BIOPHARMA

LEERINK PARTNERS

ASH: Anito-cel Ph 1 Outcomes Are Strong, Swings in Expectations Pressure ACLX

December 13, 2023

- **Bottom Line: Reflecting across a busy ASH, filled with BCMA CAR-T presentations and investor and company conversations, we continue to believe Arcellx (ACLX, OP) and Kite (GILD, MP) have a stand-out autologous BCMA CAR-T in anito-cel.** The updated Ph 1 outcomes at ASH met our ingoing progression-free survival (PFS) threshold for excitement of 20-25 months on top of highly competitive complete response (CR) and MRD (-) rates of 76% and 89% (n=28 evaluable). See HERE for our view on relevant Carvykti (cilta-cel) benchmarks. An ASH dinner with Kite management increased our confidence that the manufacturing and commercial infrastructure will continue to be a major differentiator for CAR-T in coming years, and Kite's operational excellence meaningfully increases anito-cel's revenue and profit potential.
- **What happened:** Arcellx and Kite presented an update to their Ph 1 trial in relapsed / refractory multiple myeloma (5L+, r / r MM) with anito-cel (formerly CART-ddBCMA) at American Society of Hematology (ASH). Arcellx was joined by two KOLs for an investor event (webcast) following the ASH presentation: ASH presenter Dr. Matthew Frigault (Mass General) and Dr. Krina Patel (MD Anderson Cancer Center). In this event, the company and KOLs provided additional color on clinical and real-world comparisons between anito-cel and Carvykti and Abecma (ide-cel). Also following the anito-cel presentation, we hosted a dinner with Kite management on all things CAR-T, including their enthusiasm and vision for anito-cel.
- **We heard from investors that several drivers are pressuring ACLX** (down about 13% from highs into ASH), including (1) presented outcomes falling below expectations that ran up into ASH; (2) a dataset that is relatively more immature than anticipated and hence has a higher probability for scenarios with shorter mPFS; (3) lack of near-term catalysts; and (4) repeated dependence on the same KOLs, who seem more company-aligned than independent.
- **What's next:** Arcellx and Kite are currently enrolling a Ph 2 registrational study (IMMagine-1) with anito-cel in 5L+ r/r MM. Management has guided to 2H24 for a preliminary update on that trial. Arcellx is also enrolling patients in a Ph 1 study for their universal CAR-T platform (ARC-SparX) targeting CD123 in r/r acute myeloid leukemia (see HERE for our thoughts on CD123 therapies at ASH).
- **See within for additional discussion...**

Reason for report:
PROPRIETARY INSIGHTS

S&P 500 Health Care Index:	**1,552.29**
S&P 600 Health Care Index:	**2,786.59**

Companies Highlighted

ACLX, GILD

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Ticker	Rating	Price	Price Target Current	Price Target Previous	Mkt. Cap (MM)	Current Rev Est. 2023	Current Rev Est. 2024	Previous Est. 2023	Previous Est. 2024	Current EPS Est. 2023	Current EPS Est. 2024	Previous Est. 2023	Previous Est. 2024
ACLX	OP	$48.05	$49.00	--	2,339	$71.1	$95.6	--	--	($2.21)	($1.01)	--	--
GILD	MP	$80.82	$87.00	--	101,591	$27,103.4	$28,032.5	--	--	$6.64	$7.68	--	--

Source: Company Information and Leerink Partners LLC Research.

Tidbits of importance for anito-cel from our conversation with Kite management

Kite believes they have a clear path to scale current CAR-T capacity roughly four times 2023 capacity—roughly 25K by 2026. Leveraging automation, thoughtful career trajectories/culture, and continuous process optimization, the company continues to improve their already leading position, with fast consistent delivery of current products, without any capacity limitations. For example, next year they plan to reduce manufacturing time by an additional two days with updated sterility testing, bringing their trailing vein-to-vein time from ~16 to ~14 days and maintaining ~96% manufacturing success rates.

Management is confident that they can apply their Yescarta / Tecartus learnings to anito-cel and does not anticipate any regulatory constraints on manufacturing scale-up. FDA placed scale-up gates to ensure consistent quality on BMY / TSVT and JNJ / LEGN autologous CAR-T products. Kite, however, did not face these restrictions with Yescarta or Tecartus. The manufacturing organization is currently working on compatibility testing as part of technology transfer of anito-cel from current CRO, Lonza (LZAGY, Not Rated) and Kite management said this has been successful thus far. Kite is confident in their plan for in-house lentiviral vector production—a goal where we see some risk, given that the company's commercial experience is production of γ-retroviral vectors.

Strategically, Kite is building a durable business, investing in capacity build-out today for which they plan to leverage for multiple products. We believe their aspirations are good for anito-cel and Arcellx (ACLX), as CAR-T is a business where we see considerable scale advantages from research to commercialization. Kite management said they plan to invest in internal and external innovation, across platforms from autologous ("it's working now, so how do we improve?") to NK cells and *in vivo* CAR-T. They, like the rest of industry, are very excited about the potential for CAR-T in inflammation and immunology, calling the updated data presented at ASH "revolutionary." Though hopeful for durable remissions, they believe a multi-year drug holiday has real quality and health value for these severe patients. Specifically in I&I, Kite said that they are also looking internally and externally, and that they find a bicistronic profile attractive.

As to whether the US health care system could realistically deliver all the envisioned CAR-T, management acknowledged the considerable challenge of the currently fractured nature of healthcare delivery. With Yescarta, management believes they have converted about 2/3 of transplant patients but only 10% of total eligible 2L lymphoma patients. That said, management has confidence in system change, which the company is supporting in several ways. First, Kite's product consistency and flexibility help drive up practice capacity and profitability. Second, the commercial organization is working to change the community networks from education to drive up referrals, and the overall survival (OS) benefit with Yescarta from ZUMA-7 is an important tool here. Kite is also working with top oncology groups to expand authorized treatment centers (ATCs) into the community. Kite has 140

ATCs in the US today (400 globally) and plans rapid expansion of this footprint with new ATCs and satellite ATCs in the next two years—in time for potential anito-cel launch. Kite said the CAR-T business is already profitable for ATCs, and Kite can support the center in driving up profitability through manufacturing consistency, reducing total hospitalization times (not just upfront infusion) using wearables, education, and training of peripheral sites, and development novel products with better toxicity profiles.

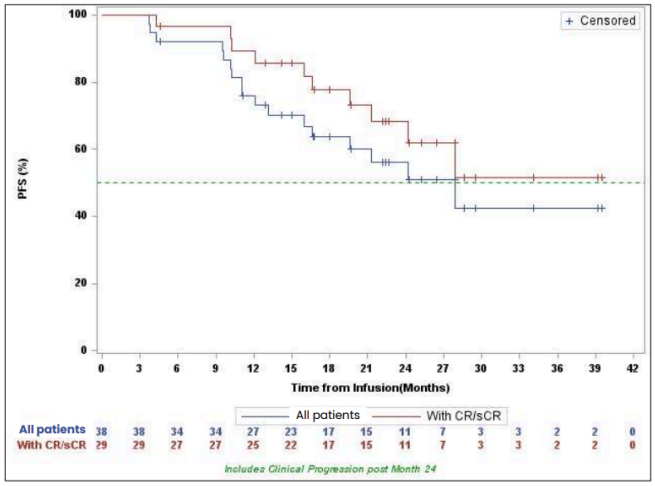
Expectations and updated ph 1 data with anito-cel in 5L+ multiple myeloma (MM)

We agree with Arcellx management and KOLs that the anito-cel outcomes are trending very much in line to greater than what we expect from market-leader cilta-cel. See the Appendix for management's presented comparisons vs competitor BCMA CAR-T products.

The 2023 ASH abstract (with a single progression from ASH 2022 to the ASH 2023 abstract) significantly raised investor expectations, such that the very promising data presented on Monday (Dec. 11) felt disappointing. Arcellx's press release on Friday (Dec. 8) may have exacerbated the situation, as median PFS (mPFS) on the Kaplan Meier (KM) curves looks to be in the range of 24-27 months (Figure 1), below the predicted median PFS (mPFS) of ~28 months that was in the PR on Friday. For example, taking the data reported on Friday, we predicted 16 total progressions (PDs) with the KM curve tail at ~51%; Monday's presentation confirmed the 16 PDs, but the KM tail is at ~41%.

The PFS curve was more immature than expected, leaving open more downside mPFS scenarios than anticipated. Other than the patient censored around month six for a protocol violation, the next censored patients are at ~11 months. We had assumed roughly 12 months additional follow-up, which considering the swimmer's plot presented at ASH in 2022, brought the expectation that the next censored patient would be at ~14-15 months.

Figure 1. PFS with anito-cel in 5L+ MM at 26.5 months median follow-up



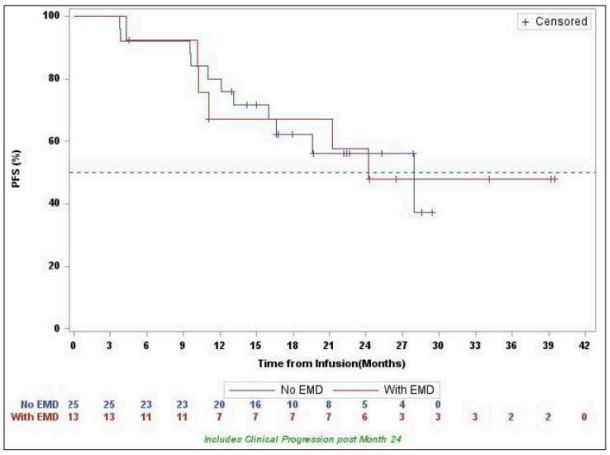
	Time (months)	PFS Estimate (%)	95% Confidence Interval (%)
All Patients (n = 38)	6	92.1	77.5, 97.4
	12	75.9	58.7, 86.6
	18	63.7	45.7, 77.2
	24	56.0	37.3, 71.1

- **Median PFS not reached for all patients (n=38)**
- **Median PFS not reached for CR/sCR patients (n=29, 76%)**
- **89% (n=25/28) of evaluable* patients MRD negative at minimum of 10^{-5} sensitivity**

Note: Data cut-off October 15, 2023; * Evaluable patients had identifiable malignant clone in the baseline bone marrow aspirate

Source : Company presentation at 2023 ASH

Figure 2. PFS with anito-cel in 5L+ MM is similar between extramedullary (EMD) and non-EMD patients, which if confirmed in a larger trial would be differentiating



	Time (months)	PFS Estimate (%)	95% Confidence Interval (%)
With EMD (n = 13)	6	92.3	56.6, 98.9
	12	67.1	34.2, 86.2
	18	67.1	34.2, 86.2
	24	57.5	25.7, 79.9

- **Median PFS not reached for patients with EMD (n=13)**
- **Median PFS not reached for Non-EMD patients (n=25)**

Note: Data cut-off October 15, 2023

Source : *Company presentation at 2023 ASH*

Figure 3. PFS with anito-cel in 5L+ MM is similar between extramedullary (EMD) and non-EMD patients, which if confirmed in a larger trial would be differentiating

Kaplan-Meier PFS Estimates	Overall	High Risk Features*	Extramedullary disease	High Risk Cytogenetics	≥ 65 years
Patients n (%)	38 (100%)	24 (63.2%)	13 (34.2%)	11 (28.9%)	20 (52.6%)
6-month PFS % (95% CI)	92.1% (77.5%, 97.4%)	91.7% (70.6%, 97.8%)	92.3% (56.6%, 98.9%)	81.8% (44.7%, 95.1%)	95.0% (69.5%, 99.3%)
12-month PFS % (95% CI)	75.9% (58.7%, 86.6%)	74.2% (51.3%, 87.5%)	67.1% (34.2%, 86.2%)	71.6% (35.0%, 89.9%)	85.0% (60.4%, 94.9%)
18-month PFS % (95% CI)	63.7% (45.7%, 77.2%)	64.6% (41.3%, 80.6%)	67.1% (34.2%, 86.2%)	71.6% (35.0%, 89.9%)	74.3% (48.7%, 88.4%)
24-month PFS % (95% CI)	**56.0% (37.3%, 71.1%)**	**58.7% (35.1%, 76.3%)**	**57.5% (25.7%, 79.9%)**	**71.6% (35.0%, 89.9%)**	**61.3% (34.9%, 79.7%)**

In all risk subgroups, including High Risk, the est. median PFS has not been reached at 24 months

Source : *Company presentation at 2023 ASH*

Arcellx KOL panel perspectives on cilta-cel (Carvykti)

The KOL panel consisting of Dr. Matthew Frigault of Mass General Hospital and Dr. Krina Patel of MD Anderson Cancer Center was liberal with their cilta-cel commentary. The two topics of considerable discussion included cilta-cel toxicity and manufacturing issues (especially in high-risk patients), and the impact on patient quality-of-life and hospital workflows. We heard from some investors that the KOL statements (summarized below) were more provocative than typical. While we appreciate the KOLs' candor on these topics, we should mention that these two KOLs were on Arcellx's panel at last year's ASH KOL event and that Dr. Frigault has presented all of Arcellx's major clinical updates and been a consistent presence at Arcellx KOL events.

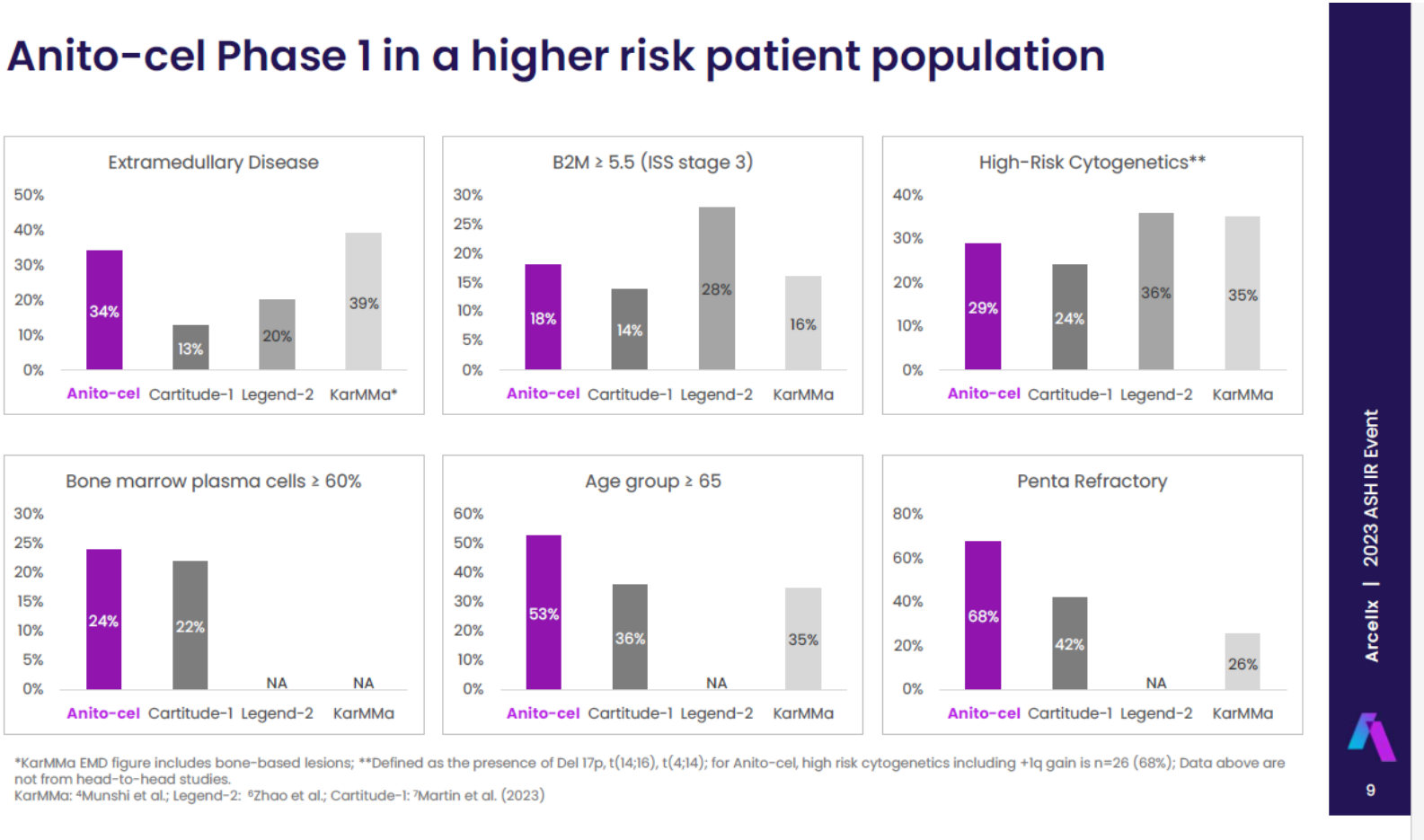
We heard a robust discussion on CAR-T toxicity (neurological events in particular) across the age and risk spectrum with potentially positive readthrough to 2seventy and BMY's Abecma (ide-cel). Dr. Patel reported that she sees neurological events in her practice with cilta-cel, anecdotally stating that approximately 10% of her patients present with facial palsies. Dr. Frigault stated that 5-6% of his patients present with parkinsonism, an adverse event (AE) that is significantly more difficult to resolve than other neurological toxicities. He went on to state that in patients at high-risk for neurological toxicity, he has paused on administering cilta-cel, preferring ide-cel plus T cell engager maintenance. Both KOLs highlighted that the burden on patients' lives favors Abecma, as their respective institutions require longer internal follow-up (i.e., patients need to stay near the hospital) for Catvykti over Abecma due to delayed toxicity risk. Dr. Patel said that her Carvykti patients stay on monitoring for 100 days post-infusion compared to 30 days for Abecma. We believe that should these opinions become widely held across the physician community, the Abecma commercial market could have a floor based on physician preference for higher-risk patients. Of course should anito-cel match Abecma on toxicity with better efficacy, which is possible, we anticipate late-line share shift to anito-cel at launch.

According to the KOLs, real-world manufacturing issues with Carvykti are stubbornly persistent, again supporting the case for Abecma in high-risk patients in the near term and anito-cel at launch. Dr. Patel took us through the arc that her institution took with Carvykti administration. When the product first launched, they wanted to bring on patients who were most like the cilta-cel registrational trial, CARTITUDE-1, so as to minimize unanticipated risks. As the team gained confidence in their workflow, they started to expand Carvykti slots to patients that are more reflective of the real-world (e.g., more complex, with multiple co-morbidities). In the last six months following the inclusions of such difficult patients, Dr. Patel stated that she has experienced a significant step-down in manufacturing consistency for Carvykti with 6-8 week turnaround times and a (surprising) 85% out-of-specification (OOS) rate in high-risk patients. She mentioned that she has not had the same experience with Abecma, citing a case where one of her patients had two consecutive manufacturing failures for Carvykti, but upon switching to Abecma, the latter product was delivered on time.

Manufacturing issues impact the hospital system at-large. Dr. Frigault, lauding Kite's manufacturing process, stated that he had never had to deploy an expanded accessibility protocol (EAP) for Kite products while EAP use is commonplace for Carvykti. Such manufacturing issues cost the hospital money, with about one-third of Dr. Frigault's research budget spent on out-of-spec (OOS) product issues. Both KOLs said OOS product also impacts their team's efficiency in handling patients and reduces overall capacity.

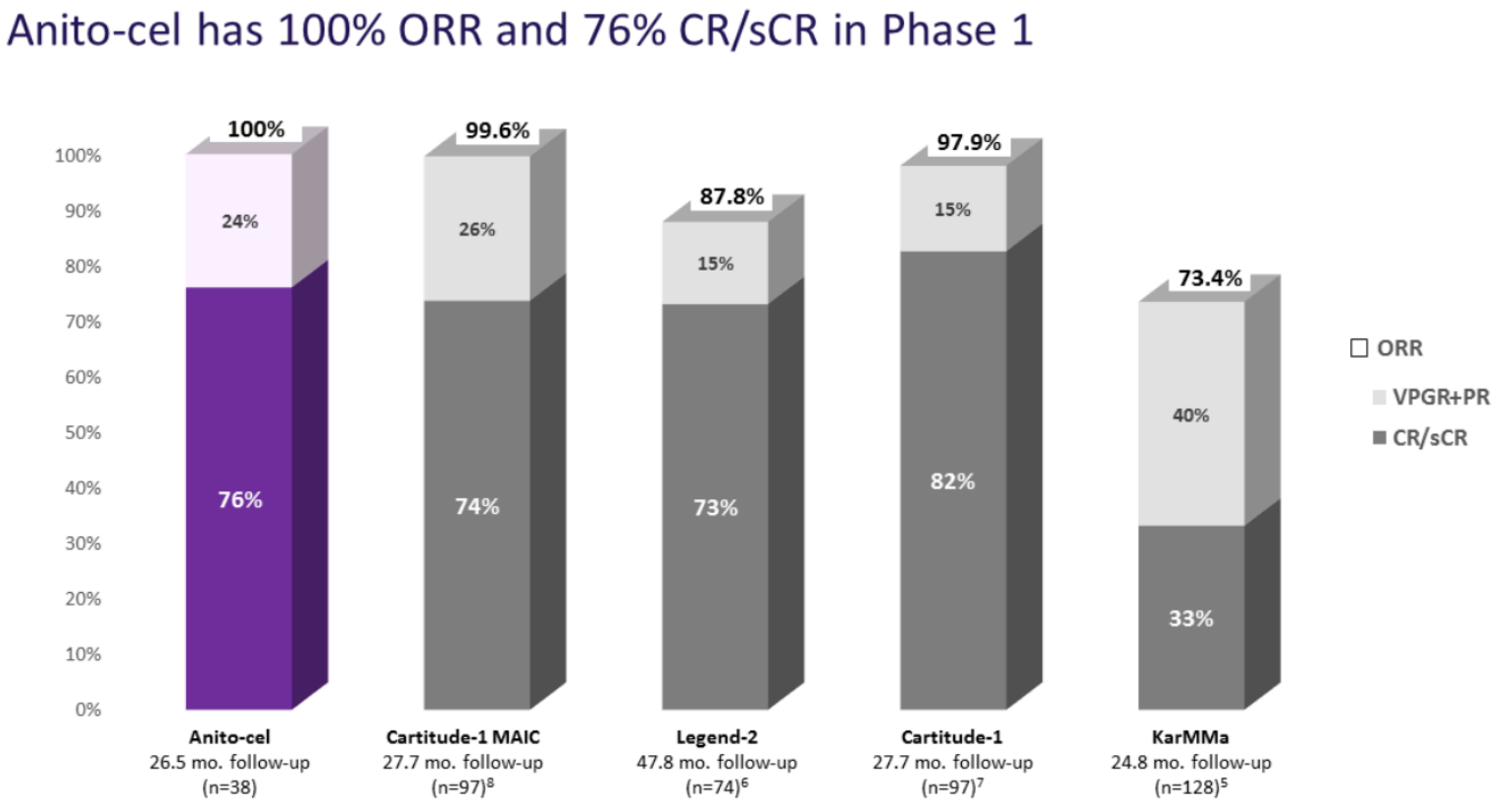
In line with JNJ / Legend guidance, the KOLs said they can dose Carvykti out-patient, monitor them remotely for fever upon which they admit patients to monitor for acute toxicity for 4-5 days. The process for Abecma is more traditional, with inpatient administration and then earlier discharge from the hospital around day 4. Dr. Patel said with their joint out-/in- patient processes, her hospital could treat 20-25 patients per month with CAR-T.

Appendix Figure A1. Comparison of baseline patient status across late-line r / r MM trials (from ACLX)



Source : [Company presentation at 2023 ASH]

Appendix Figure A2. Comparison of objective response rates across late-line r / r MM trials (from ACLX)

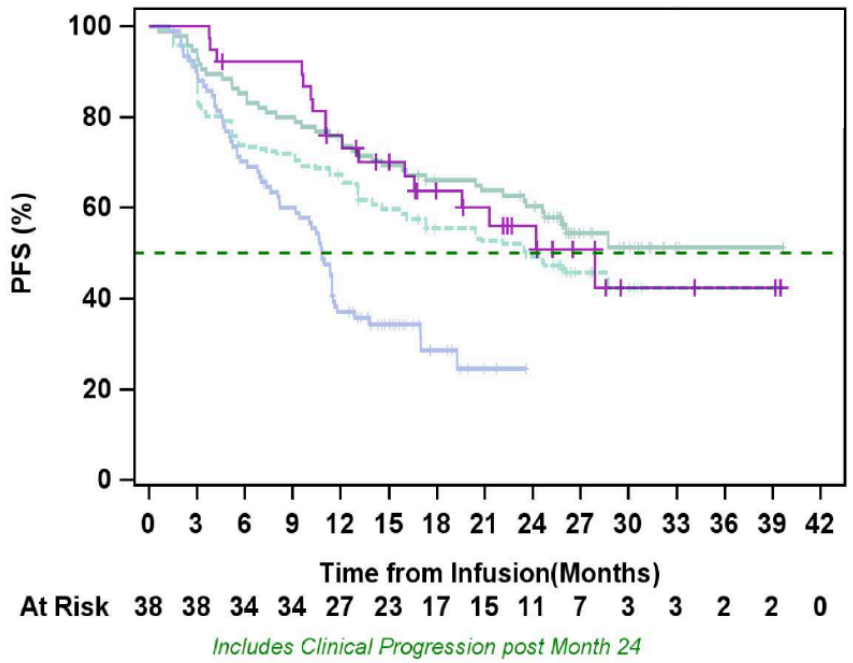


Note: MAIC is matching-adjusted indirect comparison, a J&J study comparing Cartitude-1 results by adjusting its population to match that of KarMMa; Data above are not from head-to-head studies. Cross-trial data interpretation should be considered with caution as it is limited by differences in median follow-up, study population, design and other factors
[5]Anderson et al.; [6]Zhao et al.; [7]Martin et al. (2023); [8]Martin et al. (2022)

Source : *Company presentation at 2023 ASH*

Appendix Figure A3. Comparison of progression-free survival outcomes across late-line r / r MM trials (from ACLX)

mPFS not reached at 26.5 mo median follow-up (all patients)



Anito-Cel Phase 1
median follow-up 26.5 mos

Cartitude-1
median follow-up 27.7 mos[8]

Cartitude-1 MAIC
median follow-up 27.7 mos[8]

KarMMA
median follow-up 15.4 mos[8]

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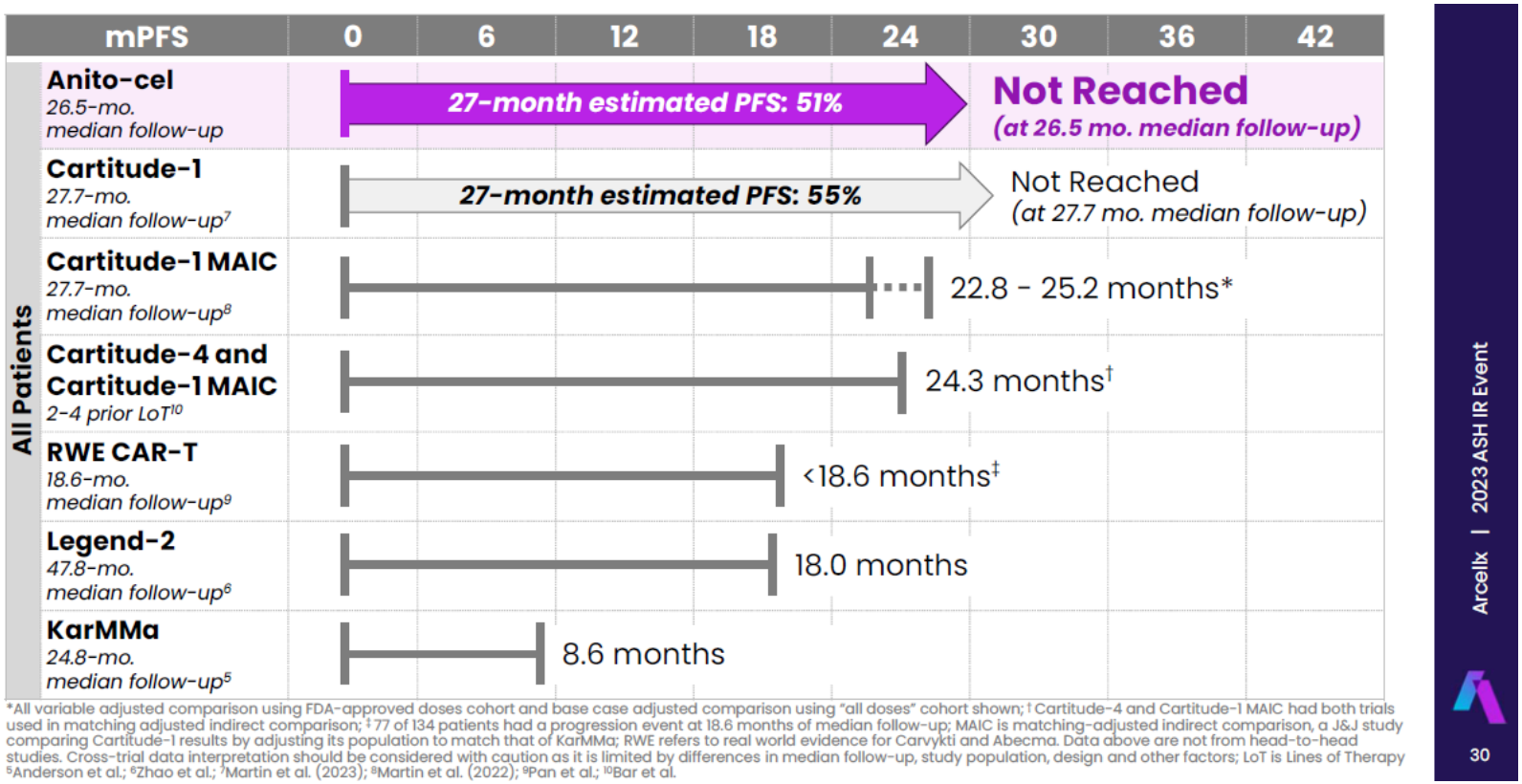
Note: MAIC is matching-adjusted indirect comparison, a J&J study comparing Cartitude-1 results by adjusting its population to match that of KarMMa; Data above are not from head-to-head studies. Cross-trial data interpretation should be considered with caution as it is limited by differences in median follow-up, study population, design and other factors
[8]Martin et al. (2022)

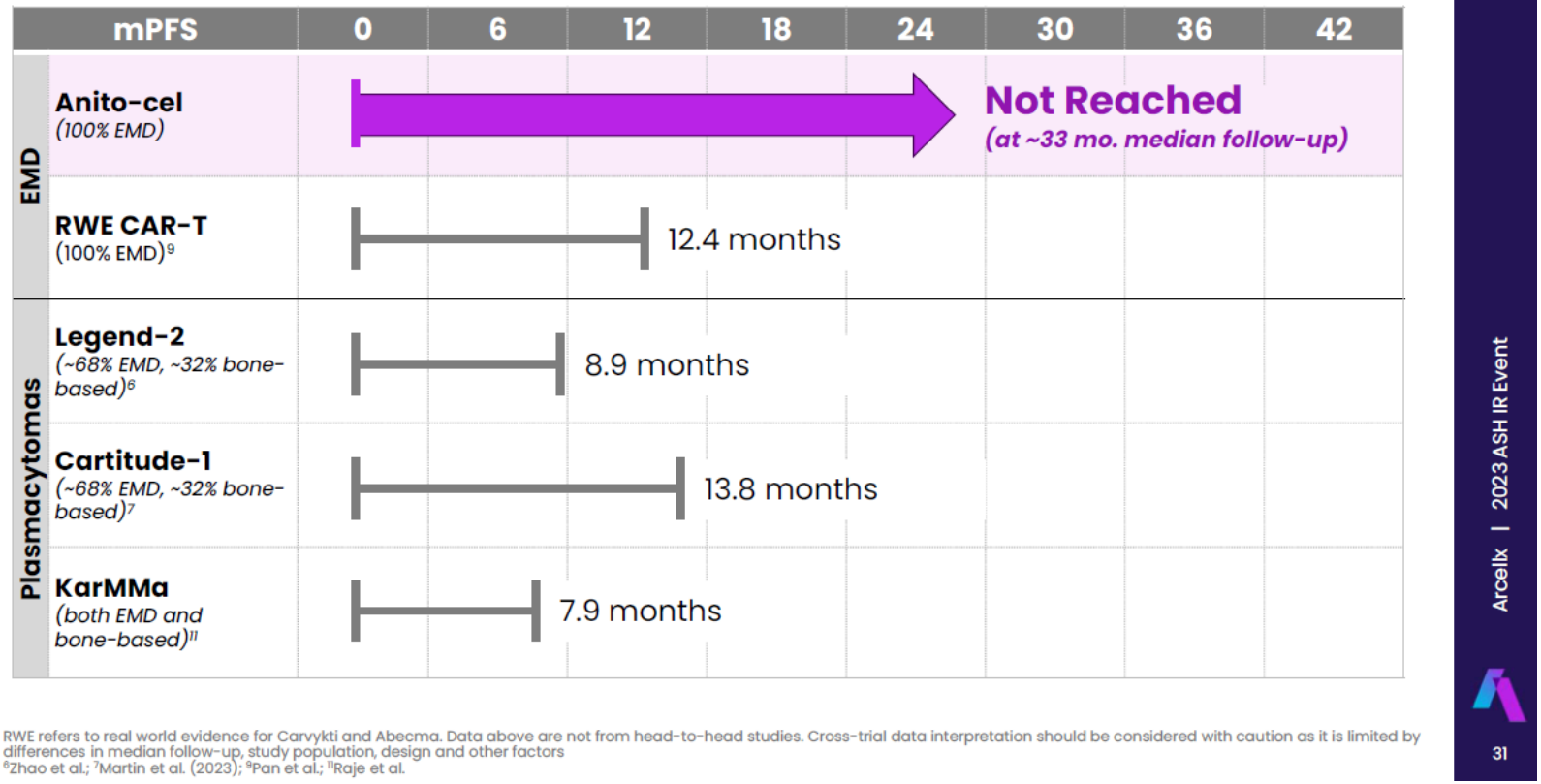
Source : Company presentation at 2023 ASH

Appendix Figure A4. Comparison of progression-free survival outcome durability across late-line r / r MM trials (from ACLX)



Source : [Company presentation at 2023 ASH]

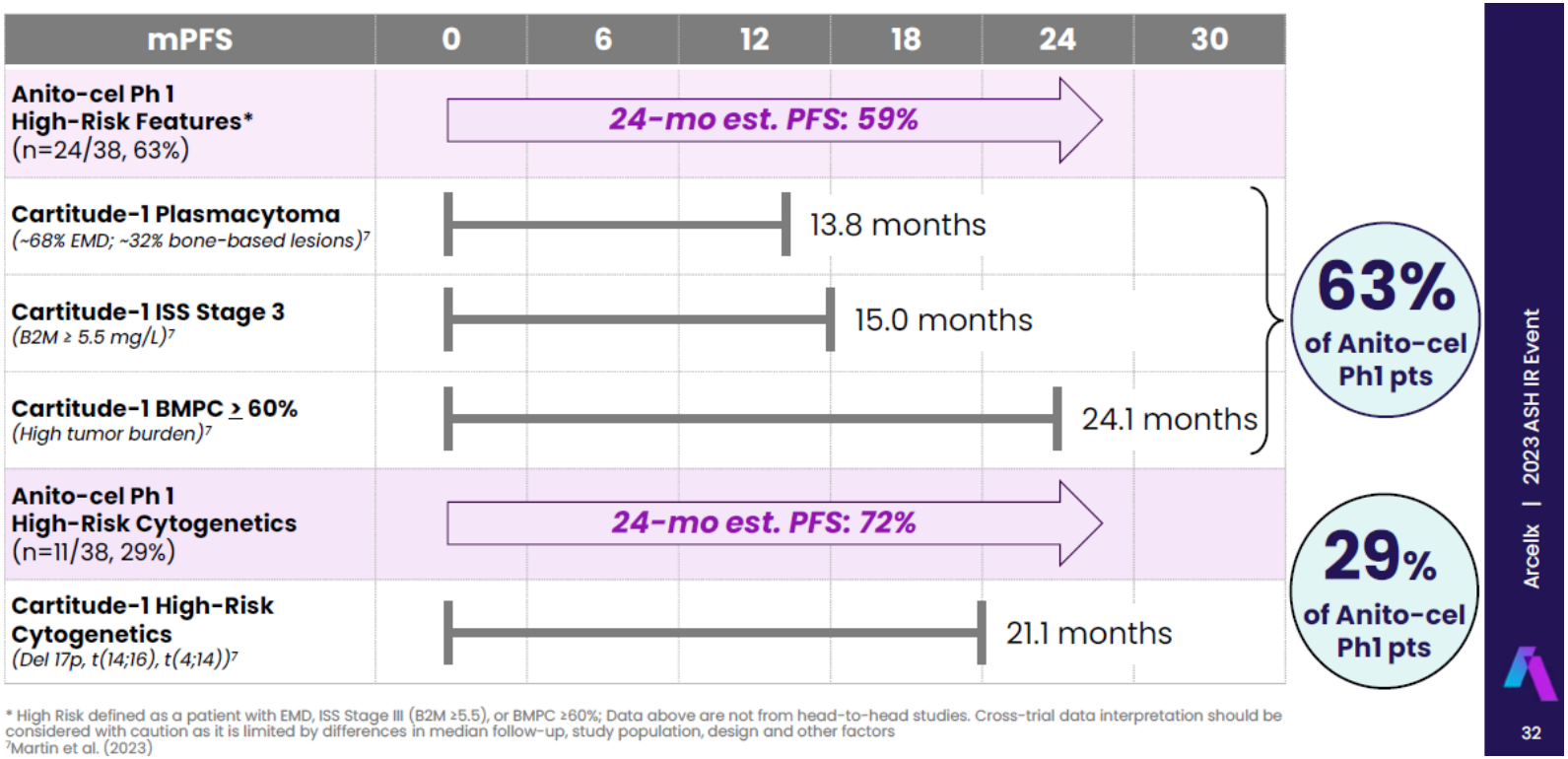
Appendix Figure A5. Comparison of progression-free survival outcome durability in extramedullary disease (EMD) patients and plasmocytoma patients (includes EMD and paramedullary disease) across late-line r / r MM trials (from ACLX)



RWE refers to real world evidence for Carvykti and Abecma. Data above are not from head-to-head studies. Cross-trial data interpretation should be considered with caution as it is limited by differences in median follow-up, study population, design and other factors
[6]Zhao et al.; [7]Martin et al. (2023); [8]Pan et al.; [11]Raje et al.

Source : Company presentation at 2023 ASH

Appendix Figure A6. Comparison of progression-free survival outcome durability across late-line r / r MM trials stratified by high-risk categories (from ACLX)



Source : [Company presentation at 2023 ASH]

ACLX Valuation: Sum-of-the-Parts (SOTP)

Component	Method 1: DCF		Method 2: Multiples		Blended Average	
	eNPV (M)	eNPV/share	eNPV (M)	eNPV/share	eNPV (M)	eNPV/share
Net cash, 1yr away	$ 450	$ 7.7	$ 450	$ 7.7	$ 450	$ 7.7
CART-ddBCMA	$ 3,119	$ 53.3	$ 1,481	$ 25.3	$ 2,300	$ 39.3
ACLX002	$ 391	$ 6.7	$ 846	$ 14.5	$ 619	$ 10.6
R&D overhead	$ (225)	$ (3.8)	$ (225)	$ (3.8)	$ (225)	$ (3.8)
G&A overhead	$ (606)	$ (10.3)	$ (606)	$ (10.3)	$ (606)	$ (10.3)
NOL	$ 91	$ 1.6	$ 91	$ 1.6	$ 91	$ 1.6
Total	$ 3,222	$ 55	$ 2,038	$ 35	$ 2,630	**$ 45**
Total w/ R&D return	**$ 3,447**	**$ 59**	**$ 2,263**	**$ 39**	**$ 2,855**	**$ 49**

Source: Leerink Partners estimates

ACLX Income statement

P&L (risk-adjusted)	A	A	A	A	A	A	E	E	E	E	E	E	E
in $M, except per share	2020	2021	2022	2023	2023	2023	2023	2023	2024	2025	2026	2027	2028
expense sub-lines est.	FY	FY	FY	Q1	Q2	Q3	Q4	FY	FY	FY	FY	FY	FY
Total Revenue	$ -	$ -	$ -	$ 17.912	$ 14.302	$ 14.957	$ 23.894	$ 71.065	$ 95.574	$ 138.804	$ 98.510	$ 89.815	$ 71.643
CART-ddBCMA	$ -	$ -	$ -	$ 17.912	$ 14.302	$ 14.957	$ 16.166	$ 63.337	$ 64.665	$ 107.895	$ 83.055	$ 89.815	$ 71.643
Profit share (US)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 6.484	$ 18.230	$ 21.253
Royalties (ex-US)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 3.589	$ 14.769	$ 21.982
Milestones	$ -	$ -	$ -	$ 17.912	$ 14.302	$ 14.957	$ 16.166	$ 63.337	$ 64.665	$ 107.895	$ 72.982	$ 56.816	$ 28.408
ACLX002	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Sales share	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Milestones	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Contracts, royalties	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Other revenue	$ -	$ -	$ -	$ -	$ -	$ -	$ 7.727	$ 7.727	$ 30.909	$ 30.909	$ 15.455	$ -	$ -
COGS	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ (33.191)	$ (85.380)	$ (109.959)	$ (113.116)
Gross Profit	$ -	$ -	$ -	$ 17.912	$ 14.302	$ 14.957	$ 23.894	$ 71.065	$ 95.574	$ 105.613	$ 13.130	$ (20.144)	$ (41.472)
R&D	$ (46.883)	$ (149.555)	$ (32.932)	$ (28.327)	$ (43.807)	$ (24.404)	$ (129.470)	$ (82.753)	$ (73.137)	$ (88.152)	$ (78.127)	$ (50.718)
SG&A	$ (18.135)	$ (41.704)	$ (15.437)	$ (15.535)	$ (16.012)	$ (16.398)	$ (63.382)	$ (69.643)	$ (63.836)	$ (49.344)	$ (46.332)	$ (56.575)
Other Operating Expenses	$ 0.049	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Operating Income	$ (64.969)	$ (191.259)	$ (30.457)	$ (29.560)	$ (44.862)	$ (16.909)	$ (121.788)	$ (56.822)	$ (31.360)	$ (124.366)	$ (144.603)	$ (148.765)
Non-operating income	$ -	$ (1.720)	$ 3.442	$ 5.424	$ 5.520	$ 0.340	$ 14.726	$ 4.524	$ 4.768	$ 4.920	$ 4.288	$ 3.574
Taxes	$ -	$ -	$ (0.329)	$ 0.282	$ 0.006	$ -	$ (0.041)	$ -	$ -	$ -	$ -	$ -
Net income	$ (64.969)	$ (192.979)	$ (27.344)	$ (23.854)	$ (39.336)	$ (16.569)	$ (107.103)	$ (52.298)	$ (26.593)	$ (119.447)	$ (140.315)	$ (145.191)
Other comprehensive gain (loss)	$ (0.020)	$ 4.300	$ 0.307	$ (0.093)	$ (0.058)	$ -	$ 0.156	$ -	$ -	$ -	$ -	$ -
Net loss attribuable to shareholders	$ (64.989)	$ (188.679)	$ (27.037)	$ (23.947)	$ (39.394)	$ (16.569)	$ (106.947)	$ (52.298)	$ (26.593)	$ (119.447)	$ (140.315)	$ (145.191)
Common Shares (M)	23.5	40.5	46.8	48.1	48.4	51.8	48.8	52.0	54.0	52.8	53.2	53.6
GAAP EPS	$ (2.85)	$ (4.56)	$ (0.58)	$ (0.50)	$ (0.81)	$ (0.32)	$ (2.21)	$ (1.01)	$ (0.49)	$ (2.26)	$ (2.64)	$ (2.71)
Shares - Basic (M)													
Shares - Diluted (M)													
Cash, cash equivalents & investments	$ 46.795	$ 104.816	$ 257.336	$ 536.094	$ 508.985	$ 444.645	$ 444.964	$ 444.964	$ 455.391	$ 498.243	$ 450.274	$ 377.634	$ 298.492

Source: Leerink Partners estimates and company reported financials

ACLX catalyst tracker

Stock (Ticker Symbol)	Lateral Impact	Drug	Product Class	Type of Event	Event or Trial Details	Expected Timing	Specific Event Date if known or specified	Impact: H(igh) > 9% M(edium) 3 - 9% L(ow) < 2%	Leerink Partners View of Expected Outcome
ACLX		ACLX001	R/R Multiple Myeloma	Phase 1 Data Presentation	Interim Clinical Data	2024		L	
ACLX		Anito-cel (CART-ddBCMA)	R/R Multiple Myeloma	Phase 2 Data Presentation	Preliminary data for Ph2 IMMagine-1	Late 2024		H	
ACLX		ACLX002	R/R AML, MDS	Phase 1 Data Presentation	Interim Clinical Data	2024		M	

Source: Company disclosures, Leerink Partners

GILD catalyst tables

Table 1: GILD near-term catalysts: Highest-impact 2024 catalysts

Stock	Drug	Indication	Type of Event	Event or Trial Details	Expected Timing	Specific Event Date if known or specified	Impact: H(igh) > 9% M(edium) 3 – 9% L(ow) < 2%	Leerink Partners View of Expected Outcome
RHHBY	**Tiragolumab** (Fc-competent anti-TIGIT)	**NSCLC** (1L, PD-L1-high)	Phase 3 Results Announcement	**SKYSCRAPER-01**: Final OS analysis results for tiragolumab + atezolizumab (anti-PD-L1) vs. atezo (LINK)	**1Q24**	-	M	Neutral
GILD	**Obeldesivir** (oral remdesivir prodrug)	**COVID-19** (standard risk)	Phase 3 Results Announcement	**OAKTREE**: Initial Ph 3 readout – trial testing standard-risk, non-hospitalized population w/ primary endpoint of time to symptom alleviation	**1Q24**	Fully enrolled; "update early next year"	M	Positive
GILD	Trodelvy (Trop2 ADC)	**NSCLC** (2/3L, all-comers)	Phase 3 Results Announcement	**EVOKE-01**: Initial Ph 3 readout - trial evaluating Trodelvy vs. docetaxel w/ OS primary endpoint; non-AGA pts post-CPI and chemo, plus relevant TKI for AGA pts (LINK)	**1H24**	ct.gov primary completion of May 2024	H	Positive
AZN	**T-DXd** (HER2 ADC)	**Breast** (2L, HR+/HER2-low)	Phase 3 Results Announcement	**DESTINY-Breast06**: Initial Ph 3 readout - trial evaluating T-DXd vs. chemo in much earlier setting than TROPiCS-02 or DB-04; also enrolling HER2-negative pts (IHC >0<1+) to better define efficacious threshold (incl in ITT pop and secondary endpoints)	**1H24**	-	M	Positive
AZN	**Dato-DXd** (Trop2 ADC)	**TNBC** (1/2L+ advanced)	Phase 3 Results Announcement	**TROPION-Breast02**: Initial Ph 3 readout - trial evaluating Dato-DXd vs. chemo in 1L PD-L1 negative or 2L post-CPI, PD-L1+ pts with dual PFS and OS primary endpoints	**2H24**	guidance ahead of ct.gov primary completion	M	Neutral
GILD	**Lenacapavir** (long-acting capsid inhibitor)	**HIV** (PrEP, younger females)	Phase 3 Results Announcement	**PURPOSE-1**: Initial Ph 3 readout - trial evaluating LEN (Q6M subQ) vs. F/TAF or F/TDF; primary endpoint of background HIV incidence	**2H24**	"late 2024", for 1 or both PURPOSE trials	M	Neutral
GILD	**Lenacapavir** (long-acting capsid inhibitor)	**HIV** (PrEP, higher risk pop.)	Phase 3 Results Announcement	**PURPOSE-2**: Initial Ph 3 readout - trial evaluating LEN (Q6M subQ) vs. F/TAF or F/TDF; primary endpoint of background HIV incidence	**2H24**	"late 2024", for 1 or both PURPOSE trials	H	Neutral
GILD	**Trodelvy** (Trop2 ADC)	**Bladder** (2/3L+ advanced)	Phase 3 Results Announcement	**TROPiCS-04**: Initial Ph 3 readout - trial evaluating monotherapy vs. chemo serves as confirmatory study for 2021 AA based on TROPHY U-01 Cohort 1 (OS primary endpoint)	**2024**	company guidance for FDA filing also in 2024	M	Positive
GILD	**Trodelvy** (Trop2 ADC)	**TNBC** (1/2L+ advanced)	Phase 3 Results Announcement	**ASCENT-03**: Initial Ph 3 readout - trial evaluating Trodelvy vs. chemo in 1L PD-L1-negative or 2L post-CPI, PD-L1+ pts with PFS primary endpoint (OS is secondary)	**2024**	guidance notably ahead of ct.gov primary completion	M	Positive
ACLX / GILD	**CART-ddBCMA** (autologous BCMA-CAR-T)	**MM** (r/r, penta-refractory)	Phase 2 Data Announcement	**iMMagine-1**: Initial Ph 2 readout - registration-directed trial is evaluating CART-ddBCMA monotherapy in the penta-refractory, BCMA tx-naïve setting w/ primary endpoint of ORR	**2H24**	guidance after resolution of partial clinical hold	M	Positive

Source: Gilead disclosures, clinicaltrials.gov, Leerink Partners research

Table 2: GILD near-term catalysts: HIV & COVID-19

Drug	Indication	Type of Event	Event or Trial Details	Expected Timing	Specific Event Date if known or specified	Impact: H(igh) > 9% M(edium) 3 - 9% L(ow) < 2%	Leerink View of Expected Outcome
Obeldesivir (oral remdesivir prodrug)	**COVID-19** (standard risk)	Phase 3 Results Announcement	**OAKTREE**: Initial Ph 3 readout - trial testing standard-risk, non-hospitalized population w/ primary endpoint of time to symptom alleviation	**1Q24**	Fully enrolled; "update early next year"	M	Positive
Lenacapavir + GS-1720 (long-acting integrase inhibitor)	**HIV Tx** (treatment experienced)	Ph 1 Data Presentation	**Ph 1**: Initial combo data for weekly oral combination regimen - heavily pretreated setting	**1H24**	Medical conference in "early 2024"	L	Neutral
Lenacapavir + TAB/ZAB (long-acting bNAB)	**HIV Tx** (treatment experienced)	Ph 2 Data Presentation	**Ph 2**: Initial Ph 2 data for long-acting injectible (Q6M) LEN + bNABs combination regimen	**2024**	-	L	Neutral
Lenacapavir + bictegravir oral (once-daily)	**HIV Tx** (treatment experienced)	Ph 2 Data Presentation	**ARTISTRY-1**: Update of Ph 2 portion evaluating 2 doses of LEN with bictegravir vs. stable baseline SoC regimen	**1H24**	Medical conference in "early 2024"	L	Neutral
Lenacapavir + islaravir (long-acting integrase inhibitor)	**HIV Tx** (treatment experienced)	Ph 2 Data Presentation	**Ph 2: Initial Ph 2 data for Merck-partnered combination**	**2024**	Our est. based on Merck mgmt.	L	Neutral
Lenacapavir (long-acting capsid inhibitor)	**HIV** (PrEP, younger females)	Phase 3 Results Announcement	**PURPOSE-1**: Initial Ph 3 readout - trial evaluating LEN (Q6M subQ) vs. F/TAF or F/TDF; primary endpoint of background HIV incidence	**2H24**	"late 2024", for 1 or both PURPOSE trials (if not early 2025)	M	Neutral
Lenacapavir (long-acting capsid inhibitor)	**HIV** (PrEP, higher risk pop.)	Phase 3 Results Announcement	**PURPOSE-2**: Initial Ph 3 readout - trial evaluating LEN (Q6M subQ) vs. F/TAF or F/TDF; primary endpoint of background HIV incidence	**2H24**	"late 2024", for 1 or both PURPOSE trials (if not early 2025)	H	Neutral
Lenacapavir (long-acting capsid inhibitor)	**HIV** (PrEP)	sNDA/sBLA/sMAA Filing	Gilead est. for LEN's first regulatory approval for LEN in PrEP - based on PURPOSE-1 and/or PURPOSE-2 results	**2H25**	"late 2025"	M	Neutral

Source: Gilead disclosures, clinicaltrials.gov, Leerink Partners research

Table 3: GILD near-term catalysts: Kite cell therapy

Drug	Indication	Type of Event	Event or Trial Details	Expected Timing	Specific Event Date if known or specified	Impact: H(igh) > 9% M(edium) 3 - 9% L(ow) < 2%	Leerink View of Expected Outcome
ACLX001 (universal BCMA-CAR-T)	**MM** (r/r, penta-refractory)	Phase 1 Data Presentation	**Ph 1**: Initial dose escalation data - focus on proof-of-mechanism for universal ARC-SparX platform (manufacturing / delivery feasibility, safety, preliminary efficacy and dose response); data presumed positive given recent Gilead opt-in and investment	**2024**		L	Positive
Yescarta (auto-CD19-CAR-T)	**LBCL** (2L r/r, outpatient)	Phase 2 Data Presentation	**ZUMA-24**: Interim Ph 2 update - trial evaluating Yescarta (axi-cel) monotherapy in the outpatient setting	**1H24**	Pushed out from prior 2H23 guidance	L	Positive
KITE-222 (CLL-1 CAR-T)	**AML** (r/r)	Phase 1 Data Announcement	**Ph 1**: FIH dose escalation trial initiated 3Q21	**2024**	*our est. based on ct.gov primary completion*	L	Neutral
CART-ddBCMA (autologous BCMA-CAR-T)	**MM** (r/r, penta-refractory)	Phase 2 Data Announcement	**iMMagine-1**: Initial Ph 2 readout - registration-directed trial is evaluating CART-ddBCMA monotherapy in the penta-refractory, BCMA tx-naïve setting w/ primary endpoint of ORR	**2H24**	guidance after resolution of partial clinical hold	M	Positive
Yescarta (auto-CD19-CAR-T)	**FL** (2L+, high-risk)	Phase 3 Results Announcement	**ZUMA-22**: Initial Ph 3 readout - trial evaluating Yescarta vs. SoC in indolent (Gr 1-3a), high-risk (i.e., POD24) pts	**2027**	our est. based on 2L+ precedent; ct.gov timing later in 2029	M	Positive
Yescarta (auto-CD19-CAR-T)	**LBCL** (1L, high-risk)	Phase 3 Results Announcement	**ZUMA-23**: Initial Ph 3 readout - trial evaluating Yescarta vs. SoC in high-risk pts (i.e., IPI ≥4), with EFS primary endpoint	**2027**	our est. based on 1L precedent (e.g., POLARIX); ct.gov timing later in 2031	M	Positive

Source: Gilead disclosures, clinicaltrials.gov, Leerink Partners research

Table 4: GILD near-term catalysts: Trodelvy

Stock	Drug	Indication	Type of Event	Event or Trial Details	Expected Timing	Specific Event Date if known or specified	Impact: H(igh) > 9% M(edium) 3 - 9% L(ow) < 2%	Leerink View of Expected Outcome
GILD	**Trodelvy** (Trop2 ADC)	**NSCLC** (2/3L, all-comers)	Phase 3 Results Announcement	**EVOKE-01**: Initial Ph 3 readout - trial evaluating Trodelvy vs. docetaxel w/ OS primary endpoint; non-AGA pts post-CPI and chemo, plus relevant TKI for AGA pts	**1H24**	ct.gov primary completion of May 2024	H	Positive
GILD	**Trodelvy / zimberelimab / domvanalimab** (Trop2 ADC / PD-1 / TIGIT)	**NSCLC** (2/3L+)	Phase 2 Data Announcement	**VELOCITY-Lung**: Initial data from NSCLC combo platform trial, Substudy 02 - cohort evaluating Trodelvy + zim + dom triplet in 2/3L+ setting (also active Trodelvy or docetaxel monotherapy comparison, though unclear if presented)	**2024**	-	L	Positive
AZN	**T-DXd** (HER2 ADC)	**Breast** (2L, HR+/HER2-low)	Phase 3 Results Announcement	**DESTINY-Breast06**: Initial Ph 3 readout - trial evaluating T-DXd vs. chemo in much earlier setting than TROPiCS-02 or DB-04; also enrolling HER2-negative pts (IHC >0<1+) to better define efficacious threshold (incl in ITT pop and secondary endpoints)	**1H24**	-	M	Positive
AZN	**Dato-DXd** (Trop2 ADC)	**TNBC** (1/2L+ advanced)	Phase 3 Results Announcement	**TROPION-Breast02**: Initial Ph 3 readout - trial evaluating Dato-DXd vs. chemo in 1L PD-L1 negative or 2L post-CPI, PD-L1+ pts with dual PFS and OS primary endpoints	**2H24**	guidance notably ahead of ct.gov primary completion of Dec 2025	M	Neutral
GILD	**Trodelvy** (Trop2 ADC)	**Bladder** (2/3L+ advanced)	Phase 3 Results Announcement	**TROPiCS-04**: Initial Ph 3 readout - trial evaluating monotherapy vs. chemo serves as confirmatory study for 2021 AA based on TROPHY U-01 Cohort 1 (OS primary endpoint)	**2024**	company guidance for FDA filing also in 2024	M	Positive
GILD	**Trodelvy** (Trop2 ADC)	**TNBC** (1/2L+ advanced)	Phase 3 Results Announcement	**ASCENT-03**: Initial Ph 3 readout - trial evaluating Trodelvy vs. chemo in 1L PD-L1-negative *or* 2L post-CPI, PD-L1+ pts with PFS primary endpoint (OS is secondary)	**2024**	guidance notably ahead of ct.gov primary completion of May 2027	M	Positive
AZN	**Dato-DXd** (Trop2 ADC)	**NSCLC** (2/3L+, AGA+ advanced)	Phase 2 Data Presentation	**TROPION-Lung05**: Updated Ph 2 data from ESMO 2023 - single arm study in 2/3L+ AGA+ pts	**2H24**	-	L	Neutral
AZN	**Dato-DXd** (Trop2 ADC)	**Solid tumors** (advanced)	Ph 1 Data Presentation	**TROPION-PanTumor01**: Ph 1 update for tumor-specific dose expansion cohorts (expected indications unclear)	**2H24**	-	L	Neutral
AZN	**Dato-DXd** (Trop2 ADC)	**NSCLC** (1L+ advanced)	Ph 1 Data Presentation	**TROPION-Lung02**: Updated Ph 1 data from WCLC 2023 - non-controlled pembrolizumab (anti-PD-1) +/- chemo arms in 1L+ NSCLC	**1H24**	-	L	Neutral
GILD	**Trodelvy** (Trop2 ADC)	**Breast** (2L, HR+/HER2-)	Phase 3 Results Announcement	**ASCENT-07**: Initial Ph 3 readout - trial evaluating Trodelvy vs. chemo in the chemo-naïve, post-ET setting; trial earlier line than TROPION-Breast01 (PFS primary endpoint)	**2H25**	ct.gov primary completion of Sep 2025	H	Positive
GILD	**Trodelvy** (Trop2 ADC)	**TNBC** (1L, PD-L1+)	Phase 3 Results Announcement	**ASCENT-04**: Initial Ph 3 readout - trial evaluating Trodelvy + pembrolizumab vs. pembro + chemo	**1H27**	ct.gov primary completion of Feb 2027	M	Positive
GILD	**Trodelvy** (Trop2 ADC)	**TNBC** (adjuvant, high-risk)	Phase 3 Results Announcement	**ASCENT-05**: Initial Ph 3 readout - trial evaluating adjuvant Trodelvy + pembrolizumab vs. pembro +/- chemo in high-risk pts after neoadj. therapy	**2H27**	ct.gov primary completion of Jun 2027	M	Positive

Source: Gilead disclosures, clinicaltrials.gov, Leerink Partners research

Table 5: GILD near-term catalysts: TIGIT

Stock	Drug	Indication	Type of Event	Event or Trial Details	Expected Timing	Specific Event Date if known or specified	Impact: H(igh) > 9% M(edium) 3 - 9% L(ow) < 2%	Leerink View of Expected Outcome
RHHBY	**Tiragolumab** (Fc-competent anti-TIGIT)	**NSCLC** (1L, PD-L1-high)	Phase 3 Results Announcement	**SKYSCRAPER-01**: Final OS analysis results for tiragolumab + atezolizumab (anti-PD-L1) vs. atezo	**1Q24**	-	M	Neutral
RCUS / GILD	**Domvanalimab / zimberelimab** (TIGIT / PD-1)	**Upper GI** (1L, advanced)	Phase 2 Data Announcement	**EDGE-Gastric**: Updated Ph 2 data with additional patient follow-up in 1L upper GI (n=41 patients) (LINK)	**2Q24**	**ASCO**: June (mini-oral)	L	Positive
RCUS / GILD	**Domvanalimab / zimberelimab** (TIGIT / PD-1)	**NSCLC** (1L, PD-L1-high)	Phase 3 Results Announcement	**ARC-10**: Initial Ph 3 readout - trial evaluating dom + zim vs. pembrolizumab (anti-PD-1) w/ OS primary endpoint; directly competing indication to Roche's SKYSCRAPER-01	**2025**	our est. based on ct.gov timing and competitor precedent (ct.gov timing earlier in 3Q24)	H	Positive
RCUS / GILD	**Domvanalimab / zimberelimab** (TIGIT / PD-1)	**Upper GI cancer** (1L, HER2-)	Phase 3 Results Announcement	**STAR-221**: Initial Ph 3 readout - trial evaluating dom + zim + chemo vs. nivolumab + chemo in 1L advanced GC/GEJC/EAC cancers	**2025**	our est. based on mgmt. commentary (ct.gov timing later in 3Q26)	H	Neutral
RCUS / GILD	**Domvanalimab / zimberelimab** (TIGIT / PD-1)	**NSCLC** (1L, all-comers)	Phase 3 Results Announcement	**STAR-121**: Initial Ph 3 readout - trial evaluating dom + zim + chemo vs. pembrolizumab + chemo in all-comer (PD-L1 / histology agnostic), AGA-excluded pts	**2025**	our est. based on mgmt. commentary (ct.gov timing later in 4Q27)	H	Positive
RCUS / GILD / AZN	**Domvanalimab** (TIGIT)	**NSCLC** (Stage III, post CRT)	Phase 3 Results Announcement	**PACIFIC-8**: Initial Ph 3 readout - AstraZeneca-partnered trial evaluating dom + durvalumab vs. durva in the currently durva-dominated Stage III setting (per PACIFIC)	**2027**	ct.gov primary completion of Jun 2027	H	Positive

Source: Gilead disclosures, clinicaltrials.gov, Leerink Partners research

Table 6: GILD near-term catalysts: Other oncology

Stock	Drug	Indication	Type of Event	Event or Trial Details	Expected Timing	Specific Event Date if known or specified	Impact: H(igh) > 9% M(edium) 3 - 9% L(ow) < 2%	Leerink View of Expected Outcome
GILD	**Magrolimab** (anti-CD47 mAb)	**NHL** (3L+ LBCL and iNHL)	Phase 1 Data Presentation	**Ph 1**: Final Ph 1b/2 data for magrolimab + rituximab in r/r LBCL or iNHL, or with rituximab + chemo (GemOx) in transplant-ineligible LBCL	**4Q23**	Timing / venue uncertain	L	Negative
GILD	**Magrolimab** (anti-CD47 mAb)	**NSCLC** (2/3L+, no AGAs)	Phase 2 Data Announcement	**ELEVATE-Lung**: Initial Ph 2 expansion results for magrolimab + docetaxel (chemo) combo	**2024**	-	L	Negative
GILD	**Magrolimab** (anti-CD47 mAb)	**AML** (1L, unfit)	Phase 3 Results Announcement	**ENHANCE-3**: Initial Ph 3 readout - trial evaluating magrolimab + venetoclax + azacitidine vs. placebo + ven + aza w/ CR and OS co-primary endpoints	**2H24**	Timing may be delayed due to ongoing partial clinical hold	L	Negative
RCUS	**AB521** (oral HIF-2α inhibitor)	**RCC** (clear cell, advanced)	Phase 1 Data Presentation	**ARC-20**: Initial monotherapy dose expansion data from ~30 advanced clear cell renal cell carcinoma (ccRCC) patients treated at 100mg QD dose level	**2H24**	"later in 2024"	L	Neutral
RCUS / GILD	**Etrumadenant / zimberelimab** (A2R antagonist / anti-PD-1 mAb)	**CRC** (2/3L, metastatic)	Phase 2 Data Announcement	**ARC-9**: Initial randomized data versus SoC in metastatic colorectal cancer (CRC) (2L/3L cohorts)	**1H24**	-	L	Negative
RCUS / GILD	**Quemliclustat / zimberelimab** (oral CD73 inhibitor / PD-1)	**Pancreatic** (1L, metastatic)	Phase 1 Data Announcement	**ARC-8**: Final randomized progression overall survival (OS) data in 1L metastatic pancreatic cancer	**1Q24**	"early 2024"	L	Neutral

Source: Gilead disclosures, clinicaltrials.gov, Leerink Partners research

GILD Valuation: DCF Analysis

DCF Valuation	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
FCFF	$8,928	$9,496	$10,573	$11,284	$12,028	$12,315	$12,427	$11,566	$11,291	$10,348
% Growth	*5%*	*6%*	*11%*	*7%*	*7%*	*2%*	*1%*	*-7%*	*-2%*	*-8%*
Discount Factor	0.99	0.93	0.87	0.82	0.77	0.72	0.68	0.63	0.59	0.56
Discounted FCFF	**$8,857**	**$8,837**	**$9,230**	**$9,241**	**$9,240**	**$8,875**	**$8,401**	**$7,335**	**$6,717**	**$5,775**

PV of Cash Flows	$104,255
PV of Terminal Value	$28,127
Total NPV (Enterprise Value)	**$132,382**
Cash (YE 2023)	$6,427
Debt (YE 2023)	$28,978
Equity Value	**$109,832**
Diluted shares O/S (YE 2023)	1,258
Equity value per share	**$87**

Assumptions:

Terminal Growth	**0.0%**	*after 2039*
Beta	**0.65**	
Cost of Equity	**7.4%**	
Cost of Debt	**3.3%**	
WACC	**6.6%**	

Long-term FCF growth	2033E	2034E	2035E	2036E	2037E	2038E	2039E
Virology FCF	$6,504	$3,902	$3,902	$3,902	$3,902	$1,951	$1,951
Non-Virology FCF	$3,252	$3,252	$3,252	$3,252	$3,252	$3,252	$3,252
Virology % Growth	***-8.3%***	***-40.0%***	***0.0%***	***0.0%***	***0.0%***	***-50.0%***	***0.0%***
Non-Virology % Growth	***0.0%***	***0.0%***	***0.0%***	***0.0%***	***0.0%***	***0.0%***	***0.0%***
Discount Factor	0.52	0.49	0.46	0.43	0.41	0.38	0.36
Discounted FCFF	**$5,108**	**$3,514**	**$3,296**	**$3,092**	**$2,901**	**$1,979**	**$1,856**
%-Growth	*-12%*	*-31%*	*-6%*	*-6%*	*-6%*	*-32%*	*-6%*

Implied TV & Growth Rate	2023-2032	2023-2039
Current Price	$74.36	$74.36
Equity Value	$93,565	$93,565
Enterprise Value	$116,116	$116,116
PV of FCFFs	$82,509	$104,255
Implied Terminal Value	$33,606	$11,861
Implied Terminal Growth Rate	**-9%**	**-9%**

Long-term worksheet		
Business	2032E rev	Est. relative GP
Virology	*68%*	***69%***
Non-Virology	*32%*	***31%***

Note: implied terminal rates based on current share price and Leerink DCF estimates; 2033-2039 FCFs not explicitly modeled bottom up, but approximated by taking the share of virology and non-virology FCF in 2032 and projecting component FCF estimates forward (notably through Biktarvy / Sunlenca LOEs in 2033 / 2037)

Source: Gilead Oncology filings, FactSet, Leerink Partners estimates

GILD Income Statement

FY ends December 31; USD in millions	A	A	A	A	E	E	E	E	E	E	E	E	E
non-GAAP actuals and estimates	**2022A**	**1Q23**	**2Q23**	**3Q23**	**4Q23**	**2023E**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Revenues:													
Product Sales	26,983	6,306	6,564	6,994	7,042	26,906	27,833	28,888	30,690	32,432	33,395	34,229	32,876
Other Revenue (incl. Royalties)	298	46	35	56	60	197	200	200	200	200	200	200	200
Total Revenue	**27,281**	**6,352**	**6,599**	**7,050**	**7,102**	**27,103**	**28,033**	**29,088**	**30,890**	**32,632**	**33,595**	**34,429**	**33,076**
Expenses:													
COGS	3,602	871	861	985	986	3,703	3,897	4,117	4,522	4,978	5,356	5,796	5,783
R&D	4,977	1,439	1,377	1,453	1,467	5,736	5,984	6,134	6,256	6,381	6,509	6,639	6,639
SG&A	5,587	1,318	1,848	1,298	1,576	6,040	5,560	5,783	5,985	6,225	6,411	6,508	6,377
Acquired IPR&D	936	481	236	91	277	1,085	-	-	-	-	-	-	-
Total Expenses	**15,102**	**4,109**	**4,322**	**3,827**	**4,305**	**16,563**	**15,441**	**16,034**	**16,763**	**17,584**	**18,276**	**18,943**	**18,799**
Operating Income (EBIT)	**12,179**	**2,243**	**2,277**	**3,223**	**2,797**	**10,540**	**12,592**	**13,054**	**14,126**	**15,048**	**15,319**	**15,486**	**14,277**
Nonop. Income and Interest exp., net	(859)	(148)	(147)	(136)	(189)	(620)	(747)	(723)	(710)	(688)	(652)	(616)	(582)
Minority Interest Adjustment and Other	26	26	*6*	*8*	*2*	42	8	*0*	*0*	*0*	*0*	*0*	*0*
Pre-tax Income (EBT)	11,346	2,121	2,136	3,095	2,610	9,962	11,852	12,331	13,417	14,360	14,667	14,870	13,695
Tax	2,188	396	448	216	548	1,608	2,193	2,281	2,482	2,657	2,713	2,751	2,533
Net Income (Adjusted)	**9,158**	**1,725**	**1,688**	**2,879**	**2,062**	**8,354**	**9,660**	**10,050**	**10,935**	**11,703**	**11,953**	**12,119**	**11,161**
Earnings Per Share (Basic)	**7.31**	**1.38**	**1.35**	**2.31**	**1.66**	**6.70**	**7.76**	**8.15**	**8.95**	**9.67**	**9.98**	**10.22**	**9.50**
Earnings Per Share (Diluted)	**7.26**	**1.37**	**1.34**	**2.29**	**1.64**	**6.64**	**7.68**	**8.06**	**8.86**	**9.57**	**9.87**	**10.11**	**9.41**
Weighted Avg. Shares (Basic)	1252	1248	1249	1248	1245	1248	1245	1233	1222	1210	1198	1186	1174
Weighted Avg. Shares (Diluted)	1262	1261	1258	1257	1258	1259	1258	1246	1234	1222	1211	1199	1187

Source: Gilead Sciences financials, Leerink Partners estimates

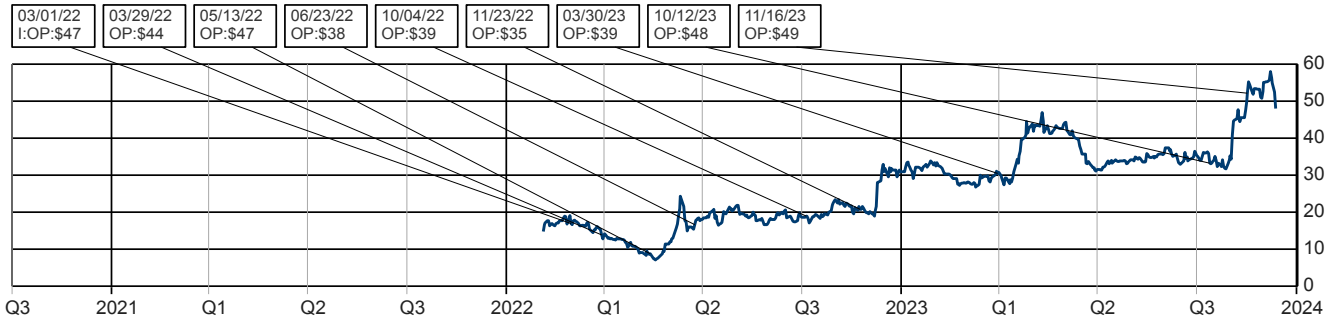
DISCLOSURE APPENDIX

Completion: December 13, 2023 7:56 A.M. EDT.
Distribution: December 13, 2023 7:56 A.M. EDT.

Analyst Certification

I, Daina M. Graybosch, Ph.D., certify that the views expressed in this report accurately reflect my views and that no part of my compensation was, is, or will be directly related to the specific recommendation or views contained in this report.

Rating and Price Target History for: Arcellx, Inc. (ACLX) as of 12-12-2023



OP = Outperform MP = Market Perform UP = Underperform D = Drop Coverage I = Initiate SC = Suspended Coverage

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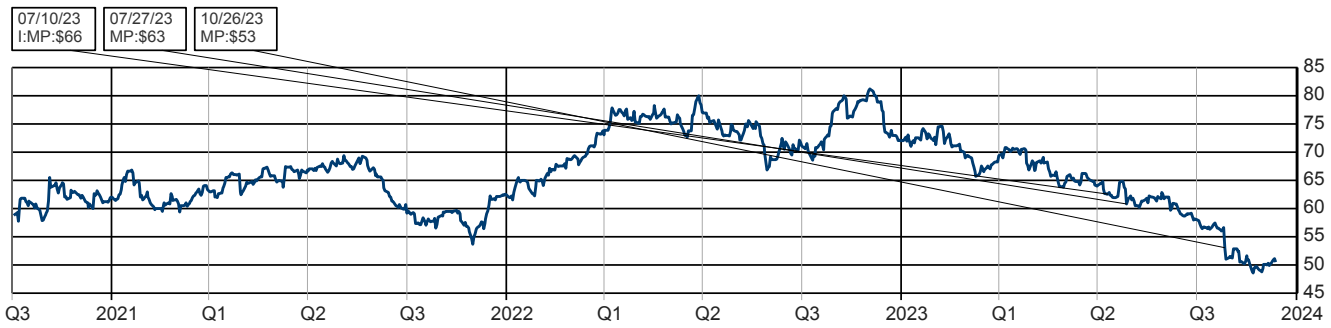
Rating and Price Target History for: Bristol-Myers Squibb Company (BMY) as of 12-12-2023



Leerink suspended coverage of BMY on March 19, 2018.

OP = Outperform MP = Market Perform UP = Underperform D = Drop Coverage I = Initiate SC = Suspended Coverage

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LEERINK PARTNERS

Rating and Price Target History for: Gilead Sciences, Inc. (GILD) as of 12-12-2023

Leerink placed a Market Perform rating on GILD on September 27, 2016.

OP = Outperform MP = Market Perform UP = Underperform D = Drop Coverage I = Initiate SC = Suspended Coverage

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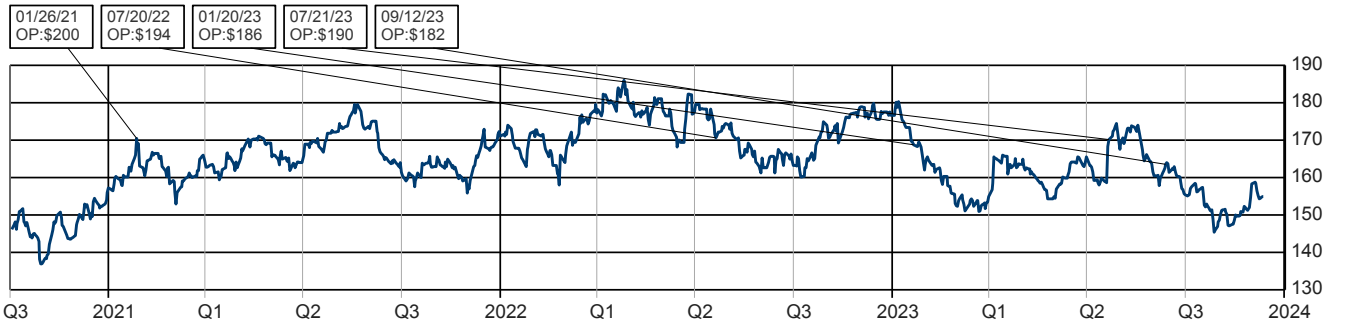
Rating and Price Target History for: Johnson & Johnson (JNJ) as of 12-12-2023



Leerink placed an Outperform rating on JNJ on January 27, 2010.

OP = Outperform MP = Market Perform UP = Underperform D = Drop Coverage I = Initiate SC = Suspended Coverage

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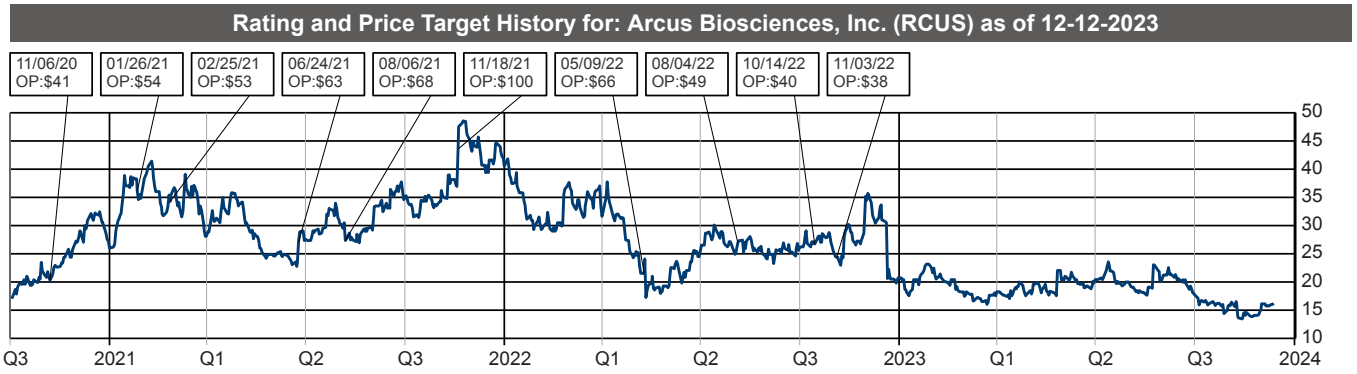

Leerink initiated coverage of RCUS with an Outperform rating on April 9, 2018.

OP = Outperform MP = Market Perform UP = Underperform D = Drop Coverage I = Initiate SC = Suspended Coverage

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OP = Outperform MP = Market Perform UP = Underperform D = Drop Coverage I = Initiate SC = Suspended Coverage

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ACLX: Valuation

Our price target of $49 is based on a blend of multiples and DCF analysis of projected revenues derived from a Monte Carlo simulation. We use an 8% WACC and account for net cash and G&A overhead. Our valuation for CART-ddBCMA is based on simulated revenues, while our valuation for ACLX002 is based on average US revenues from 2028E onward for cell therapies launching in AML. Our valuation for the remaining preclinical ARC-SparX platform is based on assumed return of "R&D overhead."

ACLX: Risks to Valuation

For us, the largest risk for Arcellx is whether the strong clinical signal observed with CART-ddBCMA will hold with more patients and follow-up. While our confidence is bolstered by supportive biology, there are differences between CART-ddBCMA and cilta-cel biology that make us question whether the two programs will continue to look similar in efficacy.

- **First, cilta-cel's impressive 83% CR rate reflects a large conversion from very-good partial response (VGPR) / partial response (PR) to CR of 61%, with over a third of the conversions taking place over 10 months following CAR-T dose.** We assume this late deepening is driven by long-persistent cilta-cel product cells; CART-ddBCMA does not look to have a similar long-tail of cell persistence, and we wonder whether this means the program will fail to demonstrate deepening with longer follow-up. On the positive side, CART-ddBCMA has consistently fast time to CR.
- **Second, cilta-cel has a unique bi-specific VHH binder that recognizes two distinct epitopes on BCMA.** This provides avidity in binding that likely explains the product's outstanding efficacy in targeting a relatively (vs. CD19) low-expression target like BCMA. CART-ddBCMA's D-domain is similar in size and binding attributes to a VHH binder but recognizes a single epitope without avidity. The impact of this difference is unclear; certainly, there could be two means to the same end. Reducing overall company risk, if avidity proves necessary, Arcellx's second BCMA program, ACLX001, has two D-domain binders in sequence.
- **Arcellx has made a unique decision to keep manufacturing outsourced.** We see no risk in this for the SparX, which should be like other standard biologics in manufacturing. For CARTddBCMA and ARC cells, however, relying on outsourced manufacturing carries capacity, scale, and quality risk. Arcellx is closely involved in quality control, and management told us they aim to have more control over release assays as they move forward. We do not dislike this approach—as capacity for cell therapy manufacturing builds externally, not having high overhead costs to build your own scale is attractive. It might also be a selling point for potential acquirers who have their own manufacturing. Should they need to change strategies, the company is also planning a contingency for buildout of their own manufacturing.
- **The largest risks we see for the ARC-SparX platform are failure to drive the desired cell kinetics, therapeutic window, and efficacy in MM and AML.** These are typical risks for a CAR-T platform with some added complexity that comes with two components and need to optimize dose schedule of both. In AML, Arcellx faces a diverse competitive landscape of CART, CAR-NK, innate / NK engagers, and multi-specific T-cell engagers.

GILD: Valuation

Our $87 PT is based on a DCF analysis for Gilead through 2039, using a 6.1% WACC discount rate, 0% terminal growth rate (after 2039), and accounting for net cash. Our projected oncology revenues are generated from a range of outcomes for the company's marketed products (Trodelvy, Yescarta, Tecartus) and select pipeline programs (zimberelimab, domvanlimab, etrumadenant, magrolimab, CART-ddBCMA, KITE-222, and KITE-363), which are derived from a Monte Carlo simulation of the entire IO industry pipeline (Leerink Partners IONIAN model). Outside of oncology, we project risk-adjusted revenues for core virology franchises (HIV, HIV, HCV, HBV/HDV), and COVID-19 (both Veklury and oral remdesivir prodrug, obeldesivir). We do not yet ascribe any value to the company's immunology and other non-virology / oncology pipeline prospects.

GILD: Risks to Valuation

To the upside, HIV franchise performance could accelerate more than anticipated with competitive pressures, Gilead could deliver surprisingly compelling oncology pipeline and M&A news flow, and the company could become a

target for strategic action given its low valuation. There are numerous oncology and immunology programs in early-phases that could have surprising good early data. To the downside, the HIV franchise could struggle to grow due to competitive and pricing pressures, long-acting HIV and new treatment combination R&D efforts could fail to pan out, oncology pipeline news flow could disappoint, and the company could engage in value-destructive acquisition activity.

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Our price target of $49 is based on a blend of multiples and DCF analysis of projected revenues derived from a Monte Carlo simulation. We use an 8% WACC and account for net cash and G&A overhead. Our valuation for CART-ddBCMA is based on simulated revenues, while our valuation for ACLX002 is based on average US revenues from 2028E onward for cell therapies launching in AML. Our valuation for the remaining preclinical ARC-SparX platform is based on assumed return of "R&D overhead."

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BMY: Valuation

Our price target is $53, which represents 7x our 2024E EPS of $7.61. Our target multiple is towards the bottom of the company's 7-16x 5-yr historical range because we forecast late-decade EPS declines.

BMY: Risks to Valuation

To the upside, key franchises (New Product Portfolio) could grow faster than anticipated, the pipeline could deliver positive surprises, and the market could be willing to pay a higher P/E multiple than we anticipate. To the downside, key franchises could fall short, IRA price negotiations could drive downside to 2026-2028 projections, the pipeline could disappoint, and the P/E multiple could face further pressure. Separately, external transactions could benefit or hurt shares depending upon the quality of assets acquired and price paid.

GILD: Valuation

Our $87 PT is based on a DCF analysis for Gilead through 2039, using a 6.1% WACC discount rate, 0% terminal growth rate (after 2039), and accounting for net cash. Our projected oncology revenues are generated from a range of outcomes for the company's marketed products (Trodelvy, Yescarta, Tecartus) and select pipeline programs (zimberelimab, domvanlimab, etrumadenant, magrolimab, CART-ddBCMA, KITE-222, and KITE-363), which are derived from a Monte Carlo simulation of the entire IO industry pipeline (Leerink Partners IONIAN model). Outside of oncology, we project risk-adjusted revenues for core virology franchises (HIV, HIV, HCV, HBV/HDV), and COVID-19 (both Veklury and oral remdesivir prodrug, obeldesivir). We do not yet ascribe any value to the company's immunology and other non-virology / oncology pipeline prospects.

GILD: Risks to Valuation

To the upside, HIV franchise performance could accelerate more than anticipated with competitive pressures, Gilead could deliver surprisingly compelling oncology pipeline and M&A news flow, and the company could become a target for strategic action given its low valuation. There are numerous oncology and immunology programs in early-phases that could have surprising good early data. To the downside, the HIV franchise could struggle to grow due to competitive and pricing pressures, long-acting HIV and new treatment combination R&D efforts could fail to pan out, oncology pipeline news flow could disappoint, and the company could engage in value-destructive acquisition activity.

JNJ: Valuation

Over the next 12 months, we believe JNJ shares can trade to our $182 price target. We apply a 16.5x P/E multiple to our 2024 EPS estimate of $11.04.

JNJ: Risks to Valuation

Risks include: 1) disappointing financial results, 2) negative talc product liability legal decisions, 3) pipeline candidate disappointments, 4) competitive pressures, 5) macroeconomic and/or inflationary pressures, and 6) other negative legal developments.

RCUS: Valuation

- Our 12-month price target of $38/share for RCUS is based on a blended two-methodology valuation:

- 1) Company DCF of our forecasted cash flows through 2039, which includes a -1.3% terminal growth rate, 8% discount rate, and assumes an R&D return on the company's investment and discovery efforts.
- 2) Peak revenue multiple-based sum-of-the-parts (SOTP) valuation for each of the company's clinical-stage programs we value--zimberelimab, domvanalimab, etrumadenant, and quemliclustat--plus the company's forward 12-month net cash & equivalents and investments position. We apply a 10x multiple to peak U.S. revenues per valued program with this methodology (assuming RCUS' portion of Gilead collaboration revenues), as well as an 8% discount rate.
- We currently do not assign explicit value to early clinical assets AB308 (Fc-competent anti-TIGIT) or AB521 (HIF-2α inhibitor), or any of Arcus' preclinical and discovery programs in either methodology.

RCUS: Risks to Valuation

- Arcus carries significant development risk until proof-of-concept for efficacy and human safety are established. We believe Arcus has considerable exposure to their own and competitor (e.g., SKYSCRAPER-01) trial data of TIGIT combinations. Investor focus is intensely focused on these read-outs, and we believe Arcus may fall below fair value with additional negative read-outs, or if sentiment shifts towards a commercial debate and larger competitors like Merck are believed to dominate the market.
- Since the majority of Arcus' assets and wholly owned combination therapies are concentrated in the adenosine pathway, if Arcus fails to demonstrate efficacy or discovers unforeseen safety liabilities from adenosine inhibition, there would be significant downside to our cash flow forecast and valuation. Further, we see risk to Arcus from failure of competitor therapies that target the adenosine pathways, particularly those assets with known issues in fully inhibiting the pathway. Finally, etrumadenant may, itself, fail to fully inhibit A2aR / A2bR as it is a competitive inhibitor that could be overcome by very high adenosine concentrations, which is a state of unknown relevance (given difficulty in measuring adenosine) in human cancers.

TSVT: Valuation

Our price target of $5 is based on a peer group multiples analysis (EV / 2028 Revenues). Our Abecma sales estimates are derived from a Monte Carlo simulation (risk adjusted) and we also adjust Abecma sales for estimated manufacturing and hospital-site infrastructure capacity limitations. Our valuation for Abecma is based on revenues accrued to 2seventy bio under its collaboration with BMY (US gross profit share), while our value for the clinical-stage programs DARIC33 and bbT369 is based on average US revenues for cell therapies launching in 2025-2029 timeframe in AML and NHL, respectively.

TSVT: Risks to Valuation

The largest upside risk to our MP rating is a return to Abecma growth in 2024 that is sustained for multiple quarters, given strong market demand and continued manufacturing supply bottlenecks. Another upside risk is building appreciation for Abecma's clinical profile, based on challenging experiences with Carvykti toxicity (e.g., delayed neurotoxicity), and/or real-world outcomes that show substantial superiority of CAR-T prior to T-cell engagers; we anticipate these shifts in perception, should they occur, will build slowly. Finally, acquisition for the Abecma revenue stream is also an upside risk.

To the downside of our MP rating, the largest risk is modest and short-lived Abecma growth in 2024, because doctors hold patients in anticipation of Carvykti's own earlier line approval; demand in earlier lines proves soft, as

community doctors elect to treat patients with all available lines of traditional therapy before referral; and/or hospital sites have limited capacity to support increasing demand for BCMA CAR-T.

Distribution of Ratings/Investment Banking Services (IB) as of 09/30/23			IB Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [OP]	211	65.1	64	30.3
HOLD [MP]	101	31.2	7	6.9
SELL [UP]	12	3.7	0	0

Explanation of Ratings

Outperform (Buy): We expect this stock to outperform its benchmark over the next 12 months.

Market Perform (Hold/Neutral): We expect this stock to perform in line with its benchmark over the next 12 months.

Underperform (Sell): We expect this stock to underperform its benchmark over the next 12 months.

The degree of outperformance or underperformance required to warrant an Outperform or an Underperform rating should be commensurate with the risk profile of the company.

For the purposes of these definitions the relevant benchmark for "Leerink Partners" branded healthcare and life sciences equity research will be the S&P 600® Health Care Index for issuers with a market capitalization of less than $2 billion and the S&P 500® Health Care Index for issuers with a market capitalization over $2 billion.

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In the past 12 months, Leerink Partners has received compensation for providing investment banking services to Arcellx, Inc. and Arcus Biosciences, Inc.

Leerink Partners expects to receive compensation for investment banking services from Arcus Biosciences, Inc. in the next 3 months.

Leerink Partners makes a market in Arcellx, Inc., Gilead Sciences, Inc., Bristol-Myers Squibb Company, Johnson & Johnson, Arcus Biosciences, Inc. and 2seventy bio, Inc.

Leerink Partners has acted as a manager for a public offering of Arcellx, Inc. in the past 12 months.

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