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Arcellx, Inc.

Competitor briefing docs offer neutral to modest positive readthrough to ACLX

Maintain Rating: BUY | PO: 84.00 USD | Price: 68.33 USD

Risk/benefit of CAR-T in focus given early OS detriment

Today, briefing documents were published ahead of FDA AdCom this Friday, which will discuss label expansion of competitor BCMA CAR-Ts into earlier line multiple myeloma (MM). Overall, the briefing docs were mainly focused on risk/benefit of Caryvkti (key competitor) in 2L+ MM in the context of early death imbalance between Carvykti arm (more deaths) than control. In-line with our preview, we continue view the prospect for class approval/commercial expansion to 3L+ MM favorably, but we defer to AdCom discussions on Friday for clarity in 2L (at risk). For ACLX, we see a theoretical argument for a late-mover advantage that a better designed trial and faster CAR-T delivery time may mitigate OS detriment seen with competitor CAR-Ts' data. We maintain Buy on ACLX given larger market opportunity and competitive profile of lead asset anito cel.

OS data bode well for 3L+, 2L possible debate at AdCom

Ahead of AdCom, we see two factors that could bode well for possible class expansion into earlier line MM: 1) Carvykti's OS (survival) benefit continued to improve as data mature, given hazard ratio (HR) improved from 0.78 in initial data to 0.57 in most recent datacut, 2) early death imbalance occurred in a small number of patients in first 3 months (7 deaths Carvykti vs 1 death control) per sponsor's documents (Exhibit 1). That said, we see debate on risk/benefit in 2L possibly more contentious than 3-4L, given early OS detriments were most pronounced in 2L vs 3-4L per FDA's post hoc analysis (Exhibit 2). Regardless of label indication and in-line with our catalyst preview, our prior KOL checks suggest OS debates + competitor CAR-T safety may likely relegate CAR-T to 3L+ commercially (for now), but we do not see negative read-across to ACLX as 3L+ is still a big market / future studies can drive push into earlier lines.

Trial design, CAR-T mfg may mitigate early OS imbalance

Briefing documents suggest lower dose intensity of bridging therapy used in Carvykti arm may have contributed to early death imbalance (by PFS). While sponsors downplay the role of manufacturing time may play in early PFS imbalance, we think under dosing of bridging therapy coupled with long CAR-T delivery time (79 days vein-to-vein per briefing doc) may have collectively contributed to early deaths. Of note, 6 out of 7 early deaths from Carvykti arm did not receive the CAR-T. As such, we see a theoretical argument for a late-mover advantage for ACLX, where a better design trial with a faster CAR-T turnaround time may mitigate early OS detriments seen with competitors' data. ACLX's anito cel has a median vein-to-vein time of 35 days in Ph1 with a contract manufacturer and expect the Gilead/Kite process (tech transfer ongoing, expected to complete this year) could eventually bring turnaround time closer to around 2 weeks.

Roster highlights scarcity in MM experts for Fri's AdCom

Per the draft meeting roster, the panel will include 11 voting members and of those, only 3 members appear to specialize in hem/onc (as opposed to solid tumors) including 1 MM expert. As such, the panel may focus on the merit of OS data from Cartitude-4 and perhaps less so on the risk-reward of early- vs late-line use of CAR-T in the context of alternative effective options in 2L/3L and rare but serious AEs such as neurotoxicity.

Timestamp: 13 March 2024 12:57PM EDT

13 March 2024

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Stock Data

Price	68.33 USD
Price Objective	84.00 USD
Date Established	8-Mar-2024
Investment Opinion	C-1-9
52-Week Range	26.65 USD - 75.10 USD
Mrkt Val (mn) / Shares Out (mn)	3,608 USD / 52.8
Free Float	73.9%
Average Daily Value (mn)	30.62 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

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ACLX: Arcellx
FDA: US Food and Drug Administration
AdCom: Advisory Committee
OS: overall survival
PFS: progression-free survival
2L / 3L: second- / third-line
CAR-T: cell therapy
BCMA: antigen
AE: adverse events
Mfg: manufacturing

Exhibit 1: Cartitude-4 OS data over time
Carvykti OS benefit improves over time as data mature (per sponsors' documents)

Table 2: CARTITUDE-4 Study: Summary of Overall Survival by Analysis Date

	1 November 2022 (Interim Analysis)	17 April 2023 (120-Day Safety Update)	13 December 2023 (Survival Sweep)
Median follow-up (months)	15.9	21.5	28.7
Total deaths	86	112	125
Cilta-cel	39	45	48
SoC	47	67	77
Hazard ratio[a] (95% CI)	0.78 (0.50–1.20)	0.63 (0.43–0.92)	0.57 (0.40–0.83)
p-value[b]	0.2551	N/A	N/A

a. Hazard ratio and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable and stratified with Investigator's choice (PVd or DPd), ISS staging (I, II, III), and number of prior lines (1 vs 2 or 3) as randomized. A hazard ratio <1 indicates an advantage for the cilta-cel arm.
b. p-value based on a standard log-rank test stratified with Investigator's choice (PVd or DPd), ISS staging (I, II, III) and number of prior lines (1 vs 2 or 3) as randomized.
DPd=daratumumab, pomalidomide, dexamethasone; ISS=International Staging System; N/A=not applicable; OS=overall survival; PVd= pomalidomide, bortezomib, dexamethasone; SoC=standard of care.

Source: FDA.gov

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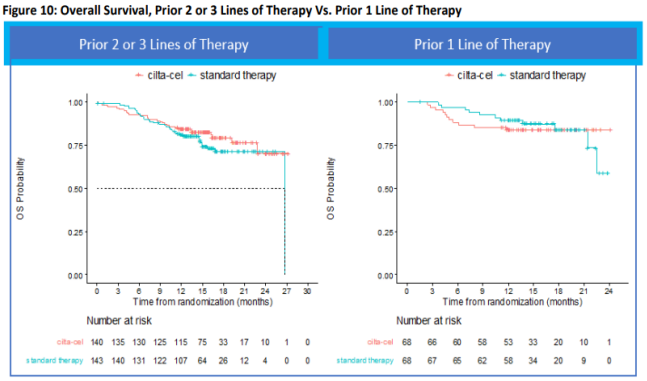
Exhibit 2: FDA post hoc analysis of Cartitude-4 OS data
Early OS imbalance was most pronounced in 2L subgroup vs 3-4L (per FDA's documents)

Figure 10: Overall Survival, Prior 2 or 3 Lines of Therapy Vs. Prior 1 Line of Therapy



Source: FDA analysis
Abbreviations: OS, overall survival

Source: FDA.gov

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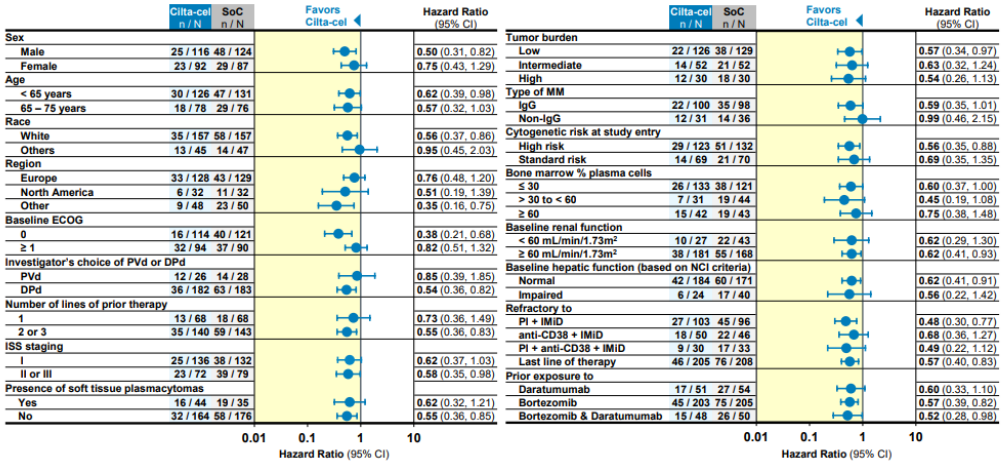
Exhibit 3: Cartitude-4 OS subgroup analysis
Sponsors' subgroup analysis on most recent datacut point to OS HR pf 0.73 in 2L subgroup, though to us the subgroup data do not necessarily negate early OS detriments in 2L

Figure 8: CARTITUDE-4 Study: Overall Survival by Subgroup (ITT Analysis Set; 13 December 2023 Survival Sweep)



Source: FDA.gov

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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

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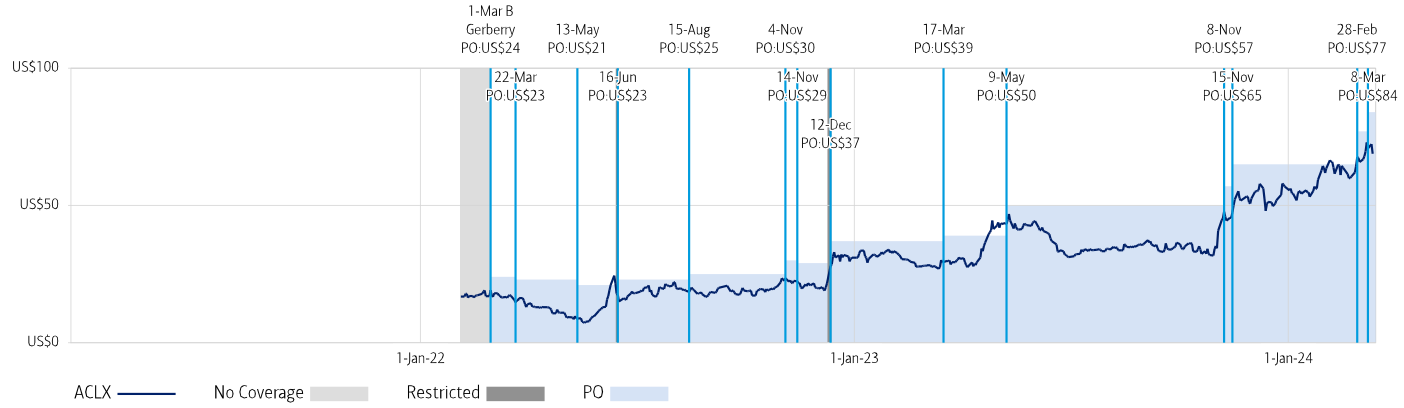
Arcellx (ACLX) Price Chart



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

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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%

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