carfilzomib, dexamethasone (IKd)		I	K	d			
		Preferred	Pomalidomide, bortezomib, dexamethasone (PVd)	P		V	d			
		Preferred	Selinexor, bortezomib, dexamethasone (SVd)			V	d			S
		Preferred	Carfilzomib, pomalidomide, dexamethasone (KPd)	P		K	d			
		Preferred	Elotuzumab, pomalidomide, dexamethasone (EPd)	P			d			E
		Preferred (2L, post-IMiD/PI)	Daratumumab, pomalidomide, dexamethasone (DPd)	P	D		d			
		Preferred (3L, post-IMiD/PI)	Isatuximab, pomalidomide, dexamethasone (IPd)	P	I		d			
		Preferred (3L, post-IMiD/PI)	Ixazomib, pomalidomide, dexamethasone (IxPd)	P		Ix	d			
4L+		Preferred	cilta-cel or ide-cel (BCMA CAR-T)						BCMA	
		Preferred	Elranatamab or teclistamab (BCMA x CD3) or talquetamab (GPRC5D x CD3)							BCMAxCD3 GPRC5DxCD3

Source: NCCN 2024

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Exhibit 3: Estimated addressable market of BCMA CAR-T in MM

Label expansion of CAR-Ts can expand utilization in earlier line of MM (bigger market vs 5L+ MM)

Line	Est US incidence	Transplant ineligible	CAR-T eligible	Est. US patients	US net price (\$k)	Est. US market (\$m)	US sales as % global	Est. global market (\$m)
1L	35,000	65%	70%	16,000	450	7,200	60%	12,000
2L	21,000	---	70%	15,000	450	6,750	60%	11,250
3L	12,000	---	70%	8,000	450	3,600	60%	6,000
4L	5,000	---	70%	3,500	450	1,575	60%	2,625
5L+	4,000	---	70%	3,000	450	1,350	60%	2,250

Source: company reports, BofA Global Research estimates

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CAR-T: early vs. late MM a likely a commercial debate

Two competitor sponsors are seeking label expansion to their CAR-T product labels (Abecma, Carvykti) into earlier line of MM. The FDA has scheduled an advisory committee (AdCom) panel for March 15th to discuss the clinical data that underpin each proposed label expansion, including overall survival (OS) data in the intended label population. We caught up with a KOL ahead of the AdCom to gauge key issues and potential read-across to ACLX's future anito-cel development in earlier line MM (Ph3 trial planned in 2024). The KOL thought the FDA panel would vote in favor of the label expansion, but would expect some difference of opinion regarding use in early vs. later-line MM. Without demonstration of an OS benefit in a crossover-allowed setting (more akin to real world), the KOL believes the clinical data to be discussed at the AdCom fail (in his view) to support that earlier use of CAR-T would lead to patients living longer vs later use, thus the commercial success of CAR-Ts may hinge on physicians' preference for how they want to sequence CAR-T in the treatment algorithm.

BCMA CAR-Ts showed PFS benefit in earlier line MM, OS benefit is an unknown

BMJ (Bristol Myers Squibb) and TSVT (2seventy Bio) conducted a Ph3 trial (KarMMa-3) to evaluate Abecma (CAR-T) vs standard of care in patients who had been treated with 2-4 prior line of therapies (i.e. 3L+ MM). The trial met its primary endpoint of PFS showing a 51% risk reduction (hazard ratio [HR] = 0.49) relative to physicians' choice of standard regimens (active control). There was no difference in overall survival (OS) between Abecma and control (HR=1.01) in the allcomer (ITT) population. However, 56% of patients on control arm crossed-over to receive Abecma as a subsequent therapy. Adjusting for cross-over (a pre-specified analysis), Abecma showed a better OS benefit vs control at HR=0.72.

JNJ (Johnson & Johnson) and LEGN (Legend) evaluated Carvykti (CAR-T) vs standard of care in a Ph3 trial (Cartitude-4) in patients who had been treated with 1-3 prior lines of therapies (i.e. 2L+ MM) and were refractory to lenalidomide on study entry. Unlike KarMMa-3, crossover was not allowed in Cartitude-4. The trial met its primary endpoint of PFS showing a 74% risk reduction (hazard ratio [HR] = 0.26) vs physicians' choice of standard regimens (mostly dara/poma/dex [DPd]). While OS was immature on topline results, there was an OS trend favoring Carvykti at HR=0.78. Detailed data table of KarMMa-3 and Cartitude-4 data can be found in Exhibit 9 from Appendix.

KOL framing potential discussion points at FDA AdCom

According to the FDA website, the AdCom will have general discussions focused on the "overall survival data" of Cartitude-4/KarMMa-3 and the "risk and benefit" of the respective CAR-T in the "intended population". Ahead of AdCom, we spoke with a multiple myeloma KOL at a large US academic center to gauge likely discussion points at the AdCom meeting:

- **Benefit of using CAR-T in early vs late line MM:** the KOL lamented Cartitude-4/KarMMa-3 did not inform early use of CAR-Ts would lead to patients ultimately living longer throughout their cancer (through any subsequent therapies till death)

as opposed to reserving CAR-T for later use, a scenario mirrored in patients from the control arm crossing over to receive CAR-T as a subsequent therapy. More specifically, in KarMMa-3, Abecma did not lead to better OS benefit vs control in all-comer population without adjusting for crossover. In Cartitude-4, immature OS data favor Carvykti vs control, but the trial did not allow crossover thus not designed the ultimate question on early vs late CAR-T usage. Said differently, if the physician can give CART in a later line (akin to the cross-over group) with comparable OS, then why subject the patient to CART related toxicities. The KOL pointed to Yescarta (CD19 CAR-T) as an example for “persuasive” OS benefit in 2L DLBCL (lymphoma; ZUMA-7 data) demonstrating OS benefit while allowing control arm to receive CAR-T as a subsequent therapy. While K-3/C-4 trials showed significant PFS benefit vs control, it is unclear how early use of CAR-T would impact a patient’s PFS outcome on subsequent therapies following CAR-T treatment.

- **Risks of using CAR-T in early vs late line MM:** the KOL thought the safety risks of CAR-Ts could be a discussion topic as it pertains to risk/benefit of using CAR-T, which carries a higher degree of scrutiny vs late line MM. Earlier line patients can live a number of years on effective treatment, thus quality of life matters more in earlier line MM. Among safety signals associated with CAR-Ts, the KOL is most concerned around rare but serious neurotoxicity such as Parkinsonism (more specific to Carvykti), as well as negative impacts to the bone marrow given some patients may have prolonged cytopenia post CAR-T, which could make giving subsequent therapies worse for those patients. Lastly, while the rate of grade 3 CRS reported were relatively low (<5%) in clinical trials, a potential need for a visit to intensive care (ICU) is not ideal for patients.
- **Patient baseline of Cartitude-4 in the context of evolving 1L landscape:** the KOL framed exposure to prior a CD38 antibody (e.g. Darzalex) in Cartitude-4 could be a topic of discussion. There has been an increasing use of Darzalex in 1L setting based on NCCN guideline and emerging clinical data of Darzalex. Only a quarter of Cartitude-4 patients enrolled had been exposed to a CD38 antibody, vs 100% of patients had prior exposure to Darzalex in KarMMa-3. We note in Cartitude-4 PFS favors Carvykti over control in dar-naïve and dar-exposed subgroups.
- **Line of therapy – study population vs label:** the KOL framed line of therapy for the drug label could be a discussion topic, given the majority (67-68%) of patients enrolled in Cartitude-4 had received 2 or more prior therapies (i.e. 3L+) (Exhibit 9). Recall, Cartitude-1 enrolled patients who had been treated with 3+ prior lines of therapy (i.e. 4L+), though Carvykti received a 5L+ label with FDA review documents citing establishment of risk/benefit in latter line population given only 17% of trial subjects were 4L vs majority were 5L+ in Cartitude-1. On the other hand, we note in Cartitude-4 PFS favors Carvykti over control in both 2L and 3-4L subgroups.
- **Composition of the AdCom panel may influence tone of discussions:** the KOL thought transplant and CAR-T specialists could be more supportive on CAR-T label expansion into earlier line MM, whereas multiple myeloma physicians could be more skeptical on earlier use of CAR-T in treatment algorithm, given neither KarMMa-3 nor Cartitude-4 data confirmed patients would live longer if they receive CAR-T earlier in disease course vs later.
- **AdCom panelist discussions may provide early insights on commercial prospects:** the KOL believes the FDA would more likely than not approve Abecma and Carvykti according to the KarMMa-3 and Cartitude-4 study populations as these trials met the primary PFS endpoint, thus leaving the physician community to decide best use of CAR-T in the treatment algorithm. The KOL predicts the CAR-Ts will mainly be used in 3L-4L setting based on the study results, whereas lack of OS benefit raises questions on risk/benefit for use in 2L and late-line patients (5L+)

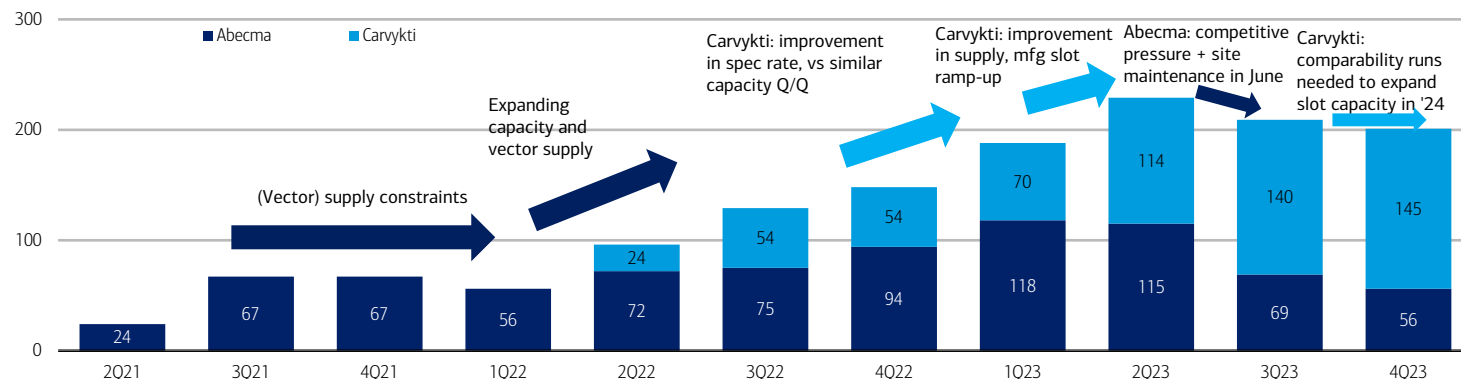
may be suboptimal for CAR-T cell production. The KOL cited Yescarta as an analog where commercial barrier to CD19 CAR-T remains in 2L+ DLBCL (community physicians' resistance to CAR-T referral) ~2 years after label expansion despite superior OS benefit demonstrated in the ZUMA-7 trial. Gilead recently noted that cell therapy penetration was ~15% in 2L+ DLBCL vs ~30% in EU, citing more gradual adoption by community physicians (80% of market) in the US.

Protracted supply constraints leave rooms for ACLX

Currently, CAR-T manufacturers cannot produce sufficient CAR-T products to address market demand in 4L/5L+ MM. Quarterly net sales of Carvykti were lumpy in 2023 as J&J/Legend continued to expand manufacturing (mfg) capacity for Carvykti, whereas sales of Abecma had slowed due to competitive pressure from BCMA-targeted therapies (e.g. Carvykti) (Exhibit 4). We estimate ~1.8k commercial doses of Abecma and Carvykti were made in the US (annualized rate based on 4Q23 reported net sales), vs. 3-4k eligible CAR-T patients. Penetration in ex-US is very low, as we estimate ~800 dose provided to ex-US patients vs est. >5k eligible patients in EU without counting patients rest of world.

Exhibit 4: US sales of BCMA CAR-T since commercial launches (\$m)

Mfg constraints had limited uptake of BCMA CAR-Ts during initial launch phase



Source: company reports

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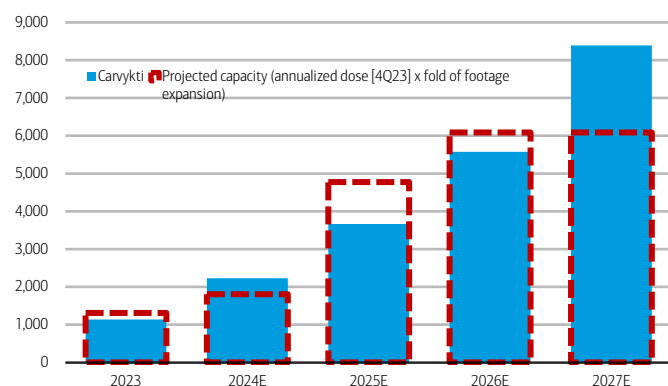
While ongoing efforts for CAR-T mfg expansion should address supply constraints in 5L+MM, the bigger question is whether JNJ/LEGN and BMY/TSVT can address increasing demand assuming their respective CAR-Ts will be approved for use in earlier line MM. While ACLX is late on timeline with 5L+ launch expected in 2026 (vs earlier line probably in 2028E+ timeframe based on KarMMA-3/Cartitude-4 timeline), persistent supply constraints should create an opportunity for late mover like ACLX to catch up in our view. By our estimates, it is unlikely that any one single manufacturer would be able to address demand if CAR-Ts become broadly used if not become standard of care in 3L or earlier line MM. We can look at this issue in a couple of different ways:

- Market size in earlier line MM exceeds market leader's aspirational goal on CAR-T capacity:** JNJ/LEGN had aspired to be in position to produce 10k commercial doses a year by 2026E, which compare to estimated ~8k/~9k US eligible patients in the US/EU in 3L vs ~15k/~17k in 2L. Beyond Cartitude-4 for 2L+ MM, JNJ/LEGN look to expand Carvykti into 1L with Ph3 trials ongoing (Cartitude-5 [non-transplant candidate], Cartitude-6 [transplant eligible]). Primarily completion date for Cartitude-5 is expected to be June 2026.

- Market lead must catch up on mfg expansion to catch up on aspirational production goal and consensus sales estimate:** JNJ/LEGN's production scale of Carvykti is annualizing at ~1.5k dose per year (based on 4Q23 reported sales). Assuming JNJ/LEGN can replicate the mfg efficiency from current cell processing location at Raritan, NJ to new mfg sites expected to come online over the next few years (expected to provide 3.5-4x square foot as current Raritan footprint), current annualized rate of Carvykti production would imply a capacity of around 6k dose per year by 2026E, by our estimates. Getting to JNJ/LEGN's aspirational goal (10k doses / year) and (JNJ) consensus estimates (8.5k doses in 2027) would require further manufacturing slot expansion in current Raritan NJ site and have that capacity replicated in other new sites. For more in-depth discussions on CAR-T manufacturing, please see our [CAR-T mfg primer report](#).

Exhibit 5: Carvykti: consensus derived patient forecast vs projected capacity based on footage expansion

Mfg site expansion trends in-line or trails cons projection on patient treated

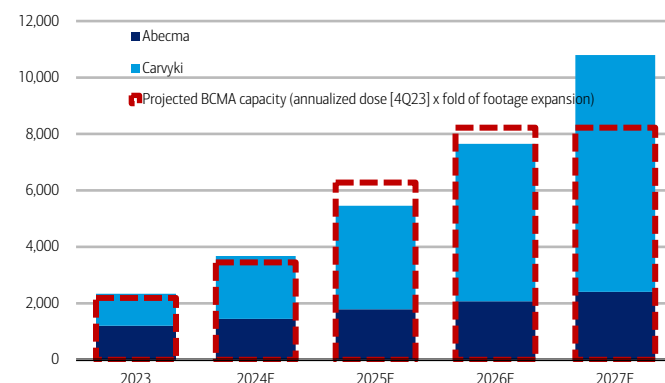


Source: Visible Alpha, company reports. Note: analysis assumes capacity expansion from sites addition at Obelisc, Ghent (impacting 24'E+ output), Eiland Zwijnaarde, Ghent ('25E+ output), and expansion at Raritan, NJ ('26E+ output).

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Exhibit 6: BMCA CAR-T: consensus derived patient forecast vs projected capacity based on footage expansion

Consensus forecast directionally trends with expected expansion in mfg site footage into '26



Source: Visible Alpha, company reports. Note: patient numbers are derived from consensus forecast on global sales and US pricing, assuming 1) 5% gross-to-net deduction on US price, 2) \$300k per dose ex-US.

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Early confirmation of anito cel profile in 2H24 pivotal data

In 2H24, ACLX plans to provide preliminary data from the ongoing pivotal trial of anito cel in 5L+ MM (iMMagine-1). At a high level, our focus for the 2H update is on additional support for anito cel's efficacy and safety profile in a larger sample size than prior Ph1 data (n=32). For context, ACLX's Ph1 data update of anito cel in 5L+ MM at ASH 2023 indicated anito cel has competitive efficacy profile vs Carvykti based on cross-trial comparisons of durability measures such as median PFS and PFS rates. The Ph1 clinical data also suggest anito cel may have potential differentiation vs Carvykti: 1) neuro safety, 2) efficacy in EMD patient subgroup, 3) manufacturing process. Detailed cross-trial comparison data table for 5L+ MM can be found in Exhibit 10 in the Appendix.

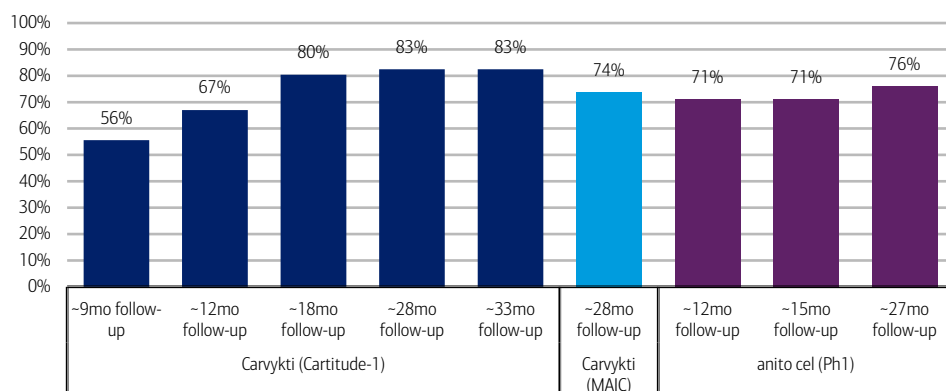
The iMMagine-1 trial is enrolling patients, with an enrollment target of ~110 patients. ACLX expects the 2H update to feature a robust sample size at complete enrollment (n~110), with a focus on complete response and MRD- (minimal residual disease) similar to initial Ph1 data of anito cel given duration of patient follow-up. On patient baseline, ACLX framed the pivotal trial would be more comparable to Cartitude-1 than ACLX's Ph1 trial, e.g. iMMagine-1 is expected to feature younger demographics and less EMD patients. Enrolling less-sick patients in iMMagine-1 would position anito cel to at least maintain efficacy profile relative to ACLX's prior Ph1 data. For the 2H update, we are most focused on complete response rate (CR), safety profile including neuro safety, and

robustness of ACLX's manufacturing success rate. Conversely, we do not expect duration of follow-up to be sufficiently long enough to interrogate PFS data in allcomer and EMD patient until a future update.

- **Complete response:** in lieu of PFS updates given duration of follow-up expected by 2H, we will look for a CR rate in the 60-70% range depending on where duration of follow-up lands by the time of datacut. As a reminder, with Cartitude-1, JNJ/LEGN had presented the data with five different data-cuts with CRs deepening over time. We note the 60%-70% CR range would compare to Carvykti's 56% in first datacut (8.8mo follow-up) and Carvykti's 67% in in second datacut (12.4mo follow-up), as well as anito-cel's 71% CR in initial Ph1 data (12.1mo follow-up). CR of that magnitude would offer initial confirmation of anito cel's efficacy profile in a larger sample size (up to n~110) vs Ph1 data (n=32), pending confirmation of durability metrics (median PFS) in a future update.

Exhibit 7: Complete response (CR) rates for CAR-Ts in 5L+MM

CR rates from prior Ph1 data deepened over time on longer follow-up



Source: company reports

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- **Neuro safety:** we will look for a neuro toxicity rate no higher than 3% and no reports (or no more than 1 case) of delayed neurotoxicity or Parkinsonian-like events in Ph2 data. Zero case of delayed neurotox will offer the cleanest comp vs Carvykti which had reports of delayed neurotox ranging from low single digit to 5% between Cartitude-1 and Cartitude-4, whereas 1 case (out of ~110 Ph2 patients + 38 Ph1 patients [across both doses]) would still compare favorably to the low end of the AE frequency range reported for Carvykti. ACLX believes the 2H update will be informative on neuro tox based on expected duration of follow-up relative to onset of neurotoxicity seen with Carvykti (label: median onset 43d, range 15-108 days). While rate of neurotoxicity for Carvykti was lower at ~3% in Cartitude-4 (2L+ MM), KOLs framed the primary neuro safety concern on Carvykti lies in the rare but serious neurotoxicity such as Parkinsonism – as these events are not transient, potentially irreversible, and lack effective remediation options. See below for a more detailed discussion on neurotox associated with CAR-T.
- **Manufacturing success:** ACLX was able to manufacture anito cel successfully in all 40 patients who had been enrolled and apheresed in Ph1. We look to confirm the robust mfg success rate (e.g. >90%) in a larger sample size in Ph2, but so far mfg metrics in Ph1 compare favorably to the clinical mfg success rate of Carvykti from Cartitude-1 (82%). ACLX's current mfg process (through a contract manufacturer) for Ph2 is the same as Ph1, whereas tech transfer of the mfg process to partner Gilead/Kite is ongoing and expected to complete this year. ACLX expects Kite's

process/expertise can offer better turnaround time than current process (Ph1: 35d median), possibly ballparks that for Yescarta (14-16d median), with similar mfg success rate as current process. Manufacturing success rate and turnaround time are important commercial factors because 1) a sponsor can only recognize revenue from an in-specification (in spec) CAR-T, 2) KOLs we spoke with consistently emphasize that they desire an effective CAR-T that they can obtain reliably and timely vs there remains supply constraints for Carvykti in 5L+ MM.

Below, we summarize PFS and EMD data of anito cel in prior Ph1, though we look to a future update post-2024 for better Ph2 characterization of anito cel.

- **Durability of efficacy by mPFS and PFS rates:** anito cel has an estimated median (m) PFS of ~28mo and a 24mo PFS rate of 56%, which stack up well against Carvykti which had shown similar data in a key benchmark study, an MAIC (matching adjusted indirect comparison)-adjusted analysis of Cartitude-1: ~25mo mPFS, low 50%'s 24-month PFS.
- **Efficacy in EMD patient subgroup:** patients with extramedullary disease (EMD) were more refractory to Abecma or Carvykti CAR-T treatments in clinical trials. In respective 5L+ MM trials, EMD patients had shorter mPFS compared to allcomers. More specifically in Cartitude-1, Carvykti showed a mPFS of 13-14 months in EMD compared to 34-35mo mPFS (not MAIC-adjusted) in allcomers. By comparison, in ACLX's Ph1 trial, anito cel's mPFS was not reached in both EMD and allcomers at 26.5mo follow-up and 24mo PFS rates were 56-58% for both EMD and allcomers. ACLX's Ph1 data suggest anito cel may work as effectively in EMD as non-EMD patients, though the observation needs to be validated in a bigger sample size (vs n=13 EMD patients in Ph1). Our discussion here is focused on PFS, as it is clear to us whether CAR-T would induce different CR rate in EMD vs non-EMD patients, given limited disclosure from sponsors (Exhibit 10), except in Legend-2 CR rate for Carvykti was lower in EMD subgroup vs allcomer (55% vs 73%). Nonetheless, by definition, we note EMD lesions must be cleared for a patient to qualify as a CR. Our prior KOL checks suggest a scenario where physicians may gravitate toward anito cel over alternatives knowing it works in EMD patients without worrying about doing additional diagnostic work to determine a patient has EMD or not (EMD is underdiagnosed in real world per KOL checks).

Neurotoxicity: a safety event of interest for CAR-T therapy

Neurotoxicity is a possible adverse event that occurs in patients after CAR-T treatment, which generally happens as a 'by-product' of cytokine release syndrome (CRS; another AE) and onset is typically within a couple of weeks after CAR-T treatment. These neuro signals are documented as ICANS (immune effector cell-associated neurotoxicity syndrome) in clinical trials and are generally reversible. Some patients may develop delayed neurotoxicity around 1-3 months after CAR-T treatment that are relatively rare in occurrence but potentially serious / protracted enough to significantly impact the patient's quality of life. Delayed neurotox may include cranial nerve palsy and Parkinsonian-like symptoms (e.g. movement disorder). Per our KOL checks, the underlying cause of the delayed neurotoxicity is not entirely clear, and these adverse events are typically not transient, potentially irreversible, and often lack effective remediation options.

Delayed neurotoxicity adverse events have been reported in different CAR-T therapies, but the AE incidence rate appears most pronounced with Carvykti. In the Cartitude-1 trial (4L+ MM, n=97), ~10% of Carvykti-treated patients reported to have grade 3 neurotoxicity AE and majority of them or 9% of patients had non-ICANS toxicity that has later onset of action (delayed neurotox). Of those, 4 patients had Parkinsonism, including three grade 3/4 cases. By comparison, incidence of grade 3+ delayed neurotox was was

lower in Cartitude-4 (2L+ MM) at ~3% or less; hypotheses for lower incidence of grade 3+ neurotox include 1) Carvykti may be better tolerated in earlier line, 2) more effective bridging therapy reducing tumor burden prior to CAR-T treatment, 3) risk-mitigation strategies. KOLs we spoke with are primarily concerned around the protracted and potentially irreversible nature of delayed neurotoxicity (even if rare in occurrence).

ACLX believes anito cel would likely ballpark Abecma on frequency of neurotoxicity and delayed neurotox in larger sample size. Incidence of delayed neurotox was perceived to be less frequent for Abecma than Carvykti per our KOL checks (based on clinical data and real world experience). Further, Abecma label lacks warning language on Parkinsonism in boxed warning whereas Carvykti label does. In both KarMMa (4L+ MM) and KarMMa-3 (3L+ MM), around 3% of Abecma-treated patients had grade 3 neurotox but there was no case of Parkinsonism reported in either trial. According to FDA review documents, one case of grade 4 cerebral edema, one case of grade 3 myelitis and one case of grade 3 Parkinsonism have occurred in other studies submitted as part of the initial BLA (drug application). These three cases collectively represent <1% of ~500 Abecma-treated patients included in the initial BLA package (4L+ MM) + KarMMa-3 (3L+ MM) by our math.

Exhibit 8: Cross-trial comparison of neurotoxicity signals from BCMA CAR-Ts

Higher incidence of neurotox had been reported for Carvykti in clinical trials

	Abecma				Carvykti		Anito cel
	KarMMa (MM-001)	KarMMa-3	MM-001 JP + MM-002	CRB-401 (Ph1)	Cartitude-1	Cartitude-4	Ph1 trial of anito cel
Population	NEJM 2021	NEJM 2023	BLA review	BLA review	Lancet 2021	ASCO 2023	ASH 2023
n	4L+ MM	3L+ MM	4L+ MM	4L+ MM	4L+ MM	2L+ MM	4L+ MM
All grade neurotox	19%	15%	---	---	21%	21%	32 (Ph2 dose), 38 (total)
Grade 3+ neurotox	3%	3%	---	---	10%	3%	19% ICANS (Ph2 dose)
All grade delayed neurotox	Not provided (see comments below)	Not provided but footnote (see below) suggests at least 1 case	---	---	12% non-ICANS	17% non-ICANS	None
Grade 3+ delayed neurotox	Not provided (see comments below)	Not provided	---	---	9% non-ICANS	2% non-ICANS	None
Comments	No Parkinsonism. All events of neurotox reported had an onset of 10d or less.	No Parkinsonism. Per NEJM paper, one patient developed encephalopathy at day 317, which was not considered to be related to ide-cel but related to worsening pneumonia and C. difficile colitis. The next longest duration of onset to a neurotoxicity event was 46 days.	One case of grade 3 myelitis and one case of grade 3 parkinsonism	One case of grade 4 cerebral edema, which triggered a study amendment to exclude patients at risk of CNS bleed	One case of grade 5 neurotox (death). 4 patients had Parkinsonism, 3 of them were grade 3/4. Other neurotox include mental status changes, peripheral neuropathy, cranial nerve paralysis, etc.	Delayed neurotox include cranial nerve palsy, peripheral neuropathy, and movement / neurocognitive disorder	No delayed neurotoxicity, no Guillain-Barré syndrome, no cranial nerve palsies, and no Parkinsonian-like syndromes in the entire population through the follow-up period

Source: FDA.gov, medical journals, company reports

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Appendix: data tables

Exhibit 9: Cross-trial comparison of BCMA CAR-T data in 2L+ MM

We summarize clinical data of KarMMa-3 and Cartitude-4 trial data from BCMA CAR-T competitors

	Abecma				Carvykti			
	KarMMa-3				Cartitude-4			
	NEJM 2023 (March)		ASH 2023 (Dec)		ASCO / EHA 2023 (June)		NEJM (July)	
	Abecma	Standard regimens	Abecma	Standard regimens	Carvykti	Standard regimens	Carvykti	Standard regimens
Follow-up (median)	18.6 mo	18.6 mo	30.9 mo	30.9 mo	15.9 mo	15.9 mo	15.9 mo	15.9 mo
Inclusion criteria								
Prior # of regimens	2 to 4	2 to 4	2 to 4	2 to 4	1 to 3	1 to 3	1 to 3	1 to 3

Exhibit 9: Cross-trial comparison of BCMA CAR-T data in 2L+ MM

We summarize clinical data of KarMMa-3 and Cartitude-4 trial data from BCMA CAR-T competitors

	Abecma				Carvykti			
	Last regimen	Last regimen	Last regimen	Last regimen	Lenalidomide	Lenalidomide	Lenalidomide	Lenalidomide
Refractory status	Allowed	Allowed	Allowed	Allowed	Not allowed	Not allowed	Not allowed	Not allowed
Crossover	Allowed	Allowed	Allowed	Allowed	Not allowed	Not allowed	Not allowed	Not allowed
Baseline								
n	254	132	254	132	208	211	208	211
Age	63	63	63	63	62	61	62	61
Time from diagnose to screening	4.1 yr	4 yr	4.1 yr	4 yr	3.0 yr	3.4 yr	3.0 yr	3.4 yr
ECOG 0 / 1 / 2	47% / 52% / <1%	50% / 47% / 3%	--- / --- / ---	--- / --- / ---	--- / --- / ---	--- / --- / ---	55% / 45% / 0.5%	57% / 42% / 0.5%
BMPC ≥50% / ≥60%	28% / ---	26% / ---	28% / ---	26% / ---	--- / 20%	--- / 21%	--- / 20%	--- / 21%
Extra-medullary disease	24%	24%	24%	24%	---	---	21%	17%
ISS Stage I / II / III	20% / 59% / 12%	20% / 62% / 11%	20% / 59% / 12%	20% / 62% / 11%	65% / 29% / 6%	63% / 31% / 7%	65% / 29% / 6%	63% / 31% / 7%
High risk cytogenetics*	42%	46%	65%	62%	59%	63%	59%	63%
Previous autologous HSCT	84%	86%	84%	86%	---	---	---	---
Prior line of therapy (median)	3	3	---	---	2	2	2	2
1	0%	0%	0%	0%	33%	32%	33%	32%
2	31%	30%	---	---	40%	41%	40%	41%
3	37%	37%	---	---	27%	27%	27%	27%
4	32%	33%	---	---	0%	0%	0%	0%
Prior exposure								
Triple	---	---	---	---	26%	26%	26%	26%
Penta	---	---	---	---	7%	5%	7%	5%
Lenalidomide (IMiD)	98%	99%	---	---	---	---	100%	100%
Pomalidomide (IMiD)	56%	59%	---	---	---	---	4%	5%
Daratumumab (CD38)	100%	100%	---	---	---	---	25%	26%
Isatuximab (CD38)	---	---	---	---	---	---	1%	1%
Bortezomib (PI)	98%	97%	---	---	---	---	98%	97%
Carfilzomib (PI)	57%	43%	---	---	---	---	37%	31%
Ixazomib (PI)	15%	16%	---	---	---	---	10%	10%
Refractory status								
Triple	65%	67%	65%	67%	14%	16%	14%	16%
Penta	6%	4%	---	---	---	---	1%	1%
Lenalidomide (IMiD)	73%	79%	---	---	100%	100%	100%	100%
Pomalidomide (IMiD)	50%	53%	---	---	---	---	4%	4%
Daratumumab (CD38)	95%	93%	95%	93%	23%	21%	23%	21%
Isatuximab (CD38)	<1%	1%	---	---	---	---	1%	1%
Bortezomib (PI)	44%	45%	---	---	26%	23%	26%	23%
Carfilzomib (PI)	41%	33%	---	---	---	---	25%	21%
Ixazomib (PI)	---	---	---	---	---	---	7%	8%
Bridging therapy	---	---	DPd (20%) Kd (11%) DVd (8%) EPd (24%) IRd (11%) Others (9%) None (17%)	DPd (31%) Kd (21%) DVd (5%) EPd (23%) IRd (15%) None (5%)	PVd or DPd ≥ 1 cycle	N/A	PVd or DPd ≥ 1 cycle	N/A
All-comer efficacy								
Regimen	Ide-cel (100%)	DPd (33%) EPd (24%) Kd (22%) IRd (16%) DVd (6%)	Ide-cel (100%)	DPd (33%) EPd (24%) Kd (22%) IRd (16%) DVd (6%)	Cilta-cel	DPd or PVd	Cilta-cel (100%)	DPd or PVd ("mostly DPd")
ORR	71%	42%	71%	42%	85%	67%	85%	67%
CR	39%	5%	44%	5%	73%	22%	73%	22%
DOR	14.8 mo	9.7 mo	16.6 mo	9.7 mo	NR	16.6 mo	---	---
PFS rates								
6-month	73%	40%	---	---	---	---	---	---
12-month	55%	30%	---	---	76%	49%	76%	49%
18-month	---	---	41%	19%	---	---	---	---
24-month	---	---	---	---	---	---	---	---
mPFS	13.3 mo	4.4 mo	13.8 mo	4.4 mo	NR	11.8 mo	NR	11.8 mo
HR	0.49		0.49		0.26		0.26	

Exhibit 9: Cross-trial comparison of BCMA CAR-T data in 2L+ MM

We summarize clinical data of KarMMa-3 and Cartitude-4 trial data from BCMA CAR-T competitors

	Abecma				Carvykti			
mPFS2	---	---	23.5 mo	16.7 mo	---	---	---	---
HR	---	---	0.79		---	---	---	---
mOS	---	---	41.4 mo	37.9 mo	---	---	---	---
HR	---	---	1.01		0.78 (immature)		---	
mOS adjusted for crossover	---	---	41.4 mo	23.4 mo	N/A	N/A	N/A	N/A
HR	---	---	0.72		N/A		N/A	
% pts crossover to Car-T		---		56%		Not allowed		Not allowed
Safety								
n	250	126	225	126	208 (ITT; safety) / 176 (as-treated; neurotox)	208	208 (ITT; safety) / 176 (as-treated; neurotox)	208
Grade 3+ AE	93%	75%	---	---	97%	94%	96.6%	94.2%
Grade 3 CRS	4%	0%	4%	0%	1%	---	1%	0%
Grade 3 neurotox	3%	0%	3%	0%	2.8% (overall gr3+) ICANS (0.1% gr3+) cranial nerve palsy (1.1% gr3+) peripheral neuropathy (0.6% gr3/4) movement/cognitive (0% gr3, 0.6% gr1-2)	---	2.8% (overall gr3+) ICANS (0.1% gr3+) other (2.3% gr3+) movement/cognitive (0% gr3, 0.6% gr1-2)	0%
Time to onset of neurotox	3 days median (1 - 317d)	N/A	---	N/A	ICANS (10d median) cranial nerve palsy (21d) peripheral neuropathy (63d) movement/neurocognitive (85d)	---	---	N/A
Grade 3 infections	24%	18%	22%	---	27%	25%	27%	25%

Source: company reports. Note: ECOG: status, ISS: International Staging System, EMD: extramedullary disease, ORR: objective response rate, CR: complete response, DOR: duration of response, PFS: median progression-free survival, OS: overall survival, m: median, HR: hazard ratio, ITT: intent-to-treat, CRS: cytokine-release syndrome, ICAN: neurotoxicity, n= subject number, AE: adverse event, ASCO/ASH: medical meeting, NEJM: medical journal.

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Exhibit 10: Cross-trial comparison of BCMA CAR-T data in 5L+ MM

We summarize ACLX's and competitors' clinical data in 5L+ MM

	Abecma KarMMa	Carvykti					ddBCMA	
	LEGEND-2	CARTITUDE-1	CARTITUDE-1	CARTITUDE-1	MAIC adj CARTITUDE-1		ddBCMA Ph1	ddBCMA Ph1
	NEJM 2021	J. Hem & Onc 2022	Lancet 2021	ASCO 2022	ASCO 2023	Curr Med Res Opin 2023	ASH 2022	ASH 2023 data
Follow-up (median)	13.3 mo	47.8mo	12.4mo	27.7mo	33.4 mo	27.7mo	~15 mo	26.5mo
Baseline								
n	70 / 54	74	97	97	97	97	38	38
Age	61 / 62	54.5	61	61	61	62	66	66
ECOG								
0	44% / 43%	41%	40%	40%	40%	33%	32%	32%
1	54% / 54%	43%	56%	56%	56%	67%	68%	68%
BMPC ≥60%	---	---	22%	22%	22%	---	24%	24%
ISS Stage III	17% / 15%	28%	14%	14%	14%	17%	13%	13%
Extra-medullary disease	49% / 30%	30%	13%	13%	13%	~40%**	34%	34%
High risk cytogenetics	29% / 44%	36%	24%	24%	24%	36%	29%	29%
Prior line of therapy	6 / 5	3	6	6	6	5	4	4
Refractory								
Triple	86% / 81%	---	88%	88%	88%	---	100%	100%
Penta	34% / 15%	---	42%	42%	42%	26%	68%	68%
All-comer efficacy								
ORR	69% / 81%	88%	97%	98%	98%	100%	100%	100%
CR	29% / 39%	73%	67%	83%	83%	74%	71%	76%
Median time to CR	2.8 mo (1.0-11.8)	---	1.9 mo (1.0-6.5)	2.9 mo (0.9-17.8)	---	---	---	---
6-month PFS	~65% / ~80%	~84%	~87%	~87%	~87%	~80%	92%	92%
12-month PFS	~35% / ~35%	~59%	~76%	~76%	~76%	~70%	73%	76%
18-month PFS	---	~50%	~55%	~65%	~65%	~57%	65%	64%
24-month PFS	---	---	~60%	~60%	~60%	~low 50%	---	56%
mPFS	10mo / 11mo	18mo	Not reached	Not reached	34.9 mo	25.2 mo	Not reached	Not reached (K-M est 28mo)
EMD-subgroup efficacy								

Exhibit 10: Cross-trial comparison of BCMA CAR-T data in 5L+ MM

We summarize ACLX's and competitors' clinical data in 5L+ MM

	Abecma		Carvykti				ddBCMA	
ORR	---	82%	---	---	---	---	100%	100%
CR	---	55%	---	---	---	---	85%	---
6-month PFS	---	---	---	---	---	---	92%	92%
12-month PFS	---	---	---	---	---	---	64%	67%
18-month PFS	---	---	---	---	---	---	64%	67%
24-month PFS	---	---	---	---	---	---	---	~57.5%
mPFS	8mo	8.9mo	---	13.8mo*	---	---	---	--- (>24mo)
Safety								
Dose	300m / 450m	0.5m / kg	0.71m / kg	0.71m / kg	0.71m / kg	0.71m / kg	100m	100m
n	74	74	97	97	97	---	32	32
Grade 3 CRS	10%	10%	4%	5%	5%	---	0%	0
Grade 3 neurotoxicity	3%	---	9%	12%	12%	---	3% ICANS	3% ICANS (no delayed neurotox nor Parkinsonian-like events)

Source: company reports. Note:*include bone-based and extramedullary plasmacytomas, ** presence of all plasmacytomas, ECOG: status, ISS: International Staging System, EMD: extramedullary disease, ORR: objective response rate, CR: complete response, m PFS: median progression-free survival, CRS: cytokine-release syndrome, ICAN: neurotoxicity, n= subject number, mo: months, ASCO: medical meeting, ASH: medical meeting

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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.

Analyst Certification

I, Jason M. Gerberry, 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 - Specialty Pharma & Biotechnology Coverage Cluster

Investment rating	Company	BofA Ticker	Bloomberg symbol	Analyst
BUY				
	Arcellx, Inc.	ACLX	ACLX US	Jason M. Gerberry
	Arrowhead Pharmaceuticals	ARWR	ARWR US	Jason M. Gerberry
	bluebird bio	BLUE	BLUE US	Jason M. Gerberry
	Catalyst Pharma	CPRX	CPRX US	Jason M. Gerberry
	Exelixis	EXEL	EXEL US	Jason M. Gerberry
	Fractyl Health	GUTS	GUTS US	Jason M. Gerberry
	Immunovant, Inc.	IMVT	IMVT US	Jason M. Gerberry
	Intra-Cellular Therapies	ITCI	ITCI US	Jason M. Gerberry
	Ionis	IONS	IONS US	Jason M. Gerberry
	Jazz Pharmaceuticals	JAZZ	JAZZ US	Jason M. Gerberry
	Lyra Therapeutics	LYRA	LYRA US	Jason M. Gerberry
	Oculus Holding AG	OCS	OCS US	Jason M. Gerberry
	Relay Therapeutics	RLAY	RLAY US	Jason M. Gerberry
	Tarsus Pharmaceuticals	TARS	TARS US	Jason M. Gerberry
	Teva Pharmaceuticals	TEVA	TEVA US	Jason M. Gerberry
	Vaxcyte Inc	PCVX	PCVX US	Jason M. Gerberry
	Xenon Pharmaceuticals	XENE	XENE US	Jason M. Gerberry
NEUTRAL				
	Alkermes	ALKS	ALKS US	Jason M. Gerberry
	Amphastar Pharmaceuticals	AMPH	AMPH US	Jason M. Gerberry
	Axsome Therapeutics	AXSM	AXSM US	Jason M. Gerberry
	Galapagos	GLPG	GLPG US	Jason M. Gerberry
	ProKidney Corp	PROK	PROK US	Jason M. Gerberry
	Roivant	ROIV	ROIV US	Chi M. Fong
UNDERPERFORM				
	Bausch Health Cos Inc	BHC	BHC US	Jason M. Gerberry
	FibroGen Inc.	FGEN	FGEN US	Jason M. Gerberry
	Harmony Biosciences	HRMY	HRMY US	Jason M. Gerberry
	Organon	OGN	OGN US	Jason M. Gerberry
	Viatis Inc.	VTRS	VTRS US	Jason M. Gerberry

iQmethodSM Measures Definitions

Business Performance

Return On Capital Employed

Return On Equity

Operating Margin

Earnings Growth

Free Cash Flow

Numerator

NOPAT = (EBIT + Interest Income) × (1 – Tax Rate) + Goodwill Amortization

Net Income

Operating Profit

Expected 5 Year CAGR From Latest Actual

Cash Flow From Operations – Total Capex

Denominator

Total Assets – Current Liabilities + ST Debt + Accumulated Goodwill

Amortization

Shareholders' Equity

Sales

N/A

N/A

Quality of Earnings

Cash Realization Ratio

Asset Replacement Ratio

Tax Rate

Net Debt-To-Equity Ratio

Interest Cover

Numerator

Cash Flow From Operations

Capex

Tax Charge

Net Debt = Total Debt – Cash & Equivalents

EBIT

Denominator

Net Income

Depreciation

Pre-Tax Income

Total Equity

Interest Expense

Valuation Toolkit

Price / Earnings Ratio

Price / Book Value

Dividend Yield

Free Cash Flow Yield

Enterprise Value / Sales

Numerator

Current Share Price

Current Share Price

Annualised Declared Cash Dividend

Cash Flow From Operations – Total Capex

EV = Current Share Price × Current Shares + Minority Equity + Net Debt +

Other LT Liabilities

Enterprise Value

Denominator

Diluted Earnings Per Share (Basis As Specified)

Shareholders' Equity / Current Basic Shares

Current Share Price

Market Cap = Current Share Price × Current Basic Shares

Sales

Basic EBIT + Depreciation + Amortization

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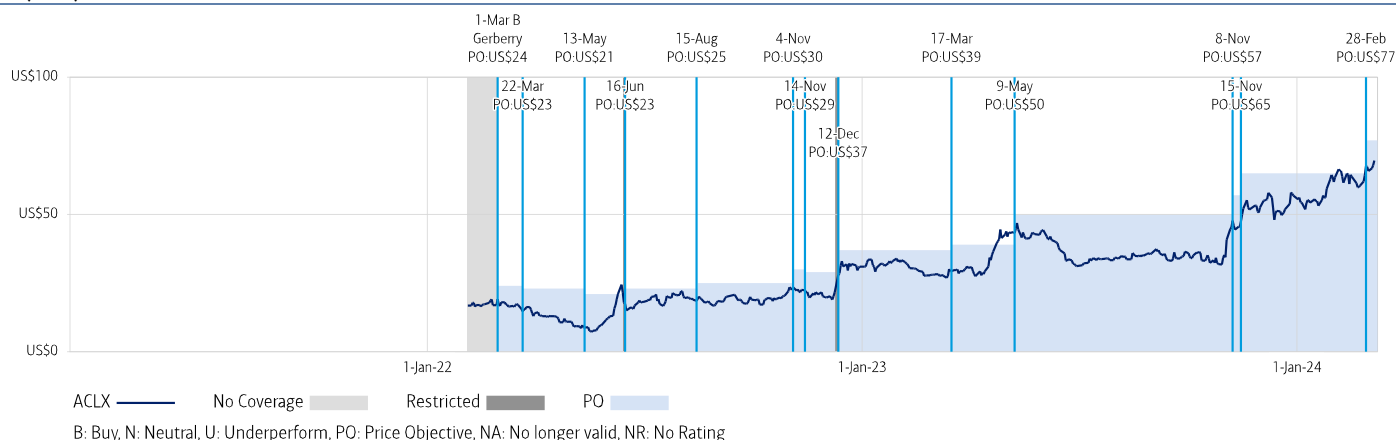
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Arcellx (ACLX) Price Chart



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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%
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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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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