BofA SECURITIES

Arcellx, Inc.

Framing the bar for ddBCMA into ASH '23 abstract drop next Thursday (11/2)

Maintain Rating: BUY | PO: 50.00 USD | Price: 32.37 USD

Preview ASH 2023 abstract: Carvykti-like is good enough

Ahead of next Thursday's (11/2) ASH abstract drop, we provide our updated thoughts on Arcellx/Gilead's ddBMCA (BCMA CAR-T) Ph1 data (multiple myeloma [MM]) update. Based on the prior study update (ASH '22) and likely added patient follow-up, we expect the abstract to offer a meaningful ddBCMA update on durability of efficacy (measured by progression free survival or PFS). While a separate pivotal Ph2 trial is ongoing, the FU data from the earlier Ph1 can solidify ddBCMA's competitive profile relative to the gold standard (J&J/Legend's Carvykti). Our forecasts assume ddBCMA secures approval with a profile similar to Carvykti (not better) but that protracted supply issues and large end-market allow ddBCMA to realize attractive peak sales; we forecast nominal ~$3bn peak global sales, inclusive of assumed contribution in earlier lines. In the ASH abstracts, we believe a good benchmark for ddBCMA is 20-months or better median PFS (or not reached) while improvement on CR (complete response) would be nice-to-have (not critical). Below, we highlight a few key statistical and patient sub-group considerations that should be considered when benchmarking the abstract data/ extrapolating ddBCMA's ultimate profile. We maintain Buy on ACLX on upside potential from catalysts.

ASH 2023 abstracts to offer meaningful update

At ASH, ACLX plans to provide an update from its Ph1 (single-arm; n=38) study for MM patients. At ASH 2022, the Ph1 had a median duration of patient follow-up (F/U) of 15-months which limited PFS assessment. In the upcoming ASH abstract, we expect ~6-months of added F/U while the final presentation in December should offer ~+12-months F/U. Given that BCMA CAR-T durability becomes clearer with median F/U in the 20-30 month range, we expect answers to 1) how the durability of ddBCMA stacks up against Carvykti; and 2) whether ddBCMA looks similar or better than Carvykti in certain high risk patient sub-groups, albeit from small sample sizes.

Durability: 20mo+ mPFS, based on study demographics

As it pertains to durability, the median PFS of Carvykti in late-line MM is wide ranging at 18-35 months (different studies); the delta based on patient enrollment demographics. So far, ACLX has disclosed landmark PFS rates but not a Kaplan-Meier (KM) PFS curve given PFS data have been immature and tend to evolve with longer patient F/U. Notably, Carvykti reported an 18-mo mPFS in Legend-2 which had an above-normal baseline level of high-risk factor EMD (30% vs. ~15% normal), 25-months per a 2022 MAIC analysis (adjusted for trial baseline differences vs Abecma trial [key comp]) and 35-months (Cartidude-1; more favorable baseline than MAIC). To support the importance of prognostic factors, Legend-2 four-year follow-up data indicate mPFS of 8.5 months in EMD patients while EMD-like patients in Cartitude-1 had mPFS of 13.8 months, both well below any of the all-comer PFS. Considering baseline characteristics across key Ph1/2 trials (Exhibit 1), for ddBCMA, a Ph1 mPFS in 18-25 month range (we'd like to see 20-mo or better; or median not reached) would be a good indication, in our view, that durability of ddBCMA clinical benefit stacks up competitively with Carvykti.

Continued on page 2: EMD sub-group consideration, cross-trial data table.

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Stock Data

Price	32.37 USD
Price Objective	50.00 USD
Date Established	9-May-2023
Investment Opinion	C-1-9
52-Week Range	18.70 USD - 48.92 USD
Mrkt Val (mn) / Shares Out (mn)	1,554 USD / 48.0
Average Daily Value (mn)	13.81 USD
BofA Ticker / Exchange	ACLX / NAS
Bloomberg / Reuters	ACLX US / ACLX.OQ
ROE (2023E)	-20.7%
Net Dbt to Eqty (Dec-2022A)	-31.3%
ESGMeter™	NLA

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Acronyms:
2L+: second-line plus
ASH: medical meeting
BCMA: antigen
BMY: Bristol Myers Squibb
CAR-T: cell therapy
CR: complete response
ddBCMA: drug name
EMD: extramedullary disease
MAIC: matching-adjusted indirect comparison
mPFS: median progression-free survival
Ph: Phase
TSVT: 2seventyBio

Differentiation in EMD sub-group tenuous, small datasets

Patients with EMD tend to have a worse prognosis than patients without EMD. In the ddBCMA pivotal trial, ACLX will control for EMD, limiting enrollment to 15% of study subjects. As such, we believe any outperformance of ddBCMA in these subjects may offer some read-through to what ddBCMA could show in 2H24 when preliminary pivotal results topline. However, given ACLX only enrolled 13 patients with EMD in Ph1 (upcoming ASH 2023 dataset), we'd caution investors from definitively concluding differentiation in the EMD sub-group. Beyond the above mentioned Carvykti data, there is also published data in TSVT/BMY's Abecma similarly showing an inferior PFS profile in patients with EMD vs those without EMD (mPFS: 7.9-mo vs. 10.4-mo without [ASH '20]).

Exhibit 1: Cross-trial comparison of BCMA CAR-T data
We summarize data benchmark (LEGEND-2) for ddBCMA Ph1 update at ASH 2023

	Abecma	Carvykti				ddBCMA		
	KarMMa	LEGEND-2	CARTITUDE-1	CARTITUDE-1	MAIC adj CARTITUDE-1	ddBCMA Ph1	ddBCMA Ph1	ddBCMA Ph1
	NEJM 2021	J. Hem & Onc 2022	Lancet 2021	ASCO 2022	Curr Med Res Opin 2023	ASCO 2022	ASH 2022	ASH 2023
Follow-up (median)	13.3 mo	47.8mo	12.4mo	27.7mo	27.7mo	12.1mo	~15mo	~27mo
Baseline								
n	70 / 54	74	97	97	97	31	38	38
Age	61 / 62	54.5	61	61	62	66	66	66
ECOG								
0	44% / 43%	41%	40%	40%	33%	---	32%	32%
1	54% / 54%	43%	56%	56%	67%	---	68%	68%
BMPC ≥60%		---	22%	22%	---	---	24%	24%
ISS Stage III	17% / 15%	28%	14%	14%	17%	---	13%	13%
Extra-medullary disease	49% / 30%	30%	13%	13%	~40%**	39%	34%	34%
High risk cytogenetics	29% / 44%	36%	24%	24%	36%	---	29%	29%
Prior line of therapy	6 / 5	3	6	6	5	5	4	4
Refractory								
Triple	86% / 81%	---	88%	88%	---	77%	100%	100%
Penta	34% / 15%	---	42%	42%	26%	68%	68%	68%
All-comer efficacy								
ORR	69% / 81%	88%	97%	98%	100%	100%	100%	100%
CR	29% / 39%	73%	67%	83%	74%	71%	71%	?
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)	---	--- (-- to 12)	---	---
6-month PFS	~65% / ~80%	~84%	~87%	~87%	~80%	---	92%	?
12-month PFS	~35% / ~35%	~59%	~76%	~76%	~70%	---	73%	?
18-month PFS	---	~50%	~55%	~65%	~57%	---	65%	?
mPFS	10mo / 11mo	18mo	Not reached	Not reached	25.2 mo	Not reached	Not reached	?
EMD-subgroup efficacy								
ORR	---	82%	---	---	---	---	100%	100%
CR	---	55%	---	---	---	---	85%	?
6-month PFS	---	---	---	---	---	---	92%	?
12-month PFS	---	---	---	---	---	---	64%	?
18-month PFS	---	---	---	---	---	---	64%	?
mPFS	8mo	8.9mo	---	13.8mo*	---	---	---	?
Safety								
Dose	300m / 450m	0.5m / kg	0.71m / kg	0.71m / kg	0.71m / kg	100m / 300m	100m / 300m	100m / 300m
n	74	74	97	97	---	25 / 6	32 / 6	32 / 6
Grade 3 CRS	10%	10%	4%	5%	---	0% / 17%	0% / 17%	?
Grade 3 ICANs	0%	0%	9%	12%	---	4% / 17%	3% / 17%	?

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. Carvykti 35 month mPFS was reported at ASCO 2023.

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Price objective basis & risk

Arcellx, Inc. (ACLX)
Our $50 per share price objective is based on a risk-adjusted, sum-of-the-parts DCF. We assume 1) a discount rate of 11% for an early 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: 1) ddBCMA Ph1 trial failure, 2) ddBCMA fails to differentiate on safety, response rates, and/or durability in larger trials.

Upside risks: 1) better-than-expected ddBCMA Ph1 data in 2022 and better-than-expected safety, response rates, and durability in late phase trials and 2) acquisition at a premium.

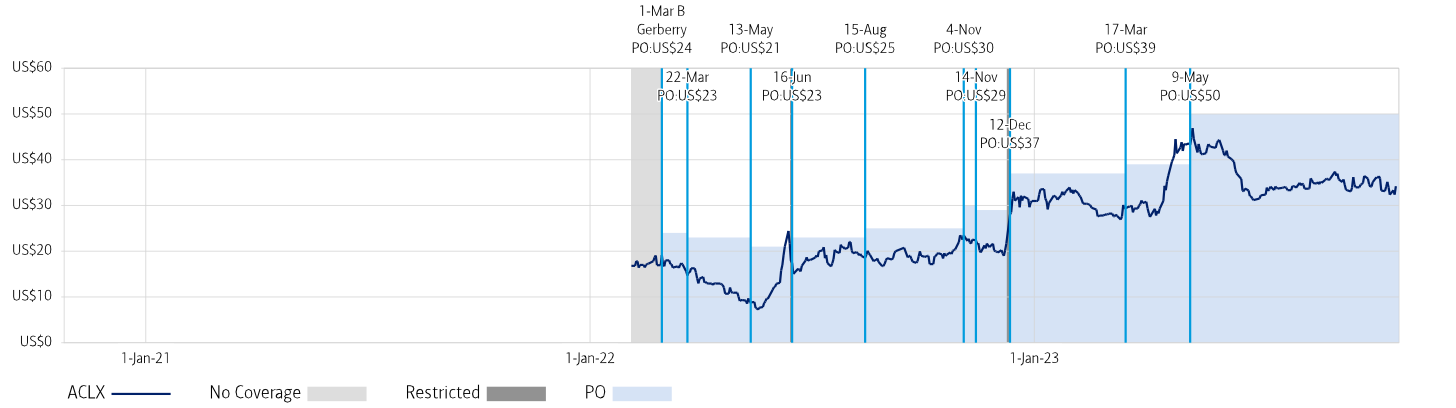
Analyst Certification

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.

Disclosures

Important Disclosures

Arcellx (ACLX) 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 30 Sep 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	233	60.21%	Buy	113	48.50%
Hold	83	21.45%	Hold	33	39.76%
Sell	71	18.35%	Sell	25	35.21%

Equity Investment Rating Distribution: Global Group (as of 30 Sep 2023)

Coverage Universe	Count	Percent	Inv. Banking Relationships [R1]	Count	Percent
Buy	1869	53.48%	Buy	1046	55.97%
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Sell	798	22.83%	Sell	370	46.37%

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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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