

Arcellx, Inc.

# Gilead manufacturing site visit: ACLX partner playing to win in BCMA CAR-T

Maintain Rating: BUY | PO: 84.00 USD | Price: 69.57 USD

## Takeaways: faster CAR-T mfg time & capacity expansion

Yesterday, we attended Gilead-Kite's cell therapy event – hosted at the company's CAR-T mfg site in Frederick, MD (see report for [Geoff Meacham's takeaways on GILD](#)). Gilead is effectively a 50-50 partner with ACLX on pivotal-stage anito-cel, a BCMA CAR-T being developed for multiple myeloma (MM). Overall, a fair amount of the event was focused on anito cel, which is not surprising given the large peak sales potential of the drug. Big picture, we came away from the meeting encouraged by the steps Gilead is taking to be launch-ready including efforts to streamline anito-cel mfg turnaround time and capacity build ahead of a planned 2026 launch in the lead indication (late line MM); Gilead will begin supplying anito-cel later this year. Not surprisingly, Gilead offered no new clinical data or updates around a planned early line MM trial design (which starts 2H), which makes sense given today's FDA panel will weigh in on competitor's early line trials. We continue to like ACLX for anito cel profile and large market potential; maintain Buy.

## Partner Gilead bullish on MM opportunity for anito cel

During the meeting, Gilead offered its latest commercial outlook for the BCMA CAR-T space, which it characterized as a \$12bn market opportunity (vs. our >\$10bn estimate). Consistent with our KOL feedback, Gilead views anito-cel's product profile as highly competitive (vs. other BCMA CAR-Ts) highlighting competitive efficacy, differentiated efficacy in EMD patients and relatively clean neuro safety profile (in data generated so far). We look for confirmation of efficacy and neuro safety when GILD/ACLX provide its first anito data-cut from the pivotal late line study (2H24). On anito cel's planned trial in 2L+ MM, Gilead noted that it plans to leverage the learnings from a competitor AdCom (later today) but largely refrained from discussing trial design strategy other than to say a future study aims to address "clinically relevant" questions reflecting the evolving treatment landscape (consistent with ACLX messaging).

## 2L lymphoma launch highlights CAR-T market building

Gilead discussed its efforts to launch its CD19 CAR-T for 2L+ lymphoma, which in the US stands at around 15% penetrated (currently). Per Gilead, driving adoption of CAR-T in the community setting will require time/effort, consistent with our KOL feedback. Currently, CAR-T treatments are concentrated in academic centers and certain community referrals, but Gilead noted 50% of US patients are not managed at an ATC and the rest receive alternative treatment options (e.g. community docs' desire to keep their patients). Gilead laid out market building efforts to add new ATCs (authorized treatment centers) and drive referrals in existing ATCs. As we [recently published](#) (see report), the market building efforts to penetrate earlier lines should provide some cushion for anito cel to catch-up to J&J/Legend in earlier line settings in the MM space.

## Expected turnaround time for anito cel: ~14d (or better)

Gilead now has a 14-day median vein-to-vein turnaround time at 96% mfg success rate for Yescarta (CD19 CAR-T), and it aspires to cut mfg time from 5d to 3d and framed the possibility of reducing QC testing time (vs current 8d). Collectively, the Gilead updates imply (to us) that turnaround times could come down to ~10 days over time. **Cont'd p2.**

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### Equity

**Jason M. Gerberry**  
Research Analyst  
BofAS  
[jason.gerberry@bofa.com](mailto:jason.gerberry@bofa.com)

**Chi M. Fong**  
Research Analyst  
BofAS  
[chi.fong@bofa.com](mailto:chi.fong@bofa.com)

**Pavan R. Patel**  
Research Analyst  
BofAS  
[pavan.r.patel@bofa.com](mailto:pavan.r.patel@bofa.com)

**Dina Ramadane**  
Research Analyst  
BofAS  
[dina.ramadane@bofa.com](mailto:dina.ramadane@bofa.com)

### Stock Data

Price	69.57 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)	3,673 USD / 52.8
Free Float	73.9%
Average Daily Value (mn)	31.23 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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GILD: Gilead (covered by Geoff Meacham)  
J&J: Johnson & Johnson (covered by Geoff Meacham)

MM: multiple myeloma

Mfg: manufacturing; MD: Maryland

KOL: expert

FDA: US Food and Drug Administration

AdCom: advisory committee

CAR-T: cell therapy; CD19, BCMA: antigen

FPI: first patient in

QC: quality control

EMD: extramedullary disease

ATC: authorized treatment center

2L: second-line

Gilead believes it can sync anito cel turnaround time to current Yescarta levels in relatively short time after completion of tech transfer (2H24E), vs ~35d median vein-to-vein time for anito cel in Ph1 via a third-party manufacturer (Lonza). Anito cel manufacturing success rates and target vein-to-vein time could be sources of competitive differentiation vs Carvykti (key BCMA CAR-T competitor). For more in-depth discussions on CAR-T manufacturing, please see our [CAR-T mfg primer report](#).

## Capacity readiness for anito cel, broader CAR-T portfolio

Gilead framed its efforts to increase CAR-T mfg capacity from current ~10k doses to >24k doses (across CAR-T portfolio) by 2026 via process automation and addition of new clean rooms within its existing infrastructure. We learned on site that the mfg facility at Frederick only occupies two-third of owned land which leaves room for physical buildout of the facility.

## Next for anito cel mfg: automation, in-house vector, etc

Next-steps planned for anito cel mfg include: 1) setting up a fully automated mfg process, 2) develop internal vector mfg process (vs via a third-party [Oxford]), 3) scale-up for commercial launch. At our lab visit, we learned anito cel is manufactured in Grade B cleanrooms (more stringent criteria) but Gilead believes it can bring the requirement down to Grade C (less stringent) which would help improve mfg capacity and efficiency.

## 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.

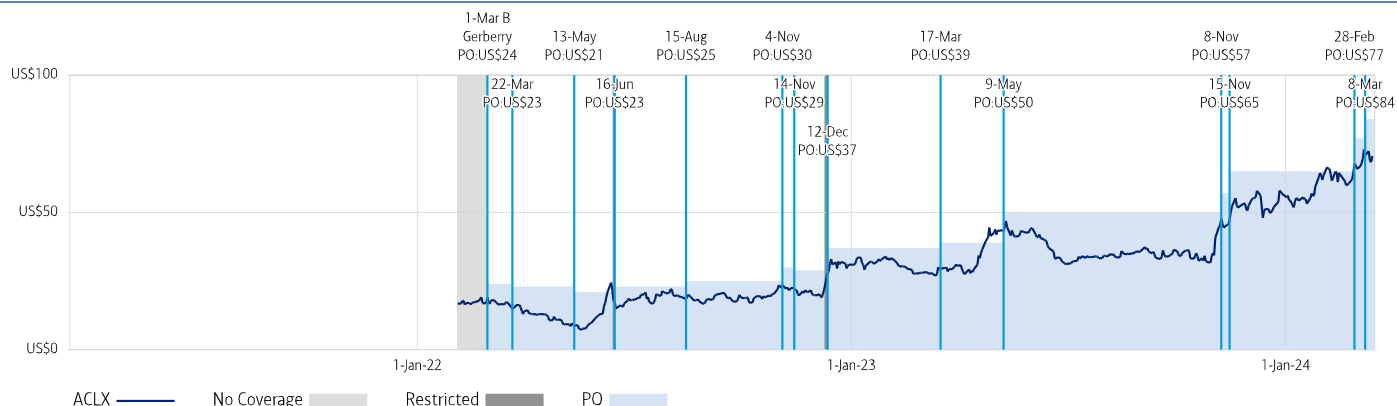
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### Arcellx (ACLX) Price Chart



ACLX — No Coverage — Restricted — PO

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Coverage Universe	Count	Percent	Inv. Banking Relationships <sup>R1</sup>	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%

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Sell	807	22.84%	Sell	383	47.46%

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Neutral	≥ 0%	≤ 30%
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