

# Kite Pharma (KITE)

## SMALL & MID CAP RESEARCH



Rating	<b>OUTPERFORM*</b> [V]
Price (14 Jul 14, US\$)	24.05
Target price (US\$)	34.00 <sup>1</sup>
52-week price range	32.15 - 23.59
Market cap. (US\$ m)	913.70
Enterprise value (US\$ m)	721.23

\*Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.

<sup>1</sup>Target price is for 12 months.

[V] = Stock considered volatile (see Disclosure Appendix).

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## First CAR T Pure Play; Initiating with an Outperform Rating and \$34 TP

We are initiating coverage of KITE with an Outperform rating and \$34 target price. Our rating reflects our enthusiasm for the CAR T and immuno-oncology space and KITE's unique position in the field and fast-to-market strategy. The primary risks to its current valuation are the several operational and clinical boxes that would still need to be checked over the next 6 months to bolster our confidence in KITE's strategy. We would use any post-IPO weakness as a buying opportunity, with a view toward clinical success in mid-2016.

- **Potential Breakthrough Immunotherapy:** Modified T-cells are emerging as a new and potentially curative therapy for B-cell malignancies and potentially a variety of other tumor types. KITE has partnered with the NCI to develop four novel therapies, and has an agreement in place to access future product candidates from the NCI. The most advanced program (KTE-C19) could start pivotal trials in 2015 and reach the market by 2017.
- **Catalysts:** We expect the next clinical update at ASH in December, followed by the initiation of a potentially pivotal Phase I/II trial in H1:15. Updates on manufacturing, FDA meetings, clinical plans in other indications, and potential Breakthrough Therapy designation could also be catalysts in 2014.
- **Valuation:** Our \$34 target price implies a \$24/share DCF valuation of KTE-C19 and \$10/share for its pipeline/technology. We model a 2017 launch, \$213,000 net price, \$30,000-\$40,000 cost of goods, 20% penetration in third-line DLBCL, 15% in other refractory B-cell indications, and a 60% probability of success.

### Financial and valuation metrics

Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US\$)	-1.16	-0.96	-1.29	-2.19
Prev. EPS (US\$)	—	—	—	—
P/E (x)	-20.7	-25.1	-18.7	-11.0
P/E rel. (%)	-114.8	-151.2	-125.5	-81.9
Revenue (US\$ m)	—	—	—	—
EBITDA (US\$ m)	-6.4	-16.0	-46.0	-86.0
OCFPS (US\$)	-1.03	-0.49	-0.95	-1.51
P/OCF (x)	—	-49.5	-25.3	-15.9
EV/EBITDA (current)	-139.0	-55.8	-19.4	-10.4
Net debt (US\$ m)	-22	-192	-149	-236
ROIC (%)	827.88	2,123.06	4,749.79	783.68
Number of shares (m)	37.99	IC (current, US\$ m)		-0.78
BV/share (Next Qtr., US\$)	3.4	EV/IC (x)		15,097.7
Net debt (Next Qtr., US\$ m)	-18.6	Dividend (current, US\$)		—
Net debt/tot eq (Next Qtr., %)	-99.7	Dividend yield (%)		—

Source: Company data, Credit Suisse estimates

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# Portfolio Manager Summary

KITE is one of a small number of companies focused on engineered T-cell therapies for the treatment of cancer. KITE's lead therapy, KTE-C19, is being developed for B-cell malignancies with a lead indication in third-line DLBCL, which has a significant unmet medical need. Over the next 12 months, we expect KITE to finalize and validate its manufacturing plans, initiate a potentially pivotal trial in DLBCL, advance KTE-C19 for other indications, and potentially generate data for other pipeline candidates.

## The Quick Bull and Bear Arguments

- **Bull Case:** CAR T technology has produced very high rates of durable responses in very late-stage patients across multiple B-cell tumors, some of which could be functional cures. KITE has a fast-to-market strategy in DLBCL and expects to be in pivotal testing in 2015 and launch in 2017. Pivotal trials are likely small (<100 patients) and have a high likelihood of clinical success. KITE is partnered with one of the leading groups in the field, Dr. Rosenberg at the National Cancer Institute (NCI). The company's technology is differentiated from other CAR T approaches by speed of manufacturing, and a relatively good safety profile reported to date. The platform also includes other T-cell therapies such as engineered TCRs, which potentially address a much larger number of tumor targets. KITE has also consolidated significant IP in the space.
- **Bear Case:** CAR T technology is patient specific and is therefore more complex and expensive than off-the-shelf solutions, such as bispecific antibodies or other novel approaches. There are several groups in the CAR T space, and it is unclear which, if any, will emerge as the clear winner. While the efficacy data from NCI/KITE is very impressive, the data in DLBCL is based on eight patients with limited follow-up. Toxicities associated with CAR T therapy are significant and have led to deaths in other CAR T therapy trials (not KITE). There also remains significant operational risk in scaling manufacturing, proving comparability, demonstrating safety in larger multicenter trials, and ultimately launching a patient-specific therapy.

## Our Positive View

We believe that the CAR T approach will emerge as a viable and very exciting new therapeutic modality initially for relapsed/refractory patients and primarily used in academic and specialty centers (not among community oncologists). We assume there will be multiple competitors in the field including Novartis, Juno, and potentially others (CELG/BLUE, PFE). We view KITE as well positioned in the field based on data, technology, strategy, and IP. As the only current public pure play in the space, KITE has significant scarcity value.

## Key Upcoming Derisking Events

Several accomplishments over the next six to 12 months could substantially derisk the overall program, including (1) acceptance of the IND and agreement with FDA on the pivotal clinical trial plan, (2) further disclosures around manufacturing plans, (3) clinical testing of cells produced using KITE's optimized process and cell freezing, (4) disclosure of plans for studies outside of DLBCL, (5) more patients and longer follow-up of DLBCL patients in the ongoing Phase I trial, and (6) better visibility on the clinical/regulatory strategy of KITE's competitors.

**Exhibit 1: KITE Pipeline**

Drug	Target	Technology	Indication	Stage
KTE-C19	CD19	CAR	Third line DLBCL	Phase I/II*
Not named	NY-ESO-1	TCR	Synovial Cell Sarcoma, Carcinoma	Phase I/II*
Not named	EGFRvIII	CAR	Glioblastoma, Head and Neck Cancer	Phase I/II*
Not named	MAGE-A3	TCR	Solid tumors	Phase I/II*
Not named	SSX2	TCR	Solid tumors	pre-IND

\* KITE-sponsored NCI proof-of-concept study.

Source: Company data, Credit Suisse estimates.

**Exhibit 2: KITE News Flow**

Product	Catalyst	Expected Date
KTE-C19	Updated data at ASH for patients treated with KTE-C19	Q4:14
KTE-C19	File IND	Q4:14
KTE-C19	Begin Phase I/II trial in DLBCL 3rd line+	H1:15
KTE-C19	Clear initial safety review	H1:15
KTE-C19	Begin registration trials in other indications (MCL, PMBCL, FL)	2015
Various	Updated data from various NCI trials	2015
KTE-C19	Potential Breakthrough Therapy Designation	2015
KTE-C19	Complete enrollment in Phase I/II 3rd line DLBCL trial	early 2016
KTE-C19	Initial results from Phase I/II 3rd line DLBCL trial	mid-2016
KTE-C19	Start trial for 2nd line DLBCL	2016
EGFRvIII CAR	IND in glioblastoma	2016
KTE-C19	BLA submission	Q4:16

Source: Company data, Credit Suisse estimates.

**Investment Positives**

- **CAR/TCR Platform:** CAR T technology, and modified T-cells more generally, are proving to be very potent anti-cancer agents with the potential for very long-lasting efficacy. Currently, KITE is the only public pure play in this space. The technology involves genetically engineering T-cells to specifically target cancer cells. It has been validated by strong, albeit limited, clinical data from various academic institutes that have now partnered exclusively with various companies including KITE, NVS, and Juno. It is likely that, over the next few years, this technology will become commercially available for B-cell lymphomas and will prove efficacious for other tumor types.
- **Robust Phase I/II Data in Refractory Lymphoma:** NCI's ongoing anti-CD19 CAR T cell trial with 24 patients has demonstrated an 86% objective response rate (ORR) with 67% of patients still in remission, the longest lasting nearly 60 months. Positive data from other groups further validate the technology, the high response rate, and durability of response.
- **Unique CRADA with NCI:** KITE has a cooperative research and development agreement (CRADA) with the NCI that gives it the right of first negotiation to the CAR- and TCR-based product candidates developed by Dr. Steven Rosenberg. The collaboration has yielded license agreements to CAR- and TCR-based

products targeting CD19, SSX2, NY-ESO-1, and EGFRvIII, while the NCI is still examining additional antigens under a joint research plan. KITE funds the NCI Phase I/II proof-of-concept studies that help inform its in-licensing decisions.

- **Strong IP Position:** KITE has consolidated patents from several sources, which broadly cover CAR and TCR constructs. We believe that KITE has freedom to operate in this space, and its broader patents may give the company leverage in negotiating any necessary cross licenses if a new IP emerges.
- **Rapid Path to Market:** Assuming a Phase III start in early 2015, KITE plans to file for approval for third-line DLBCL in late 2016 for its first product, KTE-C19. We currently project that the company will launch this product in late 2017. The timeline for other indications may be similarly short and will depend on when those studies are initiated.

## Investment Risks

- **Limited Clinical Experience:** NCI has delivered promising Phase I/II data, but the study has only enrolled 24 patients as of March 13, 2014, including eight with DLBCL, the target population for initial registration. The follow-up for the 8 DLBCL patients is also relatively short (~6 months), so the response duration in DLBCL is not well established. The NCI will primarily enroll DLBCL patients going forward.
- **Safety Risks:** After infusion back into a patient, CAR T cells rapidly expand in the body, which can result in cytokine release syndrome, tumor lysis syndrome, and CNS toxicity. If not well managed, these side effects can be serious and life threatening. A clinical hold was placed on Juno's CAR T technology (subsequently lifted) owing to two patient deaths on treatment believed to be a result of cytokine release syndrome. Overall, safety at the NCI has been better, but that may be the result of clinical practices at NCI, and safety issues could emerge in larger trials at more clinical centers.
- **Execution/Manufacturing Risk:** In general, KITE's commercial process follows the NCI process. It uses the same genetic constructs, the same viral vector, and the same cell expansion procedure. KITE has standardized the process using a closed system to control inputs and minimize risk of contamination. KITE will also introduce a freezing step to facilitate shipping. There is risk that the new process could alter the safety and/or efficacy of the product.
- **Valuation and Financial Risk:** At its current valuation, a significantly high technology value or probability of success is assumed, increasing the risk associated with any near-term setbacks. KITE may also need to raise additional capital before reaching profitability. Non-dilutive funding from a potential ex-U.S. partner could reduce the need for financing.
- **Multiple Competing CAR T Programs:** Several companies, including NVS, Juno, CELG/BLUE, and PFE are developing CAR and TCR therapies to target B-cell diseases that could be competitive with KITE's programs. We expect that one or more of these competitors will commercialize a CD19-targeting CAR program that directly competes with KITE's KTE-C19 program. The regulatory strategy and clinical timelines for competitor programs are unknown.
- **Rapidly Changing Standard of Care in Lymphoma/Leukemia:** An increasing number of new drugs are in development for B-cell lymphomas including DLBCL. We anticipate that one or more novel drugs will become competitive with KTE-C19. These include newly approved drugs such as Imbruvica (a BTK inhibitor) and drugs in development such as ABT-199 (Bcl2 inhibitor) and idelalisib (PI3K inhibitor). Other emerging therapies include antibody-drug conjugates, checkpoint inhibitors, and bispecific antibodies. We model a 20% penetration for KTE-C19 in third-line DLBCL.

## Valuation: \$34 Target Price

Our \$34 target price is based on our fully taxed, probability weighted, product-level DCF for KTE-C19 and the rest of KITE's pipeline. For our DCF analysis, we use a discount rate of 12% and a 35% tax rate.

Our model includes 20% peak penetration in third-line DLBCL, which implies multiple future competitors using both CAR T and other modalities, and assumes that not all patients will be eligible for CAR T treatment.

- **KTE-C19 (\$24/share):** We assign a 60% probability of success to adjust our future sales and launch/selling expenses. We assume a \$213,000 net price per treatment (growing at 2% per year) and \$30,000 to \$40,000 cost of treatment. We assume launch in 2017 for third-line DLBCL and 20% peak penetration by 2020. We also assume 15% penetration for later approved indications in r/r PMBCL, r/r ALL, r/r MCL, and transformed FL and 15% penetration into second-line DLBCL.
- **Pipeline (\$10/share):** We assign a 20% probability of success to the programs with clinical data (EGFRvIII CAR, NY-ESO-1 TCR, and MAGE TCR) and 15% to the preclinical SSX2 TCR candidate. We assume a peak U.S. market opportunity of \$600M per candidate. We assume launch years for EGFRvIII CAR, NY-ESO-1 TCR, anti-MAGE TCR and SSX2 TCR to range from 2019 to 2021.

**Exhibit 3: Sum-of-the-Parts Valuation**

Program	NPV	POS	per share
KTE-C19	\$1,041	60%	\$24
Pipeline	\$459	20%	\$10

<b>Total</b>	<b>\$1,501</b>	<b>\$34</b>
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Source: Company data, Credit Suisse estimates.

**Exhibit 4: KITE Income Statement**

	2012A	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Revenues</b>													
US sales of KTE-C19										32.9	105.0	239.0	364.9
Ex-US royalties on KTE-C19												1.3	4.3
Other CAR or TCR program(s)												18.0	60.0
Ex-US royalties on other CAR or TCR												0.9	3.6
<b>Total Revenues</b>										<b>32.9</b>	<b>105.0</b>	<b>259.2</b>	<b>432.8</b>
<b>Expenses</b>													
Cost of goods											22.2	44.3	66.6
Research and development	1.8	5.1	2.1	2.5	3.0	3.7	11.3	37.0	54.0	66.0	70.0	74.0	78.0
Sales, general, administrative	0.8	1.3	1.1	1.2	1.5	1.7	5.5	10.0	33.0	48.2	71.0	76.0	81.0
<b>Total Operating Expenses</b>	<b>2.6</b>	<b>6.4</b>	<b>3.2</b>	<b>3.7</b>	<b>4.5</b>	<b>5.4</b>	<b>16.8</b>	<b>47.0</b>	<b>87.0</b>	<b>122.1</b>	<b>163.2</b>	<b>194.3</b>	<b>225.6</b>
Operating income (loss)	(2.6)	(6.4)	(3.2)	(3.7)	(4.5)	(5.4)	(16.8)	(47.0)	(87.0)	(89.2)	(58.2)	64.9	207.2
Total Other Income (Expense)	0.0	0.1	0.0	0.1	0.1	0.1	0.3	0.3	0.2	0.2	0.3	0.3	0.3
Pre Tax Income	(2.6)	(6.4)	(3.1)	(3.6)	(4.4)	(5.3)	(16.5)	(46.7)	(86.8)	(89.0)	(57.9)	65.1	207.4
Income tax													
<b>Net Income</b>	<b>(2.6)</b>	<b>(6.4)</b>	<b>(3.1)</b>	<b>(3.6)</b>	<b>(4.4)</b>	<b>(5.3)</b>	<b>(16.5)</b>	<b>(46.7)</b>	<b>(86.8)</b>	<b>(89.0)</b>	<b>(57.9)</b>	<b>65.1</b>	<b>207.4</b>
EPS - basic	(\$0.46)	(\$1.16)	(\$0.66)	(\$0.65)	(\$0.20)	(\$0.14)	(\$0.96)	(\$1.29)	(\$2.19)	(\$1.89)	(\$1.22)	\$1.36	\$4.27
EPS - diluted	(\$0.46)	(\$1.16)	(\$0.66)	(\$0.65)	(\$0.20)	(\$0.14)	(\$0.96)	(\$1.29)	(\$2.19)	(\$1.89)	(\$1.22)	\$1.18	\$3.72
Shares outstanding - basic	5.59	5.47	5.57	5.61	21.82	38.07	17.77	36.27	39.67	47.13	47.50	48.07	48.55
Shares outstanding - diluted	5.59	5.47	11.19	11.22	44.62	44.73	27.94	45.01	47.46	53.97	54.71	55.26	55.81

Source: Company data, Credit Suisse estimates.

## Valuation Sensitivity Analysis

We conducted a sensitivity analysis around our current target price methodology to gauge the potential impact of achieving near-term milestones and to assess how near-term setbacks might impact sentiment.

For this, we looked at an upside and a downside modeling scenario. Neither reflect the full upside potential (FDA approval or take-out, 100% POS and valuation premium) or the full downside risk (total technology failure, value at approximately \$5 cash per share). Rather, the scenarios are designed to reflect more bullish or more bearish assumptions of success.

- **Upside (\$58):** An upside scenario likely requires increased CR rate among DLBCL patients, continued durability of response, no major safety issues, a clinical/regulatory path for non-DLBCL indications, and execution on the manufacturing side.

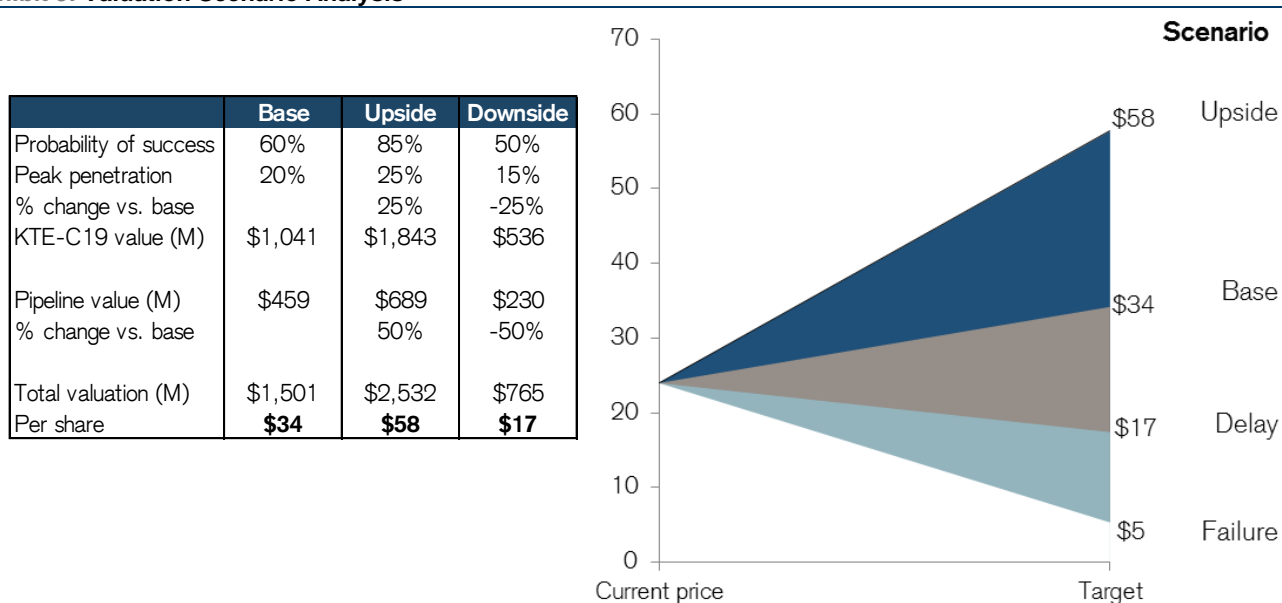
In the upside scenario, we assume a much higher 85% probability of success (60% is our base), an increase in penetration in the relapsed/refractory setting to peak penetration of 25% (20% is our base), and a 50% increase in technology value (which equates to a 30% probability of success for pipeline programs [currently 20%]). With these more bullish assumptions, our target price would increase to \$58/share (\$42 for KTE-C19 and \$16 for the pipeline).

- **Downside (\$17):** In this scenario, we assume KITE faces a material setback, which could include a safety concern, clinical/regulatory delay, mixed clinical results, or perceived advantage for one of its competitors, among others.

In the downside scenario, we assume a one-year delay in launch, a lower 50% probability of success (60% is our base), a lower 15% penetration rate (20% is our base base), and a 50% reduction in its pipeline valuation. With these more bearish assumptions, our target price would decrease to \$17/share (\$12 for KTE-C19 and \$5 for the pipeline).

- **Failure (\$5):** This scenario represents the current cash per share value.

**Exhibit 5: Valuation Scenario Analysis**



Source: Company data, Credit Suisse estimates



## Market Model Assumptions for KTE-C19 in DLBCL

We model first sales of KTE-C19 in 2017 for third-line DLBCL, reaching peak penetration of 20% in 2020. Our model projects unadjusted U.S. sales estimates of \$732M by 2021. We project ex-U.S. sales of \$243M in the same year for total worldwide sales of \$975M in 2021.

- **Pricing:** We assume that at launch KTE-C19 is priced at \$250K gross per treatment (\$213K per treatment, with a 15% gross to net adjustment) and grows 2% growth thereafter.
- **Cost:** We estimate a cost of \$30,000 to \$40,000 per patient starting at the high end at launch and dropping to the low end over two years for gross margins of 87%.
- **U.S. Market Size:** We expect KTE-C19 to initially be approved for third-line DLBCL, which has an estimated 8,100 patient population. We project 2% annual population growth and 20% peak penetration. We further assume that KTE-C19 will gain approval in other indications, including r/r PMBCL, r/r ALL, r/r MCL, and transformed FL by 2018 (total 4,900 patients) and second-line DLBCL by 2019 (~2,700 patients). We assume a conservative 15% peak penetration into second-line DLBCL and 15% peak penetration in all other markets and again a 2% patient population growth.
- **Ex-U.S. Market:** We assume that KITE will sign with an ex-U.S. partner to receive \$60M upfront and a \$90M milestone if approved and 20% net royalties from ex-U.S. sales.
- **Risk-Adjusted Market Model:** We assume a 60% probability of success.

**Exhibit 6: Market Model Build for KTE-C19**

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
<b>DLBCL</b>										
3rd or later line DLBCL (after failed transplant)	8,100	8,262	8,427	8,596	8,768	8,943	9,122	9,304	9,490	9,680
3rd line penetration				3%	8%	15.0%	20.0%	20.0%	20.0%	20.0%
<b>Treated- 3rd line DLBCL</b>				<b>258</b>	<b>701</b>	<b>1,341</b>	<b>1,824</b>	<b>1,861</b>	<b>1,898</b>	<b>1,936</b>
2nd line DLBCL (incremental to 3rd or later) penetration	2,700	2,754	2,809	2,865	2,923	2,981	3,041	3,101	3,163	3,227
						5%	8%	12%	15%	15%
<b>Treated- 2nd line DLBCL</b>						<b>149</b>	<b>243</b>	<b>372</b>	<b>475</b>	<b>484</b>
<b>Others</b>	4,900	4,998	5,098	5,200	5,304	5,410	5,518	5,629	5,741	5,856
r/r PMBCL	400	408	416	424	433	442	450	459	469	478
r/r ALL	1,800	1,836	1,873	1,910	1,948	1,987	2,027	2,068	2,109	2,151
r/r MCL	1,800	1,836	1,873	1,910	1,948	1,987	2,027	2,068	2,109	2,151
Transformed FL	900	918	936	955	974	994	1,014	1,034	1,054	1,076
Penetration					2%	5.0%	10.0%	15.0%	15.0%	15.0%
<b>Treated- Other r/r B-cell</b>				-	<b>106</b>	<b>270</b>	<b>552</b>	<b>844</b>	<b>861</b>	<b>878</b>
Total patients treated				<b>258</b>	<b>807</b>	<b>1,761</b>	<b>2,619</b>	<b>3,077</b>	<b>3,234</b>	<b>3,298</b>
Net price/dose				\$212,500	\$216,750	\$221,085	\$225,507	\$230,017	\$234,617	\$239,310
Sales subtotal US (M) - treated				\$55	\$175	\$389	\$591	\$708	\$759	\$789
Retreated						70	134	182	186	190
Net price/dose						\$127,500	\$130,050	\$132,651	\$135,304	\$138,010
Sales subtotal US (M) - retreated						\$9	\$17	\$24	\$25	\$26
<b>Sales - US (M)</b>				\$55	\$175	\$398	\$608	\$732	\$784	\$816
Cost per course				\$40,000	\$35,000	\$30,000	\$30,000	\$30,000	\$30,000	\$30,000
COGS				\$10	\$28	\$54	\$81	\$95	\$100	\$102
COGS Margin				18.8%	16.1%	13.5%	13.3%	13.0%	12.7%	12.5%
Ex-US (% of US, 1-yr lag)					15%	25%	30%	40%	50%	60%
<b>Sales - Ex-US (M)</b>					\$8.2	\$43.8	\$119.5	\$243.3	\$366.0	\$470.3
Ex-US net royalties					\$0.2	\$2.2	\$7.2	\$19.46	\$36.6	\$56.4
<b>Sales - WW</b>				<b>\$55</b>	<b>\$183</b>	<b>\$442</b>	<b>\$728</b>	<b>\$975</b>	<b>\$1,150</b>	<b>\$1,286</b>

Source: Company data, Credit Suisse estimates.

## Valuation Assumptions for Rest of Pipeline

We assign \$10 per share in total value to our \$34 target price for the four other pipeline candidates, EGFRvIII CAR for Glioblastoma, SSX2 TCR, NY-ESO-1 TCR, and anti-MAGE TCR, which are still early stage. For each of these pipeline therapies, we assume a peak post-launch U.S. market size of \$600M, which would grow at 2% thereafter. We assume that KITE enters into an ex-U.S. partnership for all four therapies and receives a 20% royalty on ex-U.S. sales. We probability adjust each of the pipeline revenues based on a 20% probability of success for the therapies with clinical data (EGFR CAR, NY-ESO-1 TCR, anti-MAGE TCR) and 15% for the preclinical program (SSX2 TCR). We assume different launch years for each of the four pipeline therapies.

**Exhibit 7: Pipeline Valuation Assumptions**

Product	Target	Indication	Adjusted Probability	Years to Market	Peak U.S. Sales	Probability Adj. Value	Per Share
EGFR CAR	EGFR vIII	Glioblastoma, Head and Neck Cancer	20%	5	\$600	\$139	\$3.16
NY-ESO-1 TCR	NY ESO-1	Solid Tumors	20%	5	\$600	\$139	\$3.16
anti-MAGE TCR	MAGE	Solid Tumors	20%	6	\$600	\$119	\$2.70
SSX2 TCR	SSX2	Solid Tumors	15%	7	\$600	\$63	\$1.43
Total						\$459.4	
Shares Outstanding (fully diluted)						43.9	
\$/Share						\$10.47	\$10.47

Source: Company data, Credit Suisse estimates.



# KITE Technology Overview

KITE's technology platform consists of two technologies that harness the tumor-killing activity of T-cells:

- Chimeric antigen receptors (CARs) and
- Modified T-cell receptors (TCRs).

These technologies were developed over many years of research in Dr. Rosenberg's laboratory at the National Cancer Institute, and similar technologies were concurrently developed at other academic institutions.

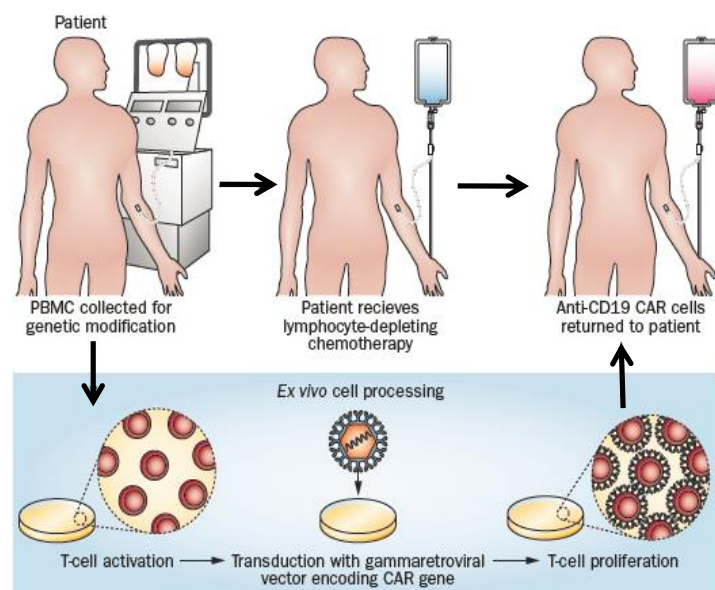
Both technologies involve the introduction of new genetic material into a patient's own T-cells, essentially reprogramming the T-cells to kill the tumor. The process for extracting the cells, introducing the genetic material, and administering the therapy to patients is also similar. (See Exhibit 8.)

- (1) For both CAR and TCR therapies, the first step is extracting cytotoxic T-cells from the patient by a standard procedure.
- (2) The extracted cells are then modified with engineered genetic material via a safe retroviral delivery vector, which leads to the stable incorporation of the blueprint of the CAR/TCR, and ultimately the expression of the desired receptor on the surface of the cells.
- (3) The modified T-cells are expanded in culture for reintroduction back into the patient.

In order for the CAR/TCR modified T-cells to expand in the body, the patient is treated with chemotherapy to kill some of the existing blood cells and make room for the new cells. The choice of conditioning regimen can have a significant impact on the safety and efficacy of the treatment.

In its planned commercial process, all of the cellular manipulations will be done in a closed system (a bag that is not exposed to the air), and the final product will also be frozen for shipment. Both of these features (closed system and freezing) are new and were not part of Rosenberg's original studies.

## Exhibit 8: Process for Producing and Administering Modified T-cells



Source: Kite Pharma

## CAR Technology

Chimeric antigen receptors (CARs) consist of an extracellular binding domain and an intracellular signaling domain, which together trigger the T-cell to kill the target tumor cell. Structurally, the CAR is composed of three regions: (1) ligand binding domain, (2) hinge/transmembrane domain, and (3) signaling domain. (See Exhibit 9.)

- The ligand binding domain contains a single chain variable region (scFv) that has the same architecture as a normal antibody binding region. This provides the highly specific recognition and binding to the antigen.

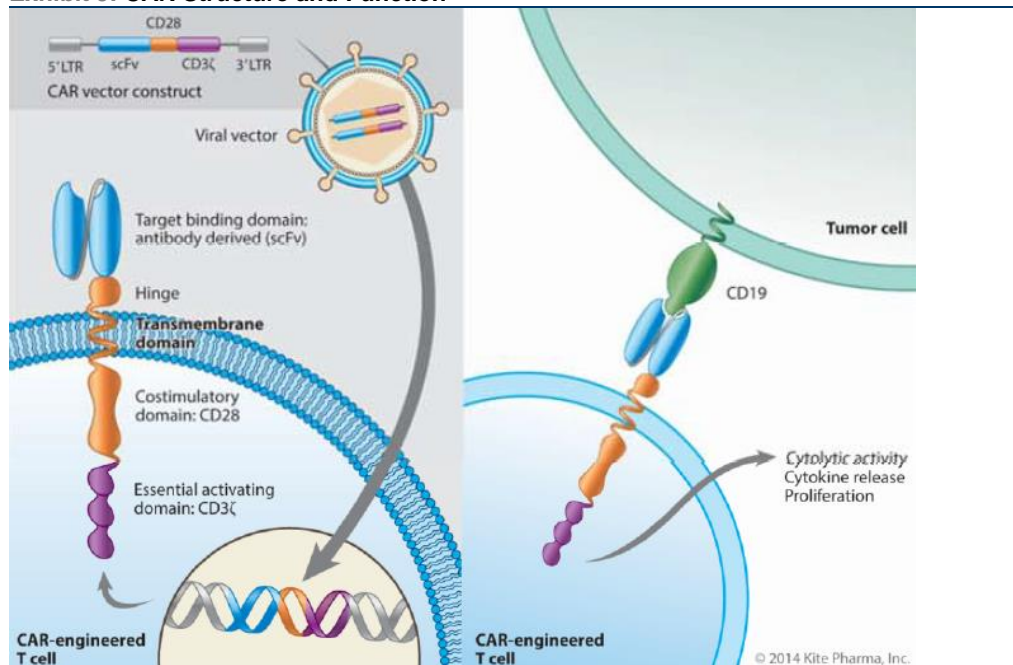
Antigen selection is crucial for a successful CAR, as the engineered T-cells will kill any cell that expresses the target. In the case of KTE-C19, the target CD19 is only expressed on B-cells and B-cell tumors. Since patients can live without B-cells, this target may have an adequate safety profile. The second CAR is targeting a splice variant of EGFR found on glioblastoma (EGFRvIII) and not on normal cells.

- The hinge/transmembrane domain links the extracellular ligand binding domain with the intracellular signaling domain. The hinge provides flexibility for the ligand binding domain to more efficiently interact with the target antigen.
- The signaling domain has two separate regions that help activate the T-cell upon binding to the target antigen. KITE uses an activation domain from CD3 and a costimulatory domain from the CD28 protein. The CD3-zeta domain is responsible for sending the activation signal to the T-cell and the CD28 costimulatory domain enhances this signal.

Other formats using different signaling domains have been successfully tested by other groups. It is not clear if there are advantages or disadvantages of the various signaling domains currently being tested.

For a discussion of the various competitors in the space, please refer to Page 26.

**Exhibit 9: CAR Structure and Function**



Source: Kite Pharma

## TCR Technology

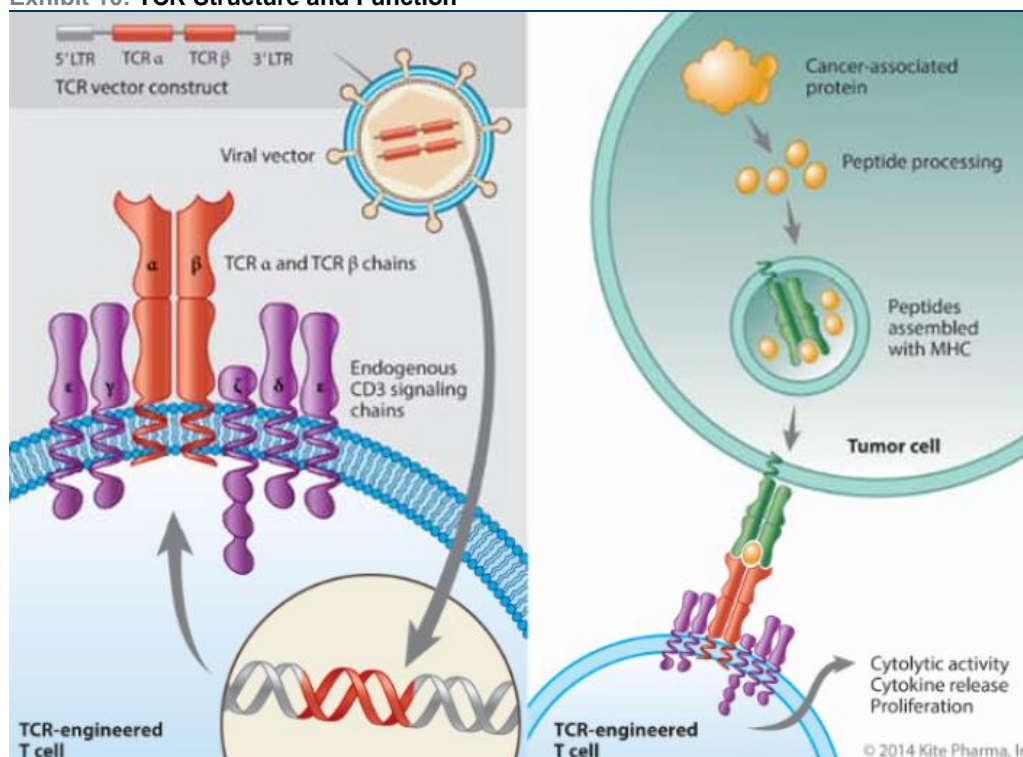
T-cells are naturally activated via the T-cell receptors (TCRs). TCRs recognize foreign peptides that are displayed on the surface of the target cell in a complex with a protein called MHC. This binding initiates signaling through CD3 and triggers the T-cell to become active.

Modified TCRs have engineered alpha and beta subunits that recognize intracellular tumor antigens presented by MHCs on the tumor cell. Just like in the normal TCR, the modified binding region then interacts with the endogenous CD3 proteins to make a functional TCR. Upon binding to the antigen, the CD3 subunits then activate the T-cell (See Exhibit 10).

Currently, KITE is funding early development at NCI of modified TCRs targeting intracellular tumor antigens including SSX2, NY-EYSO-1, and MAGE.

- **Key Benefit of TCR Technology over CAR:** Unlike CAR technology, modified TCRs can be directed against tumor-specific proteins that are not normally expressed on the cell surface. This vastly increases the number of potential tumor-specific targets, and these targets may not be adequately addressed by other antibody technologies.
- **Limitation of TCR Technology:** Since the TCR recognizes an antigen bound to MHC, the TCR is specific for only one form of the MHC. As a result, not all patients will be treatable with any given modified TCR, since different patients will utilize different MHC molecules.
- **Key Risk with TCR Technology:** As with the CAR technology, it is essential that the modified TCR is highly tumor specific or at least that the target is not on any essential tissue. It is much easier to test the specificity of an antibody versus the specificity of a TCR, since the TCR recognizes a protein complex of a tumor antigen bound to MHC.

Exhibit 10: TCR Structure and Function



Source: Kite Pharma

# Robust Efficacy in NCI Trial

## A Nonstandard Phase I/II Program

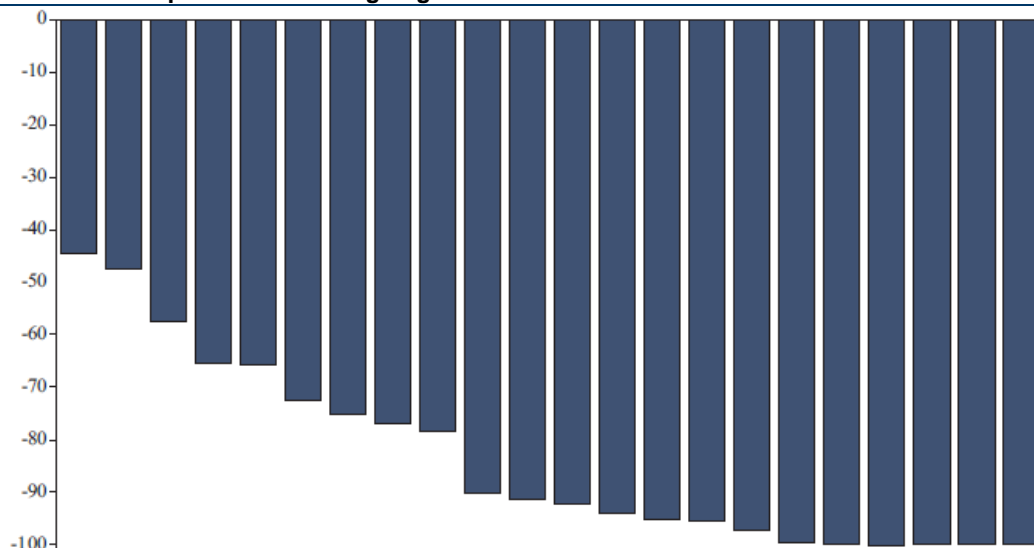
The NCI is currently conducting an ongoing trial using a noncommercial version of KTE-C19 (the same compound, but not produced using KITE's new manufacturing methodology) in relapsed/refractory lymphoma patients. It is an open-label, single arm, Phase I/II safety and efficacy trial that began in 2009 and is still enrolling with anticipation for completion in 2015. Data for the 24 patients treated in the trial has been released. The patients were enrolled in three cohorts, and the cohorts varied by dose and by conditioning regimen, and each enrolled a variety of tumor types.

- **Cohort 1:** Patients were treated with a range of high doses from 3 million cells/kg to 30 million cells/kg. For the conditioning regimen, patients received either 60 mg/kg or 120mg/kg of cyclophosphamide, 25mg/m<sup>2</sup> fludarabine, and IV IL-2. This cohort included eight patients, four with CLL and four with r/r lymphomas.
- **Cohort 2:** Dosing was lowered to 2.5 million cells/kg, and the conditioning regimen was kept the same except without IL-2. This cohort included 15 patients (two from cohort 1 that were retreated), four with CLL, and 11 with r/r lymphoma.
- **Cohort 3:** Patients received a low 1-2 million cells/kg dose range and a lower dose of cyclophosphamide and fludarabine in an effort to improve the regimen tolerability. Cohort 3 is still ongoing, but NCI has released data for three DLBCL patients, with plans to enroll only DLBCL patients in this cohort going forward.

## Impressive Efficacy in Multiple B-Cell Malignancies

Of the evaluable patients, 86% (19/22) demonstrated an overall response, with eight achieving a complete response. During the trial, two patients died from unrelated causes and were not included in the results. Exhibit 11 shows the initial tumor shrinkage for each of the 22 evaluable patients.

**Exhibit 11: 86% Response Rate in Ongoing Phase I/II Trial**



Source: Company data.

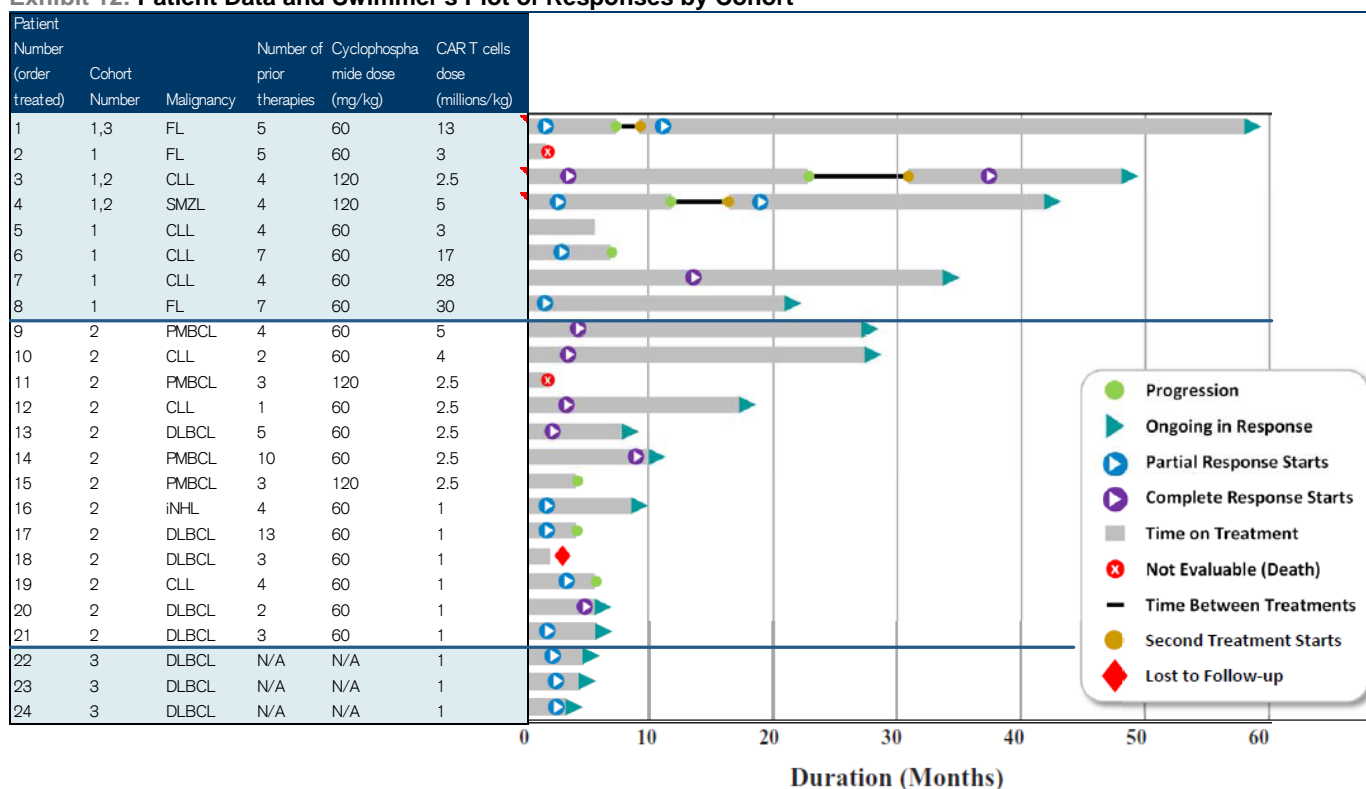
## Responses Are Durable

A more in depth look into the responses of each patient is in Exhibit 12 and Exhibit 14, which show the time of best response (CR or PR), the duration of response, and multiple responses in the few patients who were retreated after progression. Exhibit 12 shows the data by cohorts, which were enrolled sequentially, and Exhibit 14 shows the same data organized by disease type.

- **Rapid Onset of Response:** Responses typically occur quickly within the first two months, as seen by partial and complete response starts on Exhibit 13.
- **Responses Are Durable:** For example, patient 1, 3, and 4 are out over 40 months, though these three were all retreated. Patients 7-10 are out over 30 months from a single administration.
- **No Clear Dose Response:** What contributes to depth of response or response duration is not clear, since the patients treated earlier in the study (typically the ones with longest duration) were also given higher doses of CAR T cells and received different conditioning regimens.
- **Retreatment Is Effective:** Three patients received treatment twice (patient 1, 3, and 4). Two had partial responses, and one had a complete response following initial treatment. Each was treated after progression, and none has relapsed so far. Most interestingly, no patient who has progressed during the trial has died yet.

We expect updated data at ASH 2014, including longer duration from the DLBCL cohort of patients currently enrolled (key for establishing response duration) and initial data on new DLBCL patients that will be enrolled (key in confirming high response rate).

**Exhibit 12: Patient Data and Swimmer's Plot of Responses by Cohort**



Source: Company data, Credit Suisse estimates.

## Early but Promising Data in DLBCL

KITE's initial registration strategy is in third-line DLBCL.

There were only eight DLBCL patients treated in the Phase I/II trial (See Exhibit 13). These patients received the lowest dose of CAR T-cells at 1 million cells/kg. The overall response rate in DLBCL is 88% (2 CRs and 5 PRs). Because the DLBCL patients were entered into the study later, it is not possible to assess the response duration. Currently, most patients are out 5 to 6 months following treatment, but it has been only a few months since they have achieved a response. Future updates (including ASH 2014) will be critical in assessing response duration.

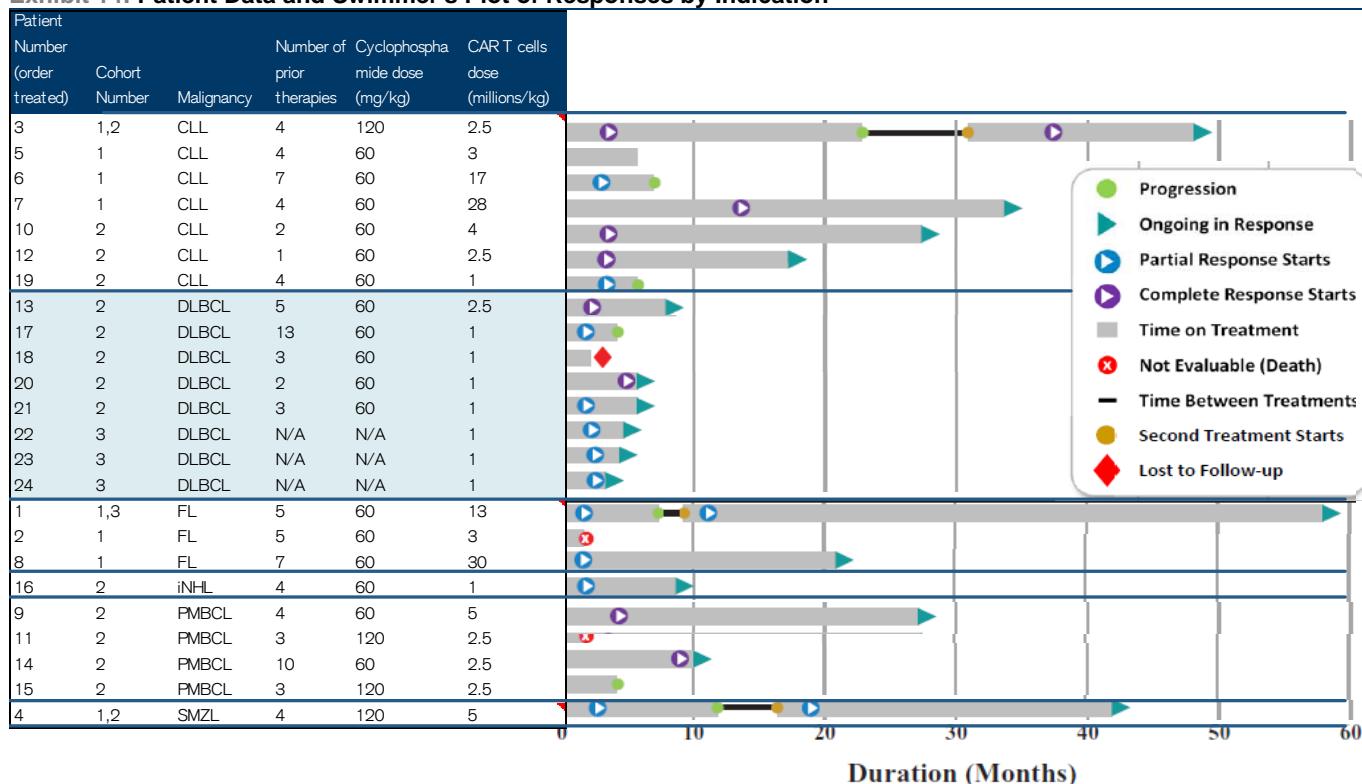
The NCI trial continues to enroll primarily DLBCL patients and will also begin treating patients with KITE's commercial CAR T cell product, KTE-C19, which should further derisk its pivotal trial that will begin next year.

**Exhibit 13: Summary of NCI Data by Indication**

Disease Indication	Patients Treated	Avg. Number of Prior Therapies	Avg. CAR T Dose (millions/kg)	Avg. Duration (months)	Number of CRs	Number of PRs	ORR
CLL	7	4	8	21	4	2	86%
DLBCL	8	5	1	5	2	5	88%
FL*	2	6	15	27	0	2	100%
iNHL	1	4	1	9	0	1	100%
PMBCL*	3	5	3	11	2	0	67%
SMZL	1	4	5	42	0	1	100%
Total	22	5	6	19	8	11	86%

\* Adjusted for deaths. Source: Company data, Credit Suisse estimates.

**Exhibit 14: Patient Data and Swimmer's Plot of Responses by Indication**



Source: Company data, Credit Suisse estimates.



## CAR T Safety

CAR T cells are a highly active and living therapy. When the T-cells enter the body and encounter tumor cells, they become activated (producing cytokines) and rapidly expand.

The following are primary serious toxicities associated with CAR T-cells:

- **Cytokine Release Syndrome (CRS):** A direct result of T-cell activation and expansion. This side effect may be related to both dose of cells and total tumor burden. In some cases, toxicity has been shown to correlate with efficacy. Cytokine release can cause severe adverse events including fever, hypotension, and hypoxia.
- **Tumor Lysis Syndrome (TLS):** Tumor lysis occurs when the T-cells rapidly kill large numbers of tumor cells, leading to a variety of serious systemic adverse events.
- **Neurologic Adverse Events:** A variety of neurologic side effects have been seen with CD19 CAR T cells including delirium, confusion, aphasia, and seizure. The mechanism of these effects is not well understood, but they have been observed with other CD19 directed T-cell modulators, such as AMGN's blinatumomab (bispecific CD19xCD3).

In general, the acute side effects are fully reversible, and the severity and duration of side effects also likely depend largely on the degree of prophylaxis and supportive care, which varies from institution to institution and makes comparisons of safety across various CAR T products more difficult. The acute side effects of CAR T cells may also depend on the conditioning regimen used prior to administering the T-cells, which is also a source of variation across trials.

### NCI Trial Safety Seems Well Managed

To date, the CD19 CAR T cells at the NCI have been relatively well tolerated. Most symptoms in the NCI study peaked during the first eight days after CAR T cell infusion and resolved completely within 3 weeks.

The most frequent Grade 3 and above adverse events included hypotension (21%), elevated creatinine (17%), and neuropathological symptoms including confusion (13%), and aphasia (13%; See Exhibit 15).

The NCI has been decreasing CAR T and conditioning agent doses (shown in Exhibit 14 primarily with different doses of cyclophosphamide 120mg/kg or 60mg/kg) in an effort to find the best balance of safety and efficacy.

### Deaths on Treatment

A competitor trial at Memorial Sloan Kettering Cancer Center (Juno) was temporarily placed on clinical hold due to two deaths while on treatment that were believed to be related to cytokine release syndrome. One was a cardiac death and the other involved seizure. The trial protocol was amended to, among other things, limit the entry of patients with cardiac disease.

The NCI trial also saw 2 deaths, although both were determined be unrelated to the CAR T technology itself. Patient 21 with PMBCL had a pre-existing heart dysfunction and died suddenly; no cause of death was established at autopsy, and it was assumed to be cardiac arrhythmia. Patient 17 died of influenza pneumonia.

Again, it is unclear whether there is a real difference in tolerability among the different CAR technologies or whether the differences are from patient selection, prophylaxis, supportive care, or other factors.



## Exhibit 15: Incidence of Adverse Events

Organ	Adverse Event	All Adverse Events (Grade 2 – Grade 5)	Grade 3	Grade 4	Grade 5
Number of Adverse Events (Percentage of Total Patients)					
Cardiac	Hypotension	5 (21%)	4 (17%)	0 (0%)	0 (0%)
	Left Ventricular Dysfunction	1 (4%)	0 (0%)	0 (0%)	0 (0%)
Metabolic	Creatinine	4 (17%)	1 (4%)	2 (8%)	0 (0%)
Neurology	Confusion	3 (13%)	2 (8%)	0 (0%)	0 (0%)
	Encephalopathy	1 (4%)	1 (4%)	0 (0%)	0 (0%)
	Agitation	1 (4%)	0 (0%)	0 (0%)	0 (0%)
	Anxiety	1 (4%)	0 (0%)	0 (0%)	0 (0%)
	Cranial Neuropathy	1 (4%)	1 (4%)	0 (0%)	0 (0%)
	Motor Neuropathy	1 (4%)	1 (4%)	0 (0%)	0 (0%)
	Pyramidal Tract Dysfunction	1 (4%)	0 (0%)	1 (4%)	0 (0%)
	Somnolence	3 (13%)	0 (0%)	3 (13%)	0 (0%)
	Aphasia	3 (13%)	1 (4%)	2 (8%)	0 (0%)
Pulmonary	Dyspnea	1 (4%)	0 (0%)	0 (0%)	0 (0%)
	Hypoxia	2 (8%)	1 (4%)	0 (0%)	0 (0%)
Vascular	Acute Vascular Leak Syndrome	1 (4%)	1 (4%)	0 (0%)	0 (0%)

Source: Company data, Credit Suisse estimates.

# Fast-to-Market Clinical Strategy

KITE expects to initiate a potentially pivotal Phase I/II trial of KTE-C19 in third-line DLBCL in early 2015, release data by mid-2016, and be on the market in 2017.

The accelerated development strategy includes the following clinical/regulatory steps:

- 1. Continue to Generate Data from the Ongoing Study:** The NCI trial will focus on generating more efficacy/safety data in DLBCL. Ongoing recruitment will focus on DLBCL patients and at least one additional clinical site will be added to confirm results outside of NCI. Product manufactured using KITE's process will also be included.
- 2. Get IND Approved to Start Pivotal Program:** KITE expects to use the NCI data and manufacturing data to file a company-sponsored IND in Q4:2014 and start a potentially pivotal Phase I/II trial of ~40-60 patients beginning H1:2015. KITE plans to use the same conditioning regimen used in the current cohort of the NCI trial and may tests CAR T cell doses between 1-2million/kg.
- 3. Generate Safety Data from the Lead in portion of the Potentially Pivotal Phase I/II Trial:** KITE expects to present data to FDA from the initial treatment experience of the first 6-8 patients in its Phase I/II trial. If there are no unexpected toxicities, KITE expects to complete the Phase I/II trial to support accelerated approval with overall response as the primary endpoint. It plans to file a BLA by Q4:2016.
- 4. Additional Indications:** In parallel, KITE may open additional cohorts in other indications, which may also provide fast to market strategies for FL, ALL, CLL, etc.

**Exhibit 16: Current and Planned Trials for KTE-C19**

Sponsor	NCI	KITE	KITE	KITE
Licensed by KITE?	Yes	Yes	Yes	Yes
Drug Candidate	KTE-C19 Non-commercial version	KTE-C19	KTE-C19	KTE-C19
Stage	Phase I/II	Phase I/II	Phase I/II	Planned Investigative Trials
Target Indication	CLL, SLL, MCL, FL, DLBCL	Third line DLBCL	Second line DLBCL	FL, MCL, CLL, ALL
Trial Size	40	40-60	N/A	N/A
Trial Design	Open label, single dose	Open label, single dose	N/A	N/A
Primary Endpoint	Safety, feasibility	ORR	ORR	N/A
Secondary Endpoint(s)	In vitro survival of CAR T cells, efficacy	N/A	N/A	N/A
Planned Start Date	02/2009	H1:2015	2016	2015
Primary End Date	04/2015	2016	2017+	N/A
Clinical Trial Identifier	NCT00924326	N/A	N/A	N/A

Source: Company data, Credit Suisse estimates.

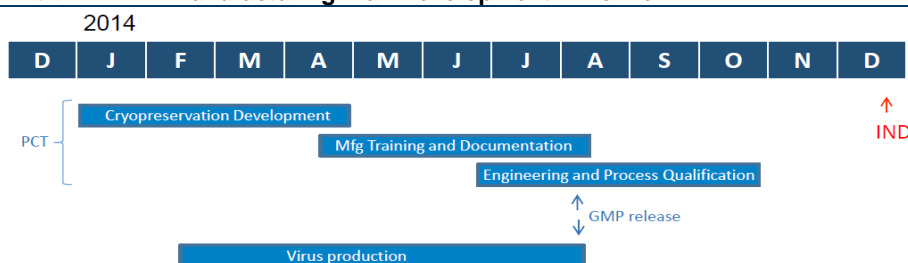
## Manufacturing Strategy

Concurrent with its clinical development, KITE also needs to further develop its manufacturing to reach approval for KTE-C19 and other therapies. We believe that KITE has already put substantial efforts into transferring the NCI technology and developing a more standardized process suitable for commercial scale.

Manufacturing KTE-C19 has several unique challenges that KITE is currently addressing.

- **Transition to a Closed System:** The NCI process was conducted in an "open" process in laboratories. The new KITE process is fully enclosed in disposable bags in which reagents can be added and removed, and the cells can be grown and harvested with minimal contact. This new process has been optimized, and we believe it is very likely to replicate the NCI product.
- **Freezing Cells for Distribution:** The NCI delivered cells directly to patients within its institute, so there was no need to ship material. The KITE process will involve a freezing step. There is some risk in this process, as not all cells will be viable after thawing. KITE plans to adjust the dose accordingly to account for loss of viability.
- **Capacity:** KITE believes it will have the capacity at launch to produce 3,000-4,000 units of its product with the potential to expand upwards of 12,000. The ultimate capacity may depend on the commercial manufacturing site used for the launch. Currently, manufacturing is outsourced to Progenitor Cell Therapy (PCT), but KITE plans to increase manufacturing capacity by either contracting with more CMOs, purchasing an appropriate facility, or building a manufacturing facility at its Santa Monica, California headquarters.

**Exhibit 17: KITE Manufacturing Plan Development Timeline**

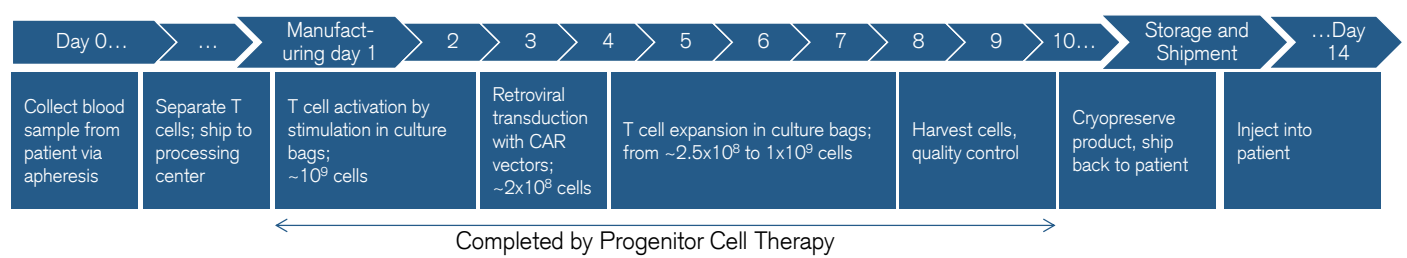


Source: Kite Pharma.

### A Closer Look at the Process

KITE has developed a relatively short manufacturing process relative to its competitors. KITE's entire manufacturing process from taking the patients' cells to delivering them again takes about two weeks, with the manufacturing step taking six days (Exhibit 18).

After collecting and isolating the patient's T cells, the cells are first activated (~2 days). Then, retroviral vectors containing the CAR blueprint are transduced (~1 day). The cells that express CARs are further allowed to expand (~3 days). After manufacturing, it takes another 2-3 days to conduct quality control, after which the product can be shipped.

**Exhibit 18: KITE Manufacturing Process and Timeline**

Source: Kite Pharma.

# CRADA Provides Access to Pipeline

KITE has a cooperative research and development agreement (CRADA) with the NCI. The CRADA is a five-year deal that ends in 2017, with the option to extend the agreement.

- The CRADA provides KITE with early access to clinical data and first negotiation rights for CAR and TCR therapies developed by Dr. Rosenberg's group at NCI, a pioneer in the immuno-oncology space.
- In return, KITE provides Dr. Rosenberg's group with direct funding (\$1M annual payments) to advance preclinical candidates and conduct Phase I/II proof-of-concept trials at the NCI. The NCI is running Phase I/II trials for KTE-C19, NY-ESO-1 TCR, and MAGE-A3.

While the right to first negotiation is not an exclusive option, to date, KITE has been able to license the NCI programs on favorable terms without competition. In part, this may be due to the long-standing relationship between KITE's founder Arie Beldegrun and Dr. Rosenberg.

Under this CRADA, KITE has already taken licenses to EGFRvIII, NY-ESO-1, and SSX2.

## Favorable Economics

Beyond research funding, KITE is also required to make licensing, milestone, and royalty payments based on the three (EGFRvIII, SSX2, and NY-ESO-1) therapies that KITE has licensed from the NCI. The total license costs for these three are one-time fees of \$350,000 plus \$88,000 for past patent expenses and annual fees of \$40,000. KITE has so far paid about \$162,000 of the one-time fees. Further, the company is required to pay a total of \$12.1M in one-time milestone fees for development and up to \$14M based on benchmark sales. Lastly, it will pay royalties on each therapy in the mid-single digits.

## Exhibit 19: Pipeline Therapies in Development at NCI

Sponsor	NCI	NCI	NCI	NCI
Licensed by KITE?	Yes	Yes	No - Pending	Yes
Drug Candidate	EGFRvIII CAR	NY-ESO-1 TCR	MAGE TCR	SSX2 TCR
Stage	Phase I/II	Phase I/II	Phase I/II	Preclinical
Target Indication	Malignant Glioma, Glioblastoma	NY-ESO-1 expressing tumors	Metastatic Melanoma, Renal Cancer, MAGE-A3+ Cancers	N/A
Trial Size	160	43	107	N/A
Trial Design	Open label, single dose	Open label, single dose	Open label, single dose	N/A
Primary Endpoint	Safety, 6 mo PFS	Tumor regression in NY-ESO-1 positive tumors	Safe dose of MAGE TCR T cell and IL2, tumor regression, toxicity profile	N/A
Secondary Endpoint(s)	In vivo survival of CART cells, radiographic changes	In vivo survival of TCR cells, toxicity profile	In vivo survival of cells	N/A
Planned Start Date	09/2011	09/2013	01/2014	N/A
Primary End Date	09/2018	03/2015	09/2015	N/A
Clinical Trial Identifier	NCT01454596	NCT01967823	NCT02111850	N/A

Source: Company data.

## Intellectual Property

We believe that KITE has consolidated a comprehensive collection of IP in the field. One of the key patents was licensed exclusively from Cabaret Biotech Ltd. and Dr. Zelig

Eshhar. This patent covers single chain scFv-based CAR products including KTE-C19 through to 2027. Others in the field are potentially infringing the patent. However, we do not assume that KITE will keep others from the market. We only assume that this broad patent provides it significant protection and ability to cross license and maintain full freedom to operate.

KITE will owe a midsingle digit royalty to Cabaret Biotech Ltd. for its CAR products.

The only patent that KITE believes it may need to access for its current product portfolio is an AMGN patent that has claims on EGFRvIII as a target.

#### Exhibit 20: Key Technologies Licenses

Licensed			
Product	Stage	Licenses	Tumor types
CD19 CAR	Phase I/II	Licensed from Dr. Zelig Eshhar of Cabaret	CLL, SLL, MCL, FL, DLBCL
EGFRvIII CAR	Phase I/II	Licensed from NIH in 2013*	Glioma, head and neck, melanoma
NY-ESO-1 TCR	Phase I/II	Licensed from NIH in 2014	Sarcoma, non-small cell, breast, ovarian, prostate, multiple myeloma, others
SSX2 TCR	Preclinical	Licensed from NIH	Exclusive: head and neck, hepatocellular, melanoma, prostate, sarcoma; Co-exclusive: certain other tumor types
Pending			
Product	Stage	Licenses	Tumor types
MAGE-A3/6 DP4 TCR	Phase I initiated	Pending, filed in Mar 2014	Broad range of tumor types
MAGE-A3 A1 TCR	IND review stage	Pending, filed in Mar 2014	Broad range of tumor types

\* Additional patent licenses may be required.

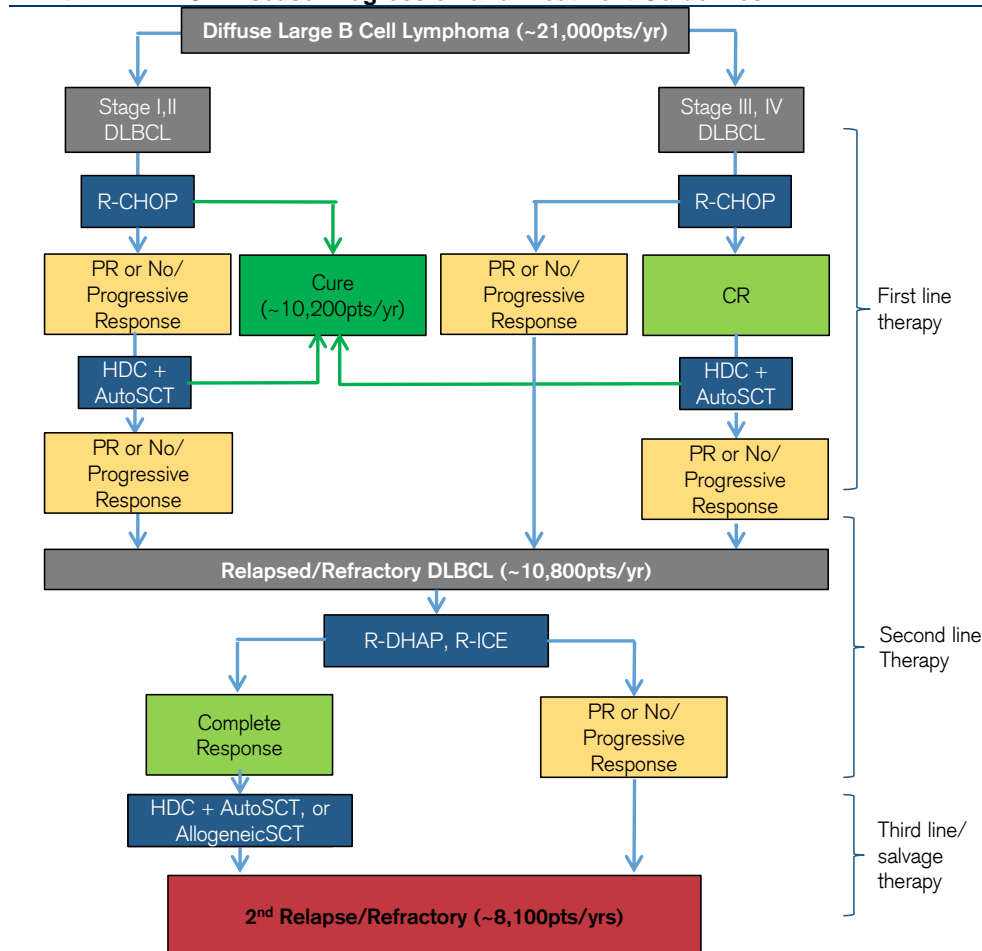
Source: Company data.

# DLBCL: High Unmet Need

Diffuse large B-cell lymphoma (DLBCL) is the most common subtype of non-Hodgkin lymphoma (NHL) and is considered an aggressive form of NHL. Approximately 70,000 patients are diagnosed with NHL each year and about 30% of those patients are diagnosed with DLBCL (~21,000 patients). The average age of diagnosis is 64 years.

DLBCL is curable for about 50% of patients; however, for the rest, DLBCL leads to many rounds of treatments with little hope for a cure. Exhibit 21 shows the NCCN recommended treatment pathway.

**Exhibit 21: DLBCL Disease Progression and Treatment Guidelines**



Source: Kite Pharma.

## Initial Therapy Can Lead to Cure

At initial diagnosis, patients are categorized into either early (stage I,II) or advanced (stage III, IV) DLBCL. Around 60% of patients fall into stage III/ IV which has a poorer prognosis.

Standard-of-care first-line treatment is R-CHOP. A complete response (CR) from a stage I/II cancer maybe be considered cured (>5 years disease free survival), whereas a CR patient from stage III/IV may have to undergo further high-dose chemotherapy (HDC) and autologous hematopoietic stem cell transplant to achieve a sustained response or cure.



### Treatment Options Are Not Good for Relapsed DLBCL

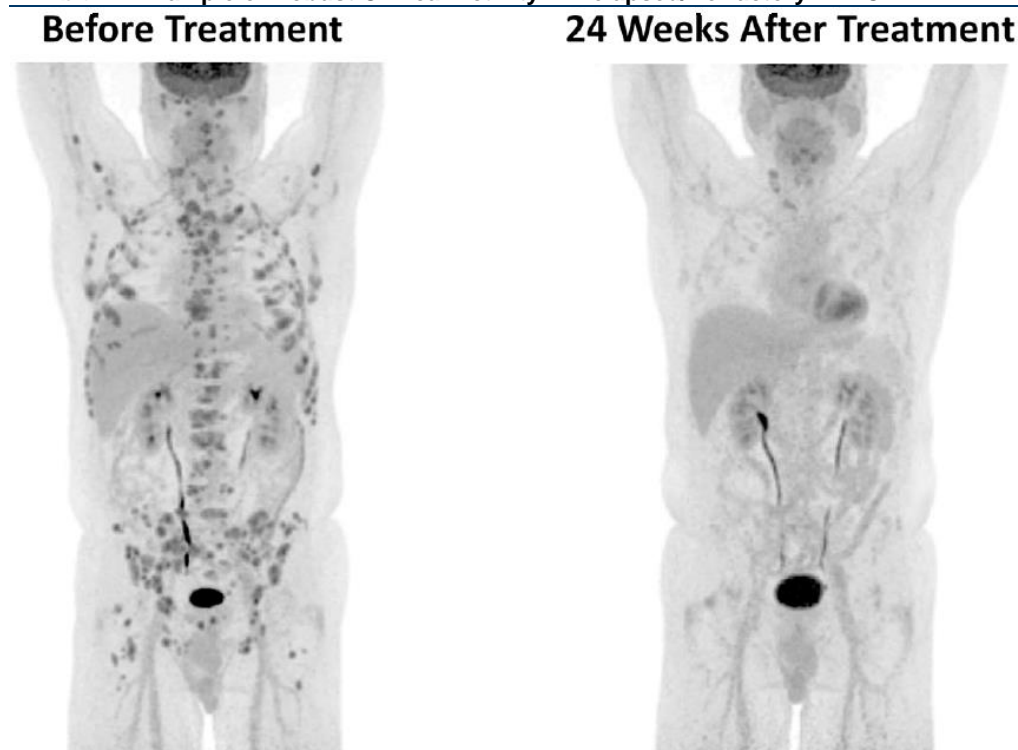
Patients who do not respond following first-line treatment and subsequent stem cell transplant are considered to have relapsed/refractory (r/r) DLBCL (~10,800 patients/year). These patients then move to second-line therapy, which includes salvage chemotherapies such as R-DHAP and R-ICE. If they respond well to second-line treatment, some patients may have the option to undergo HDC with AutoSCT or allogeneic stem cell transplant. However, stem cell transplants carry the dangers of potentially fatal (~6% of those treated with ASCT) acute toxicity during the transplantation and, with the case of allogeneic transplants, graft versus host disease (GVHD).

### Prognosis Is Poor for Third-Line DLBCL

About 40% of U.S. patients with DLBCL (~8,100) each year fall into the third-line relapsed/refractory DLBCL category, for which there are no good treatment options. For these patients, prognosis is poor, with a median survival of ~6 months.

This is the initial indication that KITE is pursuing with KTE-C19.

#### Exhibit 22: Example of Robust Clinical Activity in Relapsed/Refractory DLBCL



Source: Kite Pharma.

# CAR T Cell Competitors

CAR T cell therapy is a very active area of clinical research. All of the early work has been done at various academic institutes, and there are now at least five companies including KITE that are focused on CAR T through a combination of collaboration with academics and internal development (See Exhibit 23). In addition to KITE, the players include NVS, privately held Juno, PFE/ALCLS, and CELG/BLUE. Clinical data have been presented for CD19 specific CAR T cell programs from KITE, NVS, and Juno.

## The Current Leaders

The CAR T cell space is currently led by KITE, NVS, Juno, CELG/BLUE, and ALCLS/PFE. Each has partnered with academic institutes to access early development efforts at various universities and government labs.

- KITE is partnered with the NCI. Its lead therapy is KTE-C19, which has shown an 86% response rate across a variety of B-cell malignancies in an ongoing NCI run Phase I/II trial. Multiple other candidates using CAR and TCR technologies are being pursued.
- NVS is developing its lead CAR therapy with the University of Pennsylvania. The therapy, CTL019, is currently in Phase II for relapsed/refractory (r/r) chronic lymphocytic leukemia (CLL), r/r small lymphocytic lymphoma (SLL), and r/r acute lymphoblastic leukemia (ALL). Recent data presented at the American Association for Cancer Research (AACR) meeting in April showed that, for ALL, there was a 90% CR in 30 patients. NVS recently gain Breakthrough Therapy designation for CTL019 in r/r ALL.
- Juno is a private company focused exclusively on CAR therapy development. It is partnering with three leading cancer centers: Fred Hutchinson Cancer Research Center, Memorial Sloan-Kettering Cancer Center (MSKCC), and Seattle Children's Research Institute. Together, they are currently running Phase II trials in r/r CLL, NHL, ALL, and indolent NHL. Recent data presented at AACR showed that, for ALL, there was an 88% CR in 16 patients. Their next earliest trial completion will be in Q3:2014 for Phase I/II CLL and indolent NHL.
- CELG and BLUE recently partnered in 2013 to develop a CAR T cell candidate that is in Phase I for NHL, CLL, and ALL.
- Cellectis (ALCLS), a French company, is developing therapies based on the same CAR/TCR technology but uses allogeneic cells to treat multiple patients rather than the patient's autologous cells. Its most advanced candidate, UCART19, is still in preclinical development, with an aim for first clinical trials in Q2:15. A recently announced partnership with PFE provides funding and potential validation, which included a \$80M upfront and development/commercial milestones of \$185M. Cellectis plans to pursue the same indications as many other players in the field, including ALL, CLL, AML, and potentially some solid tumors including glioblastoma, pancreatic cancer, and non-small cell lung cancer.

## The Variables in Development

The various CD19 CAR T cell programs are more similar than different. They all use similar (1) targeting domains, (2) processes to introduce the CAR into the T-cell, and (3) cell expansion process.

The primary differences relate to:

- Construct (different signaling domains),
- Viral vector (lenti virus versus gamma retrovirus),

- Cell selection (preselect subsets of T-cells versus no pre-selection),
- Cell expansion process (beads versus no beads),
- Conditioning regimen, and
- Clinical focus.

The relative contribution of these variables is not well established, and currently, all CD19 CAR T cell programs have shown remarkable efficacy with notable side effects.

### Manufacturing Differences

KITE claims to have the fastest manufacturing time and requires two fewer steps used by others in the field.

- **Beads:** Both Novartis and Juno use beads coated with OKT3, an essential signal, and anti-CD28, a co-stimulatory signal, to amplify T-cells. The license to these beads is held exclusively by NVS, which may mean that Juno could face IP issues in the future concerning bead use.

In contrast, KITE uses OKT3 in a soluble form to provide the co-stimulatory signal.

- **T-cell selection:** Juno selects for a specific T-cell subset that are central memory cells positive for CD4 and CD8. Its rationale is that this homogenous product provides longer CAR T cell durability. Neither Novartis nor KITE use this selection process, which may add time and expense with uncertain impact on efficacy and safety.

**Exhibit 23: Current Differences Between CAR Ts**

		KITE	NVS	Juno		CELG/ BLUE	ALCLS/ PFE
Data	Academic Institution	NCI	Upenn	MSKCC	Fred Hutchinson/ Seattle Children's Hospital	Baylor	UCL
	Initial Indication	DLBCL	CLL/ALL	CLL/ALL		CLL/ALL	CLL/ALL
	Stage of Development	Phase II	Phase II	Phase II	N/A	Phase I	Predclinical
	Data to Date	86% ORR in NHL	47% ORR in CLL; 90% CR in ALL	88% CR in adult ALL	N/A	N/A	N/A
	Normal B-cell Depletion	Yes	Yes	No	N/A	No	N/A
	Regression of Malignancy	Yes	Yes	Yes	N/A	No	N/A
	CRS Toxicities	Yes	Yes	Yes	N/A	No	N/A
Structure	scFc	CD19, FMC63	CD19, FMC63	CD19, SJ25C1	CD19, FMC63	κ light chain CRL- 1758	N/A
	Fc domain	No	No	No	hlgG4 CH2-CH3, CPSC-CPPC	hlgG1 CH2-CH3	N/A
	Hinge	CD28	hCD8a	CD28	hlgG4	hlgG1	N/A
	TM	CD28	hCD8a	CD28	CD28	CD28	N/A
	Co-stimulatory	CD28	41BB	CD28	CD28	CD28	N/A
Manufacturing	Viral Vector Used	Gamma retrovirus	Lentivirus	Gamma retrovirus		Gamma retrovirus	N/A
	Need for Beads	No	Yes	Yes		No	N/A
	Need for T cell	No	No	Yes		No	N/A
	Manufacturing Time (days)	6	8-12	11-19		28-42	~17

Source: Company data.

**Exhibit 24: Significant Number of Ongoing CAR T Clinical Trials**

Sponsor(s)	Affiliated Company	Target	Stage	Disease	# of pts	Start Date	Primary completion	Conditioning Regimen	Clin trial #
NCI	KITE	CD19	1	CLL, SLL, MCL, FL, LCL	40	2/9	4/15	Fludarabine + cyclophosphamide	<a href="#">NCT00924326</a>
NCI	KITE	CD19	1	B cell leukemia, Hodgkin's lymphoma, NHL, B cell lymphoma	36	2/10	10/15	Cyclophosphamide, pentostatin	<a href="#">NCT01087294</a>
NCI	KITE	CD19	1	ALL, B cell lymphoma, leukemia, LCL, NHL	48	4/12	1.5	Fludarabine + cyclophosphamide	<a href="#">NCT01593696</a>
NCI	KITE	CD19	1	B cell leukemia, Hodgkin's lymphoma, NHL, B cell lymphoma	36	2/10	10/15	Cyclophosphamide, pentostatin	<a href="#">NCT01087294</a>
University of Pennsylvania	NVS	CD19	2	CLL, SLL	32	12/12	12/15		<a href="#">NCT01747486</a>
University of Pennsylvania	NVS	CD19	2	NHL, DLBCL, MCL, FL	55	1/14	7/15		<a href="#">NCT02030834</a>
University of Pennsylvania	NVS	CD19	2	ALL	24	1/14	7/15		<a href="#">NCT02030847</a>
University of Pennsylvania	NVS	CD19	1	Multiple myeloma	15	5/14	5/16		<a href="#">NCT02135406</a>
Fred Hutchinson Cancer Center	Juno	CD19	1/2	ALL, CLL, NHL, DLBCL, Burkitt, FL, MCL, SLL, testicular lymphoma	54	5/13	4/29		<a href="#">NCT01865617</a>
MSKCC	Juno	CD19	1/2	CLL and indolent lymphomas, leukemia	30	3/7	12/14	Cyclophosphamide	<a href="#">NCT00466531</a>
Seattle Children's Hospital	Juno	CD19	1/2	Leukemia	80	1/14	1/17		<a href="#">NCT02028455</a>
MSKCC	Juno	CD19	1	Pediatric ALL	26	9/11	9/15	Variable chemotherapy	<a href="#">NCT01430390</a>
MSKCC	Juno	CD19	1	CLL	18	11/11	8/14	Cyclophosphamide	<a href="#">NCT01416974</a>
MSKCC	Juno	CD19	1	Adult ALL	40	1/10	1/15	Either ALL re-induction or cyclophosphamide	<a href="#">NCT01044069</a>
MSKCC	Juno	CD19	1	NHL	18	4/13	4/15	Carmustine, etoposide, cytarabine, melphalan	<a href="#">NCT01840566</a>
MSKCC	Juno	CD19	1	ALL	24	5/13	5/16	cyclophosphamide	<a href="#">NCT01860937</a>
Seattle Children's Hospital	Juno	CD19	1	B cell leukemia	18	12/12	1/15		<a href="#">NCT01683279</a>
Baylor	CELG/BLUE	CD19	1/2	ALL, CLL, NHL	36	4/9	4/16	None	<a href="#">NCT00840853</a>
Baylor	CELG/BLUE	CD19	1	Lymphoma and CLL	54	2/9	2/18	Cyclophosphamide	<a href="#">NCT00586391</a>
Baylor	CELG/BLUE	CD19	1	NHL, CLL	14	2/14	2/17		<a href="#">NCT01853631</a>
Baylor	CELG/BLUE	CD19	1	NHL, ALL, CLL	56	4/14	3/18		<a href="#">NCT02050347</a>
University College London	ALCLS/PFE	CD19	1/2	Pediatric ALL	30	5/12	12/14	Fludarabine for all; vincristine and dexamethasone for MRD	<a href="#">NCT01195480</a>
Chinese PLA General Hospital	N/A	CD19	1/2	NHL, MCL	2	3/14	3/18		<a href="#">NCT02081937</a>
Jichi Medical University	N/A	CD19	1/2	NHL	18	5/14	3/17	Cyclophosphamide or bendamustine	<a href="#">NCT02134262</a>
Uppsala University	N/A	CD19	1/2	B cell lymphoma, B cell leukemia	15	4/15	4/17		<a href="#">NCT02132624</a>
Children's Hospital of Philadelphia	N/A	CD19	1	Pediatric ALL or lymphoma	20	8/11	8/16	Variable chemotherapy	<a href="#">NCT01626495</a>
Chinese PLA General Hospital	N/A	CD19	1	ALL, DLBCL, CLL, MCL, FL	12	4/13	4/17		<a href="#">NCT01864889</a>
MD Anderson	N/A	CD19	1	B-cell lymphoma and CLL	60	6/11	6/16	T cells infused 2-7 after APBSCT	<a href="#">NCT00968760</a>
MD Anderson	N/A	CD19	1	Leukemia, Lymphoma	96	12/11	12/16	None	<a href="#">NCT01497184</a>
MD Anderson	N/A	CD19	1	Leukemia, Lymphoma	54	12/12	12/15	None	<a href="#">NCT01362452</a>
Chinese PLA General Hospital	N/A	CD20	1	ALL, CLL, FL, DLBCL, FL, MCL	10	1/13	5/15		<a href="#">NCT01735604</a>
Baylor, Texas Children's Hospital	CELG/BLUE	CD28	1	Lymphoma, multiple myeloma, leukemia, CLL	54	7/9	7/19	cyclophosphamide	<a href="#">NCT00881920</a>
Baylor	CELG/BLUE	CD30	1	NHL, Hodgkin's Lymphoma	18	12/11	12/14		<a href="#">NCT01316146</a>
Chinese PLA General Hospital	N/A	CD33	1/2	AML	10	4/13	4/16		<a href="#">NCT01864902</a>
City of Hope, NCI	N/A	CD123	1	Leukemia, AML	23	8/14	8/17	cyclophosphamide	<a href="#">NCT02159495</a>
Chinese PLA General Hospital	N/A	CD138	1/2	Multiple myeloma	10	6/13	6/16		<a href="#">NCT01886976</a>
NCI	KITE	EGFR <sup>III</sup>	1/2	Malignant glioma, glioblastoma	160	9/11	9/18	aldesleukin, fludarabine, cyclophosphamide	<a href="#">NCT01454596</a>
Chinese PLA General Hospital	N/A	EGFR <sup>III</sup>	1/2	Advanced EGFR positive solid tumors	10	5/13	12/16		<a href="#">NCT01869166</a>
University of Zurich	N/A	FAP	1	Malignant pleural mesothelioma	6	4/13	10/14		<a href="#">NCT01722149</a>
NCI	KITE	GC2	1	Sarcoma, Osteosarcoma, Rhabdomyosarcoma, Ewing Sarcoma, Melanoma	72	2/14	12/16		<a href="#">NCT02107963</a>
NIH, Baylor, Texas Children's Hospital	CELG/BLUE	GD2	1	Sarcomas	26	4/14	4/18		<a href="#">NCT01953900</a>
Children's Mercy Hospital Kansas City	N/A	GD2	1	Neuroblastoma	3	10/11	10/13		<a href="#">NCT01460901</a>
Baylor	CELG/BLUE	Her2	1	Sarcoma	36	7/9	7/15		<a href="#">NCT00902044</a>
Baylor	CELG/BLUE	Her2	1	GBM	18	10/10	10/16		<a href="#">NCT01109095</a>
Baylor	CELG/BLUE	Her2	1	Her2 positive malignancies	18	5/9	7/15		<a href="#">NCT00889954</a>
Chinese PLA General Hospital	N/A	Her2	1/2	Her2 positive malignancies	10	9/13	9/16		<a href="#">NCT01935843</a>
Baylor, Texas Children's Hospital	CELG/BLUE	iC9-GD2	1	Neuroblastoma	14	8/13	8/15		<a href="#">NCT01822652</a>
University of Pennsylvania	NVS	SS1	1	Metastatic pancreatic adenocarcinoma, epithelial ovarian cancer, epithelial pleural mesothelioma	24	6/14	6/16		<a href="#">NCT02159716</a>

Source: ClinicalTrials.gov, Credit Suisse estimates.

## Other CD19 Enhanced Antibody Technology Programs

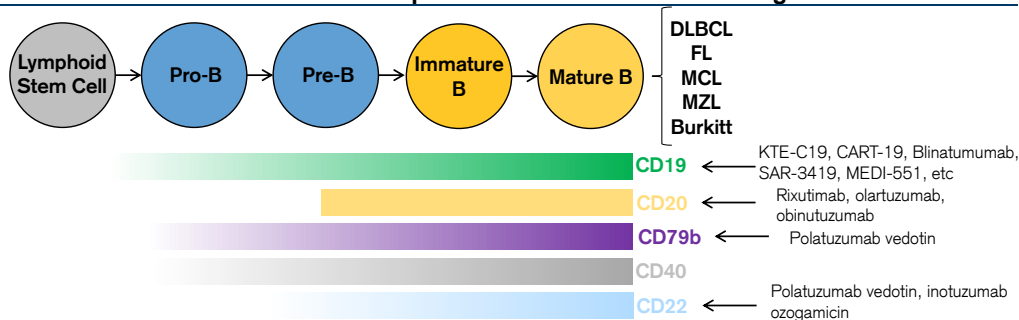
CD19 is a prime target for the development of therapies to treat lymphoma and leukemia. Its expression is limited to cells of the B-cell lineage, similar to CD20, which is the target for the blockbuster Rituxan and the recently launched Gazyva.

The two primary differences between CD19 and CD20 are:

- CD19 is expressed earlier in B-cell development, making it a valuable target a range of lymphoma / leukemia diseases; and
- CD19 is internalized (unlike CD20), which makes it an attractive target for the development of antibody-drug conjugates that can be competitive with CAR T cell therapies.

As a result of the similarities and differences to CD20 and the clinical and commercial success of Rituxan, multiple companies are pursuing enhanced antibody approaches to target CD19 primarily for diffuse large B-cell lymphoma (DLBCL) and ALL. Exhibit 25 shows the expression patterns of different CDs during B-cell maturation and the current drugs in development that are targeting them.

**Exhibit 25: B-Cell Maturation and Expression Pattern of Certain Antigens**



Source: Company data, Credit Suisse estimates.

- **AMGN:** Blinatumomab is a bispecific T-cell engager (BiTE) that combines two binding sites, CD3 for T cells and CD19 for targeting B-cells. AMGN is currently in Phase II/III for ALL, for which it was recently granted breakthrough therapy designation. Most recent data from ASCO 2014 for a Phase II trial in ALL had CR (or CR with partial hematological recovery) of 43% in 189 patients.
- **SNY/IMGN:** SAR3419 is an antibody-drug conjugate (ADC) that is currently in Phase II for r/r DLBCL and ALL. ADCs are tumor-targeting monoclonal antibodies that have additional cytotoxic agents attached to the antibody. Data from ASCO 2014 for DLBCL show ORR of 38-44%. Recent safety data shows some grade 3/4 AEs and frequent low-grade ocular toxicity with symptoms such as blurred vision, dry eye, keratopathy, eye pain, etc. SNY/IMGN's plans to progress SAR3419 for DLBCL are currently unclear.
- **AZN:** MEDI-551 is a monoclonal antibody with enhanced antibody-dependent cellular cytotoxicity (ADCC) that is in Phase II for DLBCL and CLL. Phase I/II dose escalation trial data for r/r B-cell malignancies showed 24% ORR in DLBCL.
- **MOR/XNCR:** XmAb5574/MOR-208 is an antibody with an engineered Fc region that enhances its ADCC function. It is in Phase II for NHL, ALL, and CLL. Phase I data in CLL showed a 67% PR in a dose escalation study. Most recent preliminary Phase IIa data for CLL showed 30% ORR in 27 patients. They will continue to enroll patients in

their NHL trial, which includes up to 30 patients in DLBCL. The first data is expected at ASH later this year.

- **SGEN:** SGN-CD19A is also an ADC currently in Phase I for DLBCL. Initial data presented at ASCO 2014 showed 37% ORR and 17% CR rate out of 37 patients in a dose escalation study. SGN-CD19A also showed low-grade ocular toxicity like SAR3419. Its protocol has been amended to include prophylactic steroid eye drops to help mitigate the ocular toxicity.

**Exhibit 26: Agents in Development Targeting CD19**

Company	Drug	Class	Stage
Amgen/Micromet	Blinatumomab	Bispecific	Phase II/III
AstraZeneca/MedImmune	MEDI-551	High ADCC (glyco engineered)	Phase II
Sanofi Aventis/Immunogen	SAR3419	Antibody Drug Conjugate	Phase II
Morphosys/Xencor	XmAb5574	High ADCC (Fc engineered)	Phase IIa
Kite Pharma	KTE-C19	Chimeric antigen receptor (CAR)	Phase I/II
Novartis/University of Pennsylvania	CLT19	Chimeric antigen receptor (CAR)	Phase I
Juno	CD19.CAR-CD28Z T Cells	Chimeric antigen receptor (CAR)	Phase I
Celgene	19-28z T Cells	Chimeric antigen receptor (CAR)	Phase I
Seattle Genetics	SGN-CD19a	Antibody Drug Conjugate	Phase I
Affimed Therapeutics AG	AFM11	Bispecific	Preclinical

Source: ClinicalTrials.gov, Credit Suisse estimates.

## Pipeline Overview

Beyond KTE-C19, KITE is developing multiple other CAR/TCR therapies targeting different cancer antigens. Interestingly, KITE proposes to run a future trial at which it will first genetically screen the patients' cancer to determine which tumor antigen they show and then give them the modified T-cell that targets that antigen. This may enable KITE to test all its compounds (EGFRvIII, NY-ESO-1, MAGE-A3, SSX2) at once.

- **EGFRvIII CAR:** KITE's EGFRvIII targeting CAR is the second most advanced candidate after KTE-C19 and is currently in a Phase I/II trial for glioblastoma. The trial, which is being run by the NCI, has 14 patients enrolled to date and no data available yet. KITE plans to file an IND for this therapy in 2016. Similar to KTE-C19, it works by inserting a chimeric antigen receptor (which targets antigen EGFRvIII instead of CD19) into the patient's T-cells.

EGFRvIII is a form of EGFR exclusively expressed in tumors and specifically in glioblastoma, which makes it a good target for the CAR technology to pursue. Although glioblastoma is a rare cancer, with ~3,500 patients diagnosed annually, the unmet medical need is high, with median survival at 14.6 months after diagnosis.

- **NY-ESO-1 TCR:** KITE is developing a TCR-based candidate that targets the NY-ESO-1 antigen. It is currently in a Phase II trial for metastatic cancers conducted by the NCI and has enrolled 2 patients to date. A previous clinical trial enrolled 17 patients with melanoma and synovial cell sarcoma (NY-ESO-1 has a very high 76% expression in this population). The trial saw a 45% ORR in the 11 metastatic melanoma patients and 67% ORR in the six synovial cell sarcoma patients.
- **Anti-MAGE TCR:** The NCI is also running a Phase I/IIa trial in patients expressing the MAGE-A3 tumor antigen and has enrolled 1 patient to date. MAGE-A3 is frequently expressed in a variety of cancers, including: 76% of metastatic melanomas, 47% of esophageal carcinomas, 49% in head and neck cancers, 47% in lung, and 36% in bladder cancer, which makes it an attractive antigen to target.
- **SSX2 TCR:** A planned NCI Phase I/IIa trial of this has not yet begun. KITE has an exclusive license to this technology in head and neck cancer, hepatocellular carcinoma, melanoma, prostate cancer, and sarcoma.



# KITE Management

- **Arie Beldegrun, M.D., FACS.:** Dr. Beldegrun is the current founder, executive chairman, president and chief executive officer. Currently, he serves as the chairman of several other companies including Arno Therapeutics Inc., and TheraCoat Ltd. Previously, he was the founder of Agenysys Inc., later acquired by Astellas Pharma Inc., and Chairman of Cougar Biotechnology Inc., later acquired by Johnson and Johnson. Dr. Beldegrun is also the director of the Institute of Urologic Oncology at ULCA. Prior to UCLA, he was a research fellow in surgical oncology and immunotherapy under Dr. Steven A. Rosenberg. Dr. Beldegrun holds an M.D. from Hebrew University Hadassah Medical School. He completed his post graduate studies at the Weizmann Institute of Science and his residency at Harvard Medical School. According to the S-1, Dr. Beldegrun held approximately 17.3% of the outstanding stock prior to the exercise of overallotment.
- **Cynthia M. Butitta:** Ms. Butitta is the chief financial officer and chief operating officer. Prior, she was chief financial officer at NextWave Pharmaceuticals, chief operating officer of Telik, and chief financial officer at Connetics and Insite Vision. She received her B.S. from Edgewood College and M.B.A. from the University of Wisconsin, Madison.
- **Margo R. Roberts, Ph.D.:** Dr. Roberts is the chief scientific officer and vice president of research. Prior, she was a scientific biotechnology consultant. She was also an associate professor at the University of Virginia, where she conducted research in areas of immunity and inflammation. She has also worked in lead positions at Cell Genesys, including principal scientist. She received her B.Sc. and Ph.D. from the University of Leeds in England and completed her postdoctoral fellowship at Yale University.
- **Marc Better, Ph.D.:** Dr. Better is the vice president of product sciences. Prior to joining, he was executive director of process science at Boehringer Ingelheim Pharmaceuticals and Amgen, vice president of process sciences at Abgenix, and vice president of technical development at XOMA. Dr. Better received his B.S. from Michigan State University and his Ph.D. from Brandeis University.
- **Rizwana F. Sproule, Ph.D.:** Dr. Sproule is the vice president of regulatory affairs. Prior, she held several senior positions at Amgen Inc., including executive director of oncology global regulatory affairs. She also held a postdoctoral research position from the Institute of Biotechnology at Cambridge University. Dr. Sproule received her B.Sc. with honors and her Ph.D. from the University of Warwick.
- **Jeffrey Wiezorek, M.D.:** Dr. Wiezorek is the vice president of clinical development. Before joining KITE, he held several senior positions at Amgen, including executive medical director of global development. Prior to joining Amgen, he held a postdoctoral research position at the California Institute of Technology. He received his B.A. from the University of Pennsylvania and a M.D. from Columbia University. He completed his residence at the Stanford medical Center and his fellowship at UCLA.

# Financial Statements

## Exhibit 27: Income Statement

	2012A	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
<b>Revenues</b>														
US sales of KTE-C19										32.9	105.0	239.0	364.9	439.2
Ex-US royalties on KTE-C19												1.3	4.3	11.7
Other CAR or TCR program(s)												18.0	60.0	120.0
Ex-US royalties on other CAR or TCR												0.9	3.6	12.0
<b>Total Revenues</b>										<b>32.9</b>	<b>105.0</b>	<b>259.2</b>	<b>432.8</b>	<b>582.9</b>
<b>Expenses</b>														
Cost of goods											22.2	44.3	66.6	79.0
Research and development	1.8	5.1	2.1	2.5	3.0	3.7	11.3	37.0	54.0	66.0	70.0	74.0	78.0	82.0
Sales, general, administrative	0.8	1.3	1.1	1.2	1.5	1.7	5.5	10.0	33.0	48.2	71.0	76.0	81.0	86.0
<b>Total Operating Expenses</b>	<b>2.6</b>	<b>6.4</b>	<b>3.2</b>	<b>3.7</b>	<b>4.5</b>	<b>5.4</b>	<b>16.8</b>	<b>47.0</b>	<b>87.0</b>	<b>122.1</b>	<b>163.2</b>	<b>194.3</b>	<b>225.6</b>	<b>247.0</b>
Operating income (loss)	(2.6)	(6.4)	(3.2)	(3.7)	(4.5)	(5.4)	(16.8)	(47.0)	(87.0)	(89.2)	(58.2)	64.9	207.2	335.9
Total Other Income (Expense)	0.0	0.1	0.0	0.1	0.1	0.1	0.3	0.3	0.2	0.2	0.3	0.3	0.3	0.3
Pre Tax Income	(2.6)	(6.4)	(3.1)	(3.6)	(4.4)	(5.3)	(16.5)	(46.7)	(86.8)	(89.0)	(57.9)	65.1	207.4	336.2
Income tax														117.7
<b>Net Income</b>	<b>(2.6)</b>	<b>(6.4)</b>	<b>(3.1)</b>	<b>(3.6)</b>	<b>(4.4)</b>	<b>(5.3)</b>	<b>(16.5)</b>	<b>(46.7)</b>	<b>(86.8)</b>	<b>(89.0)</b>	<b>(57.9)</b>	<b>65.1</b>	<b>207.4</b>	<b>218.5</b>
EPS - basic	(\$0.46)	(\$1.16)	(\$0.66)	(\$0.65)	(\$0.20)	(\$0.14)	(\$0.96)	(\$1.29)	(\$2.19)	(\$1.89)	(\$1.22)	\$1.36	\$4.27	\$4.46
EPS - diluted	(\$0.46)	(\$1.16)	(\$0.66)	(\$0.65)	(\$0.20)	(\$0.14)	(\$0.96)	(\$1.29)	(\$2.19)	(\$1.89)	(\$1.22)	\$1.18	\$3.72	\$3.88
Shares outstanding - basic	5.59	5.47	5.57	5.61	21.82	38.07	17.77	36.27	39.67	47.13	47.50	48.07	48.55	49.03
Shares outstanding - diluted	5.59	5.47	11.19	11.22	44.62	44.73	27.94	45.01	47.46	53.97	54.71	55.26	55.81	56.37

Source: Company data, Credit Suisse estimates.

## Exhibit 28: Condensed Balance Sheet

Balance sheet	2012A	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Total Assets	\$8.9	\$23.0	\$20.3	\$67.1	\$198.1	\$193.3	\$193.3	\$149.5	\$236.7	\$153.8	\$98.4	\$164.9	\$380.3	\$607.6
Total Liabilities	\$1.0	\$1.4	\$1.6	\$1.6	\$1.6	\$1.6	\$1.6	\$1.6	\$11.6	\$11.6	\$7.6	\$1.6	\$1.6	\$1.6
Convertible securities	\$14.2			\$50.0										
Additional paid-in capital	\$0.1	\$37.0	\$37.2	\$37.6	\$223.0	\$223.6	\$223.6	\$226.4	\$390.5	\$396.5	\$403.1	\$410.4	\$418.4	\$427.2
Accumulated deficit	(\$6.4)	(\$15.4)	(\$18.6)	(\$22.2)	(\$26.6)	(\$31.9)	(\$31.9)	(\$78.6)	(\$165.4)	(\$254.3)	(\$312.3)	(\$247.1)	(\$39.7)	\$178.8
Total stockholders' deficit & liabilities	\$8.9	\$23.0	\$20.3	\$67.1	\$198.1	\$193.3	\$193.3	\$149.5	\$236.7	\$153.8	\$98.4	\$164.9	\$380.3	\$607.6

Source: Company data, Credit Suisse estimates.

## Exhibit 29: Condensed Cash Flow Statement

Cash Flow Statement	2012A	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Cash flow from operations	(\$2.8)	(\$5.6)	(\$3.1)	(\$2.3)	(\$3.7)	(\$4.5)	(\$13.6)	(\$42.9)	(\$71.8)	(\$82.0)	(\$54.3)	\$67.4	\$216.4	\$228.3
Cash flow from investing	(\$0.0)	(\$0.3)	(\$0.5)	(\$0.2)	(\$0.2)	(\$0.2)	(\$1.1)	(\$0.8)	(\$0.8)	(\$0.8)	(\$1.0)	(\$1.0)	(\$1.0)	(\$1.0)
Cash flow from financing	\$0.3	\$19.6	(\$0.1)	\$50.0	\$134.9		\$184.8		\$160.0					
Net Cash Increase (Decrease)	(\$2.5)	\$13.7	(\$3.7)	\$47.5	\$131.0	(\$4.7)	\$170.1	(\$43.7)	\$87.4	(\$82.8)	(\$55.3)	\$66.4	\$215.4	\$227.3
Beginning Cash	\$11.2	\$8.7	\$22.4	\$18.6	\$66.1	\$197.2	\$22.4	\$192.5	\$148.8	\$236.3	\$153.5	\$98.2	\$164.6	\$380.1
Ending Cash	\$8.7	\$22.4	\$18.6	\$66.1	\$197.2	\$192.5	\$192.5	\$148.8	\$236.3	\$153.5	\$98.2	\$164.6	\$380.1	\$607.4

Source: Company data, Credit Suisse estimates.

**Companies Mentioned** (Price as of 14-Jul-2014)

**Amgen Inc.** (AMGN.OQ, \$118.98)  
**AstraZeneca** (AZN.L, 4369.5p)  
**Celgene Corp.** (CELG.OQ, \$88.37)  
**ImmunoGen, Inc.** (IMGN.OQ, \$11.08)  
**Kite Pharma** (KITE.OQ, \$24.05, OUTPERFORM[V], TP \$34.0)  
**Pfizer** (PFE.N, \$30.24)  
**Sanofi** (SASY.PA, €76.47)  
**Seattle Genetics** (SGEN.OQ, \$36.93)  
**Xencor, Inc** (XNCR.OQ, \$10.73)  
**bluebird bio** (BLUE.OQ, \$34.19)

## Disclosure Appendix

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#### Price Target: (12 months) for Kite Pharma (KITE.OQ)

**Method:** Our \$34 target includes \$1,041M DCF valuation of KTE-C19 and \$459M for its pipeline/technology value. We model a 2017 launch, \$213,000 net price, \$30,000-\$40,000 cost of goods, 20% penetration in third line DLBCL (15% in other B-cell indications), and a 60% probability of success.

**Risk:** Risks to our \$34 target are (1) unexpected safety signal in the ongoing Phase I/II and proposed pivotal study for KTE-C19, (2) better than expected clinical data from competitive CD19 targeting agents, (3) manufacturing risk for KTE-C19 and other CAR and TCR agents, and (4) financing risk.

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