

Equity Research

July 15, 2014

**Price: \$24.05** (07/14/2014)

**Price Target: NA**

**OUTPERFORM (1)**

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**Key Data**

Symbol	NASDAQ: KITE
52-Week Range:	\$32.65 - 22.82
Market Cap (MM):	\$913.7
Net Debt (MM):	\$200.5
Cash/Share:	\$4.04
Dil. Shares Out (MM):	45.0
Enterprise Value (MM):	\$895.1
ROIC:	NA
ROE (LTM):	NA
BV/Share:	\$3.33
Dividend:	NA

FY (Dec)	2013A	2014E	2015E
<b>Revenue (MM)</b>			
Q1	\$0.0	\$0.0A	-
Q2	NA	\$0.0	-
Q3	NA	\$0.0	-
Q4	NA	\$0.0	-
Year	\$0.0	\$0.0	\$0.0

<b>Earnings Per Share</b>			
Q1	\$(0.20)	\$(0.66)A	-
Q2	NA	\$(0.10)	-
Q3	NA	\$(0.10)	-
Q4	NA	\$(0.11)	-
Year	\$(1.43)	\$(0.50)	\$(1.00)

Initiating Coverage

*Initiation: Come Fly With Kite*

**The Cowen Insight**

We are initiating coverage of Kite Pharma with an Outperform rating. A broad collaboration with the NCI and a strong IP position establish Kite as a leader in the burgeoning field of engineered Autologous T Cell Therapy (eACT). Lead candidate KTE-C19 will enter a potentially pivotal Phase I/II trial in 3rd-line DLBCL in H1:15. We expect KITE shares to appreciate as this and other eACTs advance.

**Kite Is Taking Immune Oncology To New Highs**

First-generation eACTs pioneered by several leading academic groups have demonstrated the ability to induce potent and durable responses in highly refractory cancer populations. The race is now on to bring such products to commercial feasibility. Kite was early to appreciate the promise of eACTs. In 2012, it signed a major collaboration with the NCI providing it with rights to multiple eACT product offerings. In 2013, it completed its efforts to consolidate several key patents in the space. These assets, along with an accomplished management team and a clear development strategy, should enable Kite to maintain a leadership position in this exciting area of cancer immunotherapy.

**KTE-C19 Gliding Toward A Potential Approval In DLBCL**

Kite's relationship with the NCI has provided the company with multiple Chimeric Antigen Receptor (CAR) and T Cell Receptor (TCR)-based development programs. The NCI has conducted a study of Kite's leading program, a CAR T cell therapy directed against lymphomas and leukemias that express the CD19 antigen. This trial demonstrated an 86% response rate with durable remissions in patients with a variety of late-stage B cell malignancies. Kite intends to file its own corporate IND on KTE-C19 by year end, and will target development toward diffuse large B cell lymphoma (DLBCL). A trial in 3rd-line patients will start in H1:15, and we think compelling results from this single-arm study could support FDA approval in light of the poor prognosis and lack of treatment alternatives. We view refractory DLBCL as a potential \$1B+ U.S. opportunity for KTE-C19.

**Plenty of Wind Left In KITE's Sails**

Kite raised \$136MM in a June IPO. The company is financed into 2017 and through multiple potential value-creating milestones. Although KITE shares have been well received, the stock is trading substantially below our \$43/share estimate for the fair value of KTE-C19's potential opportunity in refractory DLBCL. We expect development progress on KTE-C19 and multiple other CAR and TCR therapies to drive outperformance in KITE shares.

## At A Glance

### Our Investment Thesis

Kite is financed into 2017 and through multiple potential value creating milestones. We believe lead candidate KTE-C19 has sales potential in excess of \$1B in refractory Diffuse Large B Cell Lymphoma (DLBCL). The stock is trading substantially below our \$43/share fair value estimate for this opportunity. We expect development progress on KTE-C19 and multiple other CAR and TCR therapies to drive outperformance in KITE shares.

### Base Case Assumptions

- KTE-C19 manufacturing process is certified in time to start Phase I/II trial in DLBCL during H1:15
- KTE-C19 gains accelerated approval in 3rd line DLBCL
- KTE-C19 becomes a commercial success with U.S. sales of ~\$1B in DLBCL

### Price Performance



Source: Bloomberg

### Upside Scenario

- EGFRvIII CAR program generates positive data
- MAGE TCR program generates positive data
- Kite's NY-ESO-1 TCR program demonstrates improved efficacy relative to Adaptimmune's NY-ESO-1 program

### Forthcoming Catalysts

- Data update from the NCI's Phase I/II trial of anti-CD19 CAR in Q4:14
- File IND for KTE-C19 by YE:14
- Initial data from the MAGE and NY-ESO-1 TCR Phase I/II NCI trials in 2015

### Downside Scenario

- KTE-C19 is associated with a meaningful safety concern
- The FDA requires randomized controlled data on KTE-C19 prior to approval
- Kite is unable to execute on a viable commercial manufacturing strategy

### Company Description

Kite is a pioneer in the use of engineered Autologous T Cell Therapy (eACT), a personalized approach that directs a patient's immune system to fight his or her cancer. eACTs have demonstrated the ability to induce highly potent (response rates of 80%+) and durable (multi-year) responses in several refractory forms of cancer. Kite's collaboration with the NCI and intellectual property make it a leader in the field. Lead product KTE-C19, is a chimeric antigen receptor (CAR) therapy targeting CD19, an antigen found on several lymphomas and leukemias. KTE-C19 is expected to enter a multicenter PI/II trial in 3<sup>rd</sup>-line DLBCL in early 2015. If data from this single-arm trial are compelling, it might support accelerated FDA approval. Trials for KTE-C19 in 2<sup>nd</sup>-line DLBCL and other refractory lymphomas/leukemias, as well as for eACT's targeting EGFRvIII, MAGE-A3, NY-ESO-1, and SSX2, are in planning.

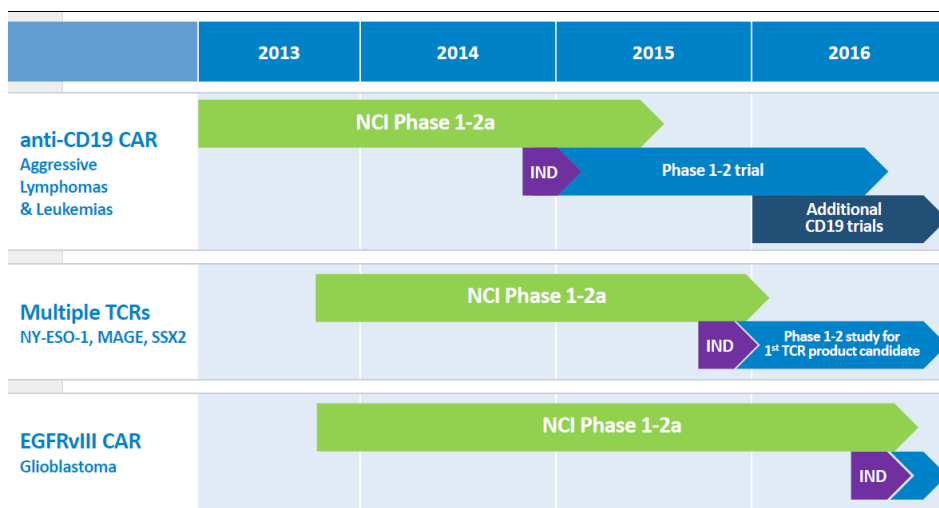
### Analyst Top Picks

	Ticker	Price (07/14/2014)	Price Target	Rating
Sunesis Pharmaceuticals	SNSS	\$6.00	\$NA	Outperform
Relysa	RLYP	\$23.80	\$NA	Outperform
Kite Pharma	KITE	\$24.05	\$NA	Outperform

## Investment Summary

Kite Pharma is a cancer immunotherapy company that seeks to develop and commercialize T cell-based therapies. Kite is a pioneer in the use of engineered Autologous T Cell Therapy (eACT), a personalized approach that directs a patient's immune system to fight his or her cancer. eACTs have demonstrated the ability to induce highly potent (response rates of 80%+) and durable (multi-year) responses in several refractory forms of cancer. We believe Kite's broad relationship with the NCI and foundational intellectual property will make it a leader in this exciting field. Lead product KTE-C19 is a chimeric antigen receptor (CAR) T cell therapy directed at CD19, an antigen found on several types of lymphomas and leukemias. KTE-C19 is expected to enter a multicenter Phase I/II trial in 3<sup>rd</sup>-line diffuse large B-cell lymphoma (DLBCL) in early 2015. If data from this single-arm trial are compelling, they might support FDA approval in an area of high unmet need. Additional trials for KTE-C19 in 2<sup>nd</sup>-line DLBCL and other refractory lymphomas/leukemias, as well as for several other eACTs directed at other cancer antigens including NY-ESO-1 (sarcoma, other solid tumors), MAGE-A3 (epithelial cancers), SSX2 (HCC, other solid tumors), and EGFRvIII (glioblastoma, head & neck cancer), are in planning.

### Kite Pharma Pipeline



Source: Kite Pharma

### T Cell Immunotherapy: What Is All The Fuss About?

Growing interest in using a patient's own T cells to fight cancer has gained support from a multitude of trials conducted at academic centers including the National Cancer Institute (NCI), University of Pennsylvania, Memorial Sloan Kettering, the Fred Hutchinson Cancer Research Center, Baylor College of Medicine, and Seattle Children's. While each academic group has employed a slightly different approach and technique, a consistent theme has emerged from the results: engineered Autologous T Cell Therapy (eACT) can be highly efficacious, even in late stage patients. The compelling nature of the clinical datasets has prompted several companies to jump into the field in an effort to commercialize the promise of eACTs. In addition to Kite, these include Novartis, Juno, Cellectis/Pfizer, AdaptImmune, bluebird/Celgene and others.

In general, eACTs can be divided into two platforms: chimeric antigen receptor (CAR) therapies and T Cell Receptor (TCR) therapies. In both cases the approach is autologous: a patient's own T cells are collected, engineered outside the body with novel functionality that directs them to attack a cancer cell antigen, and re-infused back into the patient. In either case, the infused T cells have the potential to become a living part of the patient with the potential to induce long-term control of the cancer.

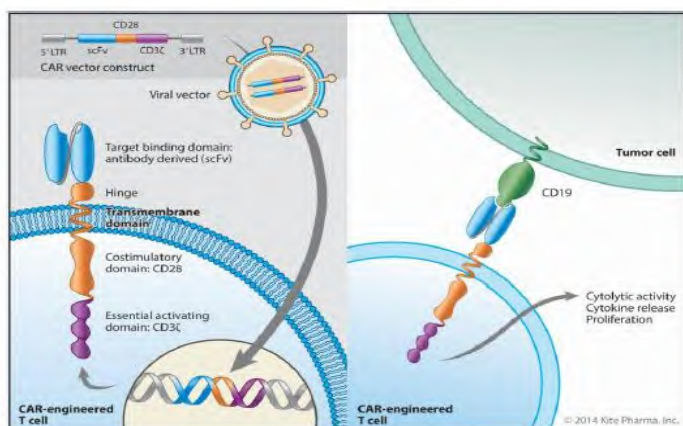
In the case of CAR-based therapy, a patient's T cells are engineered to express an artificial receptor that uses an antibody fragment to direct the T cells against an antigen on the outside of a tumor cell. Once the engineered T cell comes into contact with the cancer cell antigen, the intracellular portion of the CAR construct activates the T cell, causing a flurry of cytolytic activity and/or cytokine release. Because CARs can only recognize antigens expressed on the outside of a tumor, they can only be deployed against cancers (typically hematologic malignancies) that overexpress cancer antigens on their cell surface.

In the case of TCR-based therapy, a patient's T cells are engineered to express a novel T cell receptor (TCR) that allows them to recognize a cancer-associated protein that has been processed inside the cell and presented on the cancer cell's surface in the context of an MHC complex. Binding of the engineered TCR to the cancer antigen:MHC complex stimulates T cell activation, proliferation, and cell killing. TCR-based therapy has the potential to be directed against intracellular cancer antigens, but as these therapies are also required to recognize a specific MHC complex, they need to be "matched" to the HLA-type of the patient.

## Two Major Approaches To eACTs: CARs and TCRs

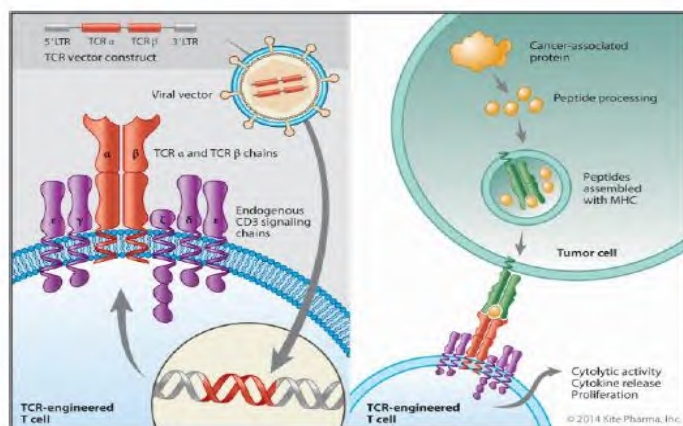
### Chimeric Antigen Receptor (CAR) Products

**Target molecules on cell surface**  
**Activity in blood cancers**  
**Not HLA-restricted**



### T Cell Receptor (TCR) Products

**Target molecules are intracellular**  
**Activity in solid tumors**  
**HLA-restricted**



Source: Kite Pharma

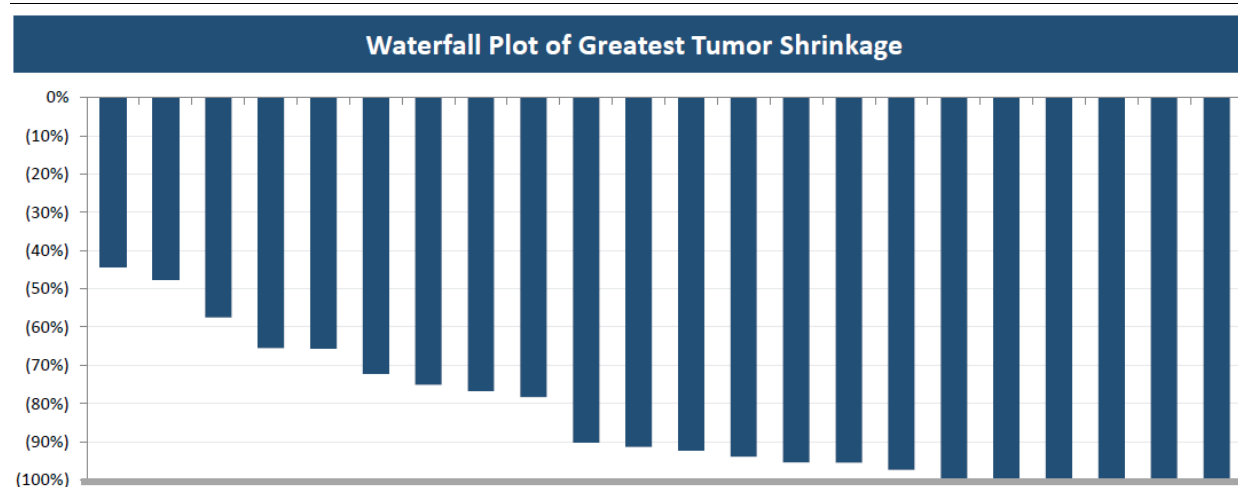
## Kite Was Endowed With A Couple Key Assets

Kite's leadership position in the eACT space is largely derived from two important assets. The first is the company's collaboration with the NCI. In the 1980s, the company's founder, chairman and CEO, Dr. Arie Beldegrun, completed a fellowship in surgical oncology at the NCI, where he worked with Dr. Steven Rosenberg, one of the leading academic inventors of eACT. In September 2012, Kite signed a cooperative research and development agreement (CRADA) with Dr. Rosenberg's group at the NCI that is effective for 5 years and essentially provides Kite with an option to license many of the eACT products being invented and pioneered within the NCI's surgery branch. The NCI's portfolio of products (CARs and TCRs) is broad, and effectively provides Kite with a pipeline of candidates for the foreseeable future. Second, Kite was early to appreciate the potential of CARs, and began to consolidate much of the early intellectual property in the space. Kite's portfolio includes 11 issued U.S. patents, including a seminal patent covering the basic CAR construct that was issued to Israeli scientist Dr. Zelig Eshhar for work performed in the early 1990s. This patent expires in 2027, and should provide Kite with not only freedom to operate, but also a potentially valuable bargaining chip as IP within the eACT space gets sorted out.

## Lead Program KTE-C19 Has Blockbuster Potential

The most advanced product Kite has in-licensed from the NCI is an anti-CD19 CAR therapy. As of March 2014, the NCI had treated 24 patients with late stage B cell malignancies under an academic IND. Of the 22 evaluable patients (two patients died early for reasons unrelated to therapy), 19 experienced an objective response to therapy (86%). Responses were seen in 7 of 8 patients with DLBCL, with all 7 responses ongoing as of the last update. Anti-CD19 therapy was well tolerated with the chief toxicity being grade III (25% incidence) and IV (25%) neurological impairment, a class toxicity of all anti-CD19 CAR therapies.

### Waterfall Plot From NCI's Anti-CD19 CAR Phase I Trial



Source: Kite Pharma

Kite is refining the production process around this candidate, and intends to file a company IND on what will be its lead development candidate, KTE-C19, in late 2014. An initial Phase I/II trial will be conducted in 3<sup>rd</sup>-line DLBCL, an indication with a very poor prognosis (~6 month life expectancy) and one with no standard of care. We believe that compelling data from a moderately sized, single-arm study could support FDA approval. With >8,000 deaths per year from DLBCL in the U.S., KTE-C19 could serve a \$1B+ U.S. market.

### So What Is It All Worth?

Kite Pharma completed an IPO in June, raising net proceeds of approximately \$136MM. Inclusive of \$69MM in pro forma cash as of March 2014, we believe the company is financed well into 2017 and through several important milestones.

#### Kite Pharma - Upcoming Milestones/Events

Indication/Milestone	Timing
Additional data from NCI run Phase I/II trials on anti-CD19 CAR	Q4:14
File IND for KTE-C19	YE:14
Begin Phase I/II trial on KTE-C19 for 3 <sup>rd</sup> line DLBCL	H1:15
Potential breakthrough designation for KTE-C19	2015
Initial data from the MAGE and NY-ESO-1 TCR Phase I/II NCI Trials	2015
Transfer manufacturing on EGFRvIII CAR and various TCRs from NCI to Kite	2015
File IND on 1 <sup>st</sup> TCR-based product	2015
Initial data on KTE-C19 in 3 <sup>rd</sup> line DLBCL	H2:15
File IND on EGFRvIII CAR in Glioblastoma	2016
Complete enrollment in registrational trial on KTE-C19	2016
Possible BLA submission on KTE-C19 for 3 <sup>rd</sup> line DLBCL	Late 2016/early 2017

Source: Cowen and Company

Shares of KITE have been well received by the public markets, and have appreciated ~40% from the IPO offering price. The company sports a market cap of approximately \$875MM. While Kite's stock has performed well, we believe Kite's valuation still provides for substantial upside should KTE-C19 succeed in becoming a mainstay of therapy in DLBCL. Based upon peak U.S. revenues of just over \$1B in 3<sup>rd</sup>-line DLBCL, our NPV analysis suggests this opportunity alone could be worth \$43/share (see page 22). Additional upside could be supported by KTE-C19 revenues in other tumor types or success associated with any of Kite's other eACT therapies.

Kite Quarterly P&L

	2013A	Q1:14A	Q2:14E	Q3:14E	Q4:14E	2014E
KTE-C19 Revenue	0.0	0.0	0.0	0.0	0.0	0.0
Collaborative and Grant Revenue	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total Revenue</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<i>Y/Y growth</i>						
COGS	0.0	0.0	0.0	0.0	0.0	0.0
<i>GMs</i>						
R&D	5.1	2.1	2.0	2.0	2.2	8.3
SG&A	1.3	1.1	1.5	2.5	2.7	7.8
<b>Total Expenses</b>	<b>6.4</b>	<b>3.2</b>	<b>3.5</b>	<b>4.5</b>	<b>4.9</b>	<b>16.1</b>
<b>Operating Income/Loss</b>	<b>(6.4)</b>	<b>(3.2)</b>	<b>(3.5)</b>	<b>(4.5)</b>	<b>(4.9)</b>	<b>(16.1)</b>
Interest Income	0.0	0.0	0.0	0.0	0.0	0.0
Other (expense) Income	0.0	0.0	0.0	0.0	0.0	0.0
Series A Preferred Stock Dividend	1.4	0.6	0.0			0.6
<b>Pre-tax Income/Loss</b>	<b>(7.8)</b>	<b>(3.7)</b>	<b>(3.5)</b>	<b>(4.5)</b>	<b>(4.9)</b>	<b>(16.6)</b>
<i>Tax rate (%)</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Income (Loss)</b>	<b>(7.8)</b>	<b>(3.7)</b>	<b>(3.5)</b>	<b>(4.5)</b>	<b>(4.9)</b>	<b>(16.6)</b>
<b>GAAP EPS</b>	<b>(\$1.43)</b>	<b>(\$0.66)</b>	<b>(\$0.10)</b>	<b>(\$0.10)</b>	<b>(\$0.11)</b>	<b>(\$0.50)</b>
Diluted Shares	5.5	5.6	36.0	45.0	45.5	33.0

Source: Cowen and Company

Kite Annual P&L

	2013A	2014E	2015E	2016E	2017E	2018E
KTE-C19 Revenue	0.0	0.0	0.0	0.0	2.0	50.0
Collaborative and Grant Revenue	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total Revenue</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>2.0</b>	<b>50.0</b>
<i>Y/Y growth</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>2400%</i>
COGS	0.0	0.0	0.0	0.0	0.7	15.0
R&D	5.1	8.3	37.0	58.0	60.0	64.0
SG&A	1.3	7.8	12.0	14.0	70.0	80.0
<b>Total Expenses</b>	<b>6.4</b>	<b>16.1</b>	<b>49.0</b>	<b>72.0</b>	<b>130.7</b>	<b>159.0</b>
<b>Operating Income/Loss</b>	<b>(6.4)</b>	<b>(16.1)</b>	<b>(49.0)</b>	<b>(72.0)</b>	<b>(128.7)</b>	<b>(109.0)</b>
Interest Income	0.0	0.0	0.0	0.0	0.5	1.0
Other (expense) Income	0.0	0.0	0.0	0.0	0.0	(0.2)
Series A Preferred Stock Dividend	1.4	0.6				
<b>Pre-tax Income/Loss</b>	<b>(7.8)</b>	<b>(16.6)</b>	<b>(49.0)</b>	<b>(72.0)</b>	<b>(128.2)</b>	<b>(108.2)</b>
<i>Tax rate (%)</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Income (Loss)</b>	<b>(7.8)</b>	<b>(16.6)</b>	<b>(49.0)</b>	<b>(72.0)</b>	<b>(128.2)</b>	<b>(108.2)</b>
<b>GAAP EPS</b>	<b>(\$1.43)</b>	<b>(\$0.50)</b>	<b>(\$1.00)</b>	<b>(\$1.45)</b>	<b>(\$2.40)</b>	<b>(\$1.90)</b>
Diluted Shares	5.5	33.0	49.0	49.5	53.5	57.0

Source: Cowen and Company



## Cancer Immunotherapy 101: T Cell Responses Needed

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For over 30 years it has been shown that humans are capable of developing immune cells that recognize, infiltrate, and ultimately kill some tumor cells. However, cancer patients are often incapable of using these cells to control/clear a tumor because (1) their activity is blocked through any number of inhibitory signaling pathways (ex. CTLA-4, PD-1, PD-L1) or (2) the necessary T cell specificities are either absent or present at too low of a frequency to be effective. Much excitement has been generated by the clinical success of “checkpoint inhibitors” such as ipilimumab (Yervoy) and nivolumab, which address the first problem. In addition, multiple academic research groups have attempted to address the second problem by isolating tumor infiltrating lymphocytes, expanding them *ex vivo*, and then returning these, now more numerous cells, to the tumor.

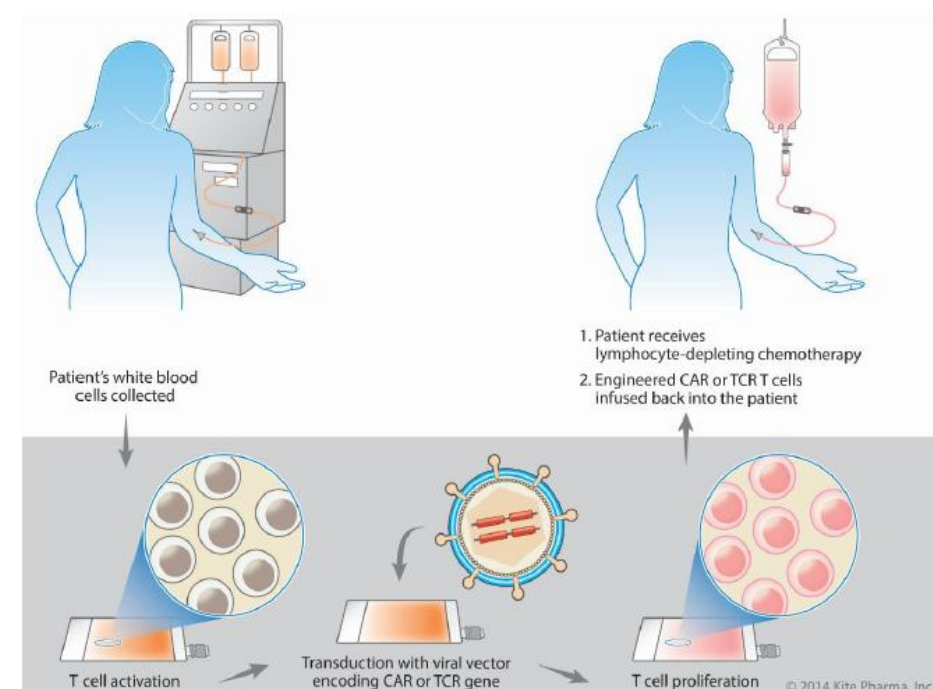
While these approaches can be highly effective, they rely on the patient’s immune system being capable of recognizing the tumor independent of medical interventions. Consequently, the efficacy of these approaches is highly variable between tumor types and from patient to patient. Recently, multiple groups including Kite and its collaborators at NCI have developed methods for engineering anti-tumor T cell responses. These approaches manipulate T cells *ex vivo* to recognize specific antigens, thereby avoiding the problems inherent with reliance upon *in vivo* antigen recognition. In general, these approaches consist of 5 steps:

1. Isolating a patient’s T cells (regardless of their specificity)
2. Activating the isolated T cells
3. Transducing the T cells with genes encoding tumor recognizing receptors
4. *Ex vivo* proliferation of the transduced T cells
5. Infusion of the patient’s transduced T cells back into the patient

In theory, although this process is complex, its potential utility is only limited by the ability of scientists to identify antigens sufficiently specific to a disease state (tumor, bacteria, virus, etc.) and isolate/engineer a receptor specific for this antigen.



## Engineered Autologous T-cell Therapy (eACT)



Source: Kite Pharma

The use of autologous cells minimizes the risk of the engineered T cells being recognized as foreign and rejected by the patient's preexisting immune system. However, it also presents multiple manufacturing challenges. First, the patient's immune system must possess functional T cells which are amenable to isolation and manipulation. Second, T cells must efficiently take up and express the transgene that encodes the engineered receptor. Third, patient appointments, clinical staff, and company manufacturing processes must be coordinated as the cells are shipped back and forth between the manufacturing facility and clinic. Importantly, unlike dendritic cells (Dendreon's Provenge), T cells are capable of being cryopreserved. Therefore, time is less of a factor and the logistical challenges of *ex vivo* manipulation during eACT are lower than with dendritic cell-based approaches. In addition, the ability to freeze excess cells presents the opportunity to retreat patients without repeating the isolation and processing steps.

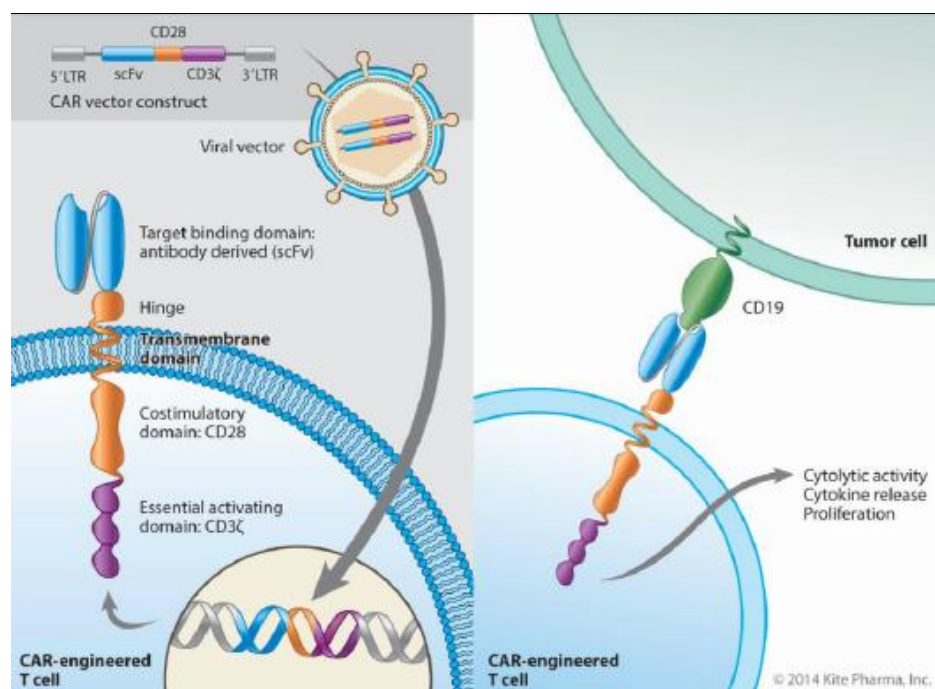
### CARs Merge Antibody Targeting With T cell Functionality

Kite utilizes two independent approaches for engineering a T cell to be specific for an antigen of interest. The most clinically advanced method is termed a chimeric antigen receptor (CAR). A CAR merges the specificity of antibodies with the functional ability of a T cell. This is accomplished by engineering a gene construct which encodes (1) the binding domain of an antibody, (2) a hinge region, (3) a transmembrane domain, (4) a T cell costimulatory domain (CD28, 4-1BB, etc), and (5) the CD3 $\zeta$  (a component of the natural T cell receptor) activating domain.

When the CAR's binding domain recognizes and binds its cognate antigen the CAR's intracellular domains become active. Once activated, the costimulatory and CD3 $\zeta$  domains propagate an activation signal throughout the T cell's cytoplasm as if they

had been activated through a natural T cell receptor binding event. Upon activation, the engineered T cell can proliferate, release cytokines, and/or exhibit cytolytic activity. Notably, it has been shown that the inclusion of both a costimulatory and activating domain are required for maximal T cell activation. Using the CAR approach a T cell can theoretically be targeted against any antigen which is expressed on the surface of a cell. However, there are practical limitations to the ability of scientists to successfully generate antibodies against targets of interest. If an antibody cannot be successfully generated, its gene cannot be isolated and a CAR cannot be constructed. It is also possible that Kite will encounter difficulty successfully expressing some antibody constructs in the context of a T cell. In addition, it is estimated that up to 80% of proteins are intracellular. Therefore, these proteins and any associated diseases would be inaccessible to CAR based eACTs.

#### Chimeric Antigen Receptor (CAR) Constructs And Target Recognition



Source: Kite Pharma

#### Eshhar Patent Controls The CAR Space

The "Eshhar patent" (US #7,741,465) is the seminal patent in the chimeric antigen receptor field. Kite has obtained an exclusive license from Cabaret Biotech for the Eshhar patent. Kite management believes the Eshhar patent gives Kite the pole position in terms of intellectual property until its expiration in 2027. The Eshhar patent is titled *Chimeric Receptor Genes and Cells Transformed Therewith*, and includes claims:

1. To a chimeric DNA encoding an scFv domain, a flexible linker, a transmembrane domain, and an intracellular domain which causes the activation of lymphocytes upon binding of the scFv domain. Additional scFV claims go on to specifically claim the use of sequences specific for tumor cells, virus infected cells, and HIV infected cells. Similarly, additional activating domain claims cite the use of sequences from the IL-2 receptor, CD3 $\alpha$ , CD3 $\beta$ , CD3 $\gamma$ , CD3 $\delta$ , CD16 $\alpha$ , and F $_C$  receptors for IgE and IgG.
2. To the generation of an expression vector comprising the above chimeric DNA
3. To the transformation of lymphocytes with the above expression vector

The first claim is general enough to include scFv domains derived from any antibody and the activation domain of any lymphocyte activating molecule. Therefore, Eshhar's claims appear to give Kite rights to any single chain CAR product that utilizes an antibody fragment on its surface and a naturally occurring lymphocyte activation domain. This could allow Kite to pursue infringement claims against competitors like Juno and Novartis. However, it is more likely that management will not seek to exclude others from the field, but rather enter into licensing agreements with other CAR companies in return for royalties and/or access to complementary intellectual property.

While the Eshhar patent forms an umbrella that provides broad protection for CARs, it is not the end of Kite's patent portfolio. Kite and its NCI collaborators have been granted or are applying for composition of matter patents on individual CAR and TCR constructs as well as method of use patents for the use of these constructs to target particular antigens within the context of each disease indication. As a result, Kite is able to form multiple layers of intellectual property protection for each eACT product.

### T cell Receptors Expand The Target Universe

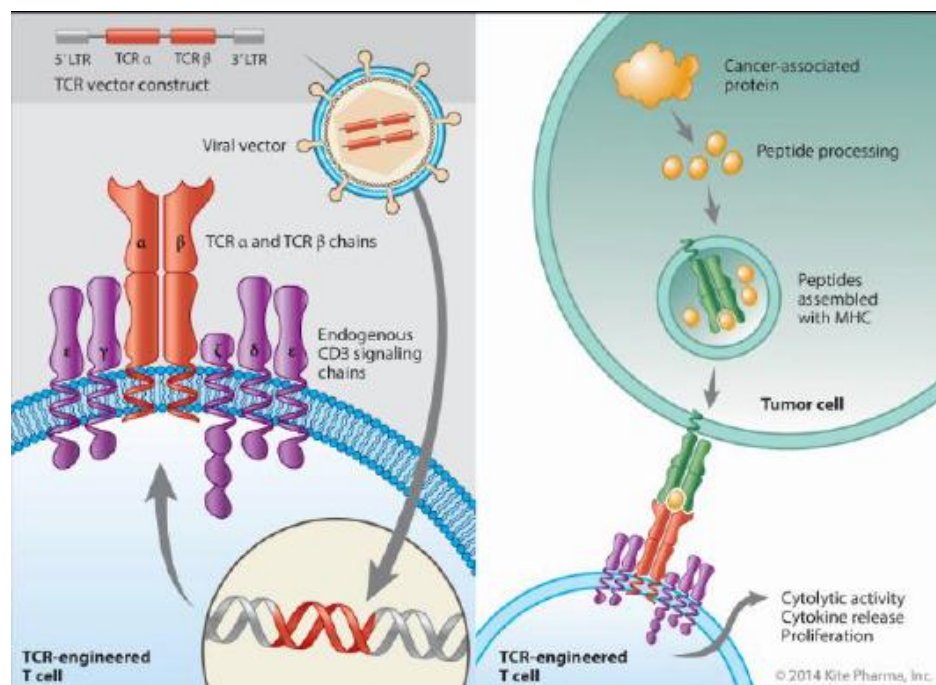
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NCI and others have developed a second approach to generating desired T cell specificities that avoids the limitations of antibody-based cellular targeting. This approach involves introducing engineered genes encoding T cell receptor (TCR)  $\alpha$  and  $\beta$  chains. When the  $\alpha$  and  $\beta$  chains are co-localized on the T cell surface they combine to recognize antigenic peptides presented on MHC molecules and interact with the naturally occurring CD3 $\epsilon$ ,  $\gamma$ ,  $\delta$ , and  $\zeta$  chains to enable signaling. This approach can be utilized to develop T cells capable of recognizing peptides presented by either MHC class I molecules (generally presenting peptides expressed within that cell) or MHC class II molecules (generally expressed by professional antigen presentation cells which present peptides obtained via phagocytosis), although Kite is focusing on antigens presented by MHC class I. Both MHC class I and class II genes are highly variable across the population. Significantly, different antigenic peptides are presented by different subsets of MHC genes. In addition, different TCR sequences are capable of recognizing different subsets of MHC proteins. Therefore, a patient's MHC genotype will have to be matched to particular TCR constructs. This means that in order to provide therapy to all patients afflicted with a particular disease Kite will have to make multiple TCR constructs for each antigen identified as being specific for that disease.

Kite's transduction process does not alter the T cell's naturally occurring  $\alpha$  and  $\beta$  chains. Consequently, it is possible for a transduced  $\alpha/\beta$  chain to combine with a

native  $\beta/\alpha$  chain. This unintended combination would be incapable of recognizing the desired antigen, and may be capable of recognizing an alternative unintended antigen. However, unintended antigen recognition is yet to be observed in humans. In addition, Kite's National Cancer Institute collaborators are developing methods of using mouse:human hybrid TCR sequences to prevent mispairing of  $\alpha$  and  $\beta$  chains.

#### Engineered T Cell Receptor Constructs And Target Recognition



Source: Kite Pharma

Once a CAR or TCR recognizes its target antigen the natural intracellular signaling machinery of the T-cell is engaged to generate effector functions (release of cytokines and/or cytotoxic molecules). Consequently, this signaling is subject to the T-cell's natural inhibitory mechanisms including PD-1/PD-L1 signaling. Therefore, it is possible that overexpression of inhibitory molecules such as PD-L1 on the target tissue could block the function of eACT cells. In addition, chronic T-cell activation can lead to upregulation of inhibitory molecules such as PD-1. The mechanisms by which this occurs are left intact by current eACT approaches. As a result, eACT cells could become less effective over time. Potency has not been an issue in eACT trials as of yet. But, if the checkpoint inhibition mechanisms become a problem, it may be necessary to combine eACTs with the checkpoint inhibitors currently being developed by other companies.

#### Kite and NCI Collaborate To Develop eACTs

In September 2012, Kite established a 5-year cooperative research and development agreement (CRADA) with Dr. Steven Rosenberg and the National Cancer Institute. Under this agreement Kite and NCI are working together to 1) screen, validate, and develop new CAR and TCR constructs, 2) optimize manufacturing processes, and 3) identify new targets for CAR and/or TCR development.

Under the terms of this agreement, Kite provides \$1MM in annual research funds to the NCI. Under the direction of a jointly developed research plan, NCI conducts research activities from discovery through Phase I clinical trials. While conducting Phase I trials, NCI has the ability to iteratively alter eACT constructs, dosages, treatment schedules, etc. Management believes that the NCI's ability to coordinate with the FDA enables these potentially vital iterations to occur more quickly than would occur if a private sector company held a similar product. Management advises that it and the NCI envision the transition from Phase I to Phase II trials will generally occur following the treatment of 5-7 patients by NCI. Upon this transition, Kite becomes responsible for conducting all clinical trials as well as commercialization activities.

Intellectual property developed under the CRADA is owned solely or jointly depending upon whether the inventing scientists are Kite and/or NCI employees. If CRADA IP is owned by the NCI, it is responsible for filing patent applications. NCI is required to notify Kite of all patent applications and Kite is entitled to the right of first negotiation on a license. In order to evaluate the licensing opportunity, Kite is given access to all data on these NCI-owned programs and has 4 months from patent filing to express a desire to negotiate a license. If Kite expresses a desire to license the IP, a 10-month exclusive negotiation period is initiated. The negotiations will use a model United States Public Health License as a framework for establishing royalty rates, maintenance fees, etc. Importantly, licenses for CRADA derived intellectual property are not subject to publication and/or objection via the federal register.

In addition to the right of first negotiation, Kite is entitled to ownership of all data resulting from the CRADA. Therefore, in the event that Kite declines its negotiation option or fails to come to terms with the NCI, competitors would be forced to negotiate a license in the absence of supporting non-public data, repeat all CRADA funded preclinical and Phase I trials, and lack any insights provided by other enabling experiments.

### **KTE-C19: A Personalized Product With Many Applications**

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Kite's lead pipeline candidate is KTE-C19. KTE-C19 is an eACT expressing a CAR specific for CD19, which is a B cell marker. KTE-C19 is in a Phase I/II trial for B cell malignancies where it has generated an 86% ORR. This is a striking result as patients in the study were generally heavily pretreated and refractory to chemotherapy. Kite intends to initially bring KTE-C19 forward in 3<sup>rd</sup> line diffuse large B cell lymphoma (DLBCL). We estimate there are approximately 8,000 3<sup>rd</sup> line DLBCL patients in the U.S. and that KTE-C19 could generate greater than \$1B in U.S. sales within this indication. Since KTE-C19 targets all B cells it also has potential applications in multiple B cell malignancies (ex. ALL, CLL, NHL, etc.).

### **CD19 Chimeric Antigen Receptor: Reducing CARS To Practice**

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KTE-C19 consists of autologous T cells transduced with a gene construct encoding a CD19 specific CAR. The CAR construct consists of an extracellular antibody derived scFv domain that binds CD19 on a target surface linked to intracellular CD28 costimulatory and CD3 $\zeta$  activating domains. By packaging this construct inside of a gammaretrovirus, Kite is able to transduce T-cells. Following transduction, T cells gain the ability to recognize CD19 on a target cell's surface and respond as if their native T cell receptor has been engaged. As a result, in the presence of CD19 expressing cells (B cells) KTE-C19 cells will proliferate, produce cytokines and/or exhibit cytotoxic activity. The cytotoxic activity exerts the clinical effect of clearing all B cells from a

patient following administration of KTE-C19. Importantly, a patient is expected to be devoid of B cells for as long as KTE-C19 cells are present in their body.

#### **Anti-CD19 CARs Have Generated Impressive Phase I/II Data**

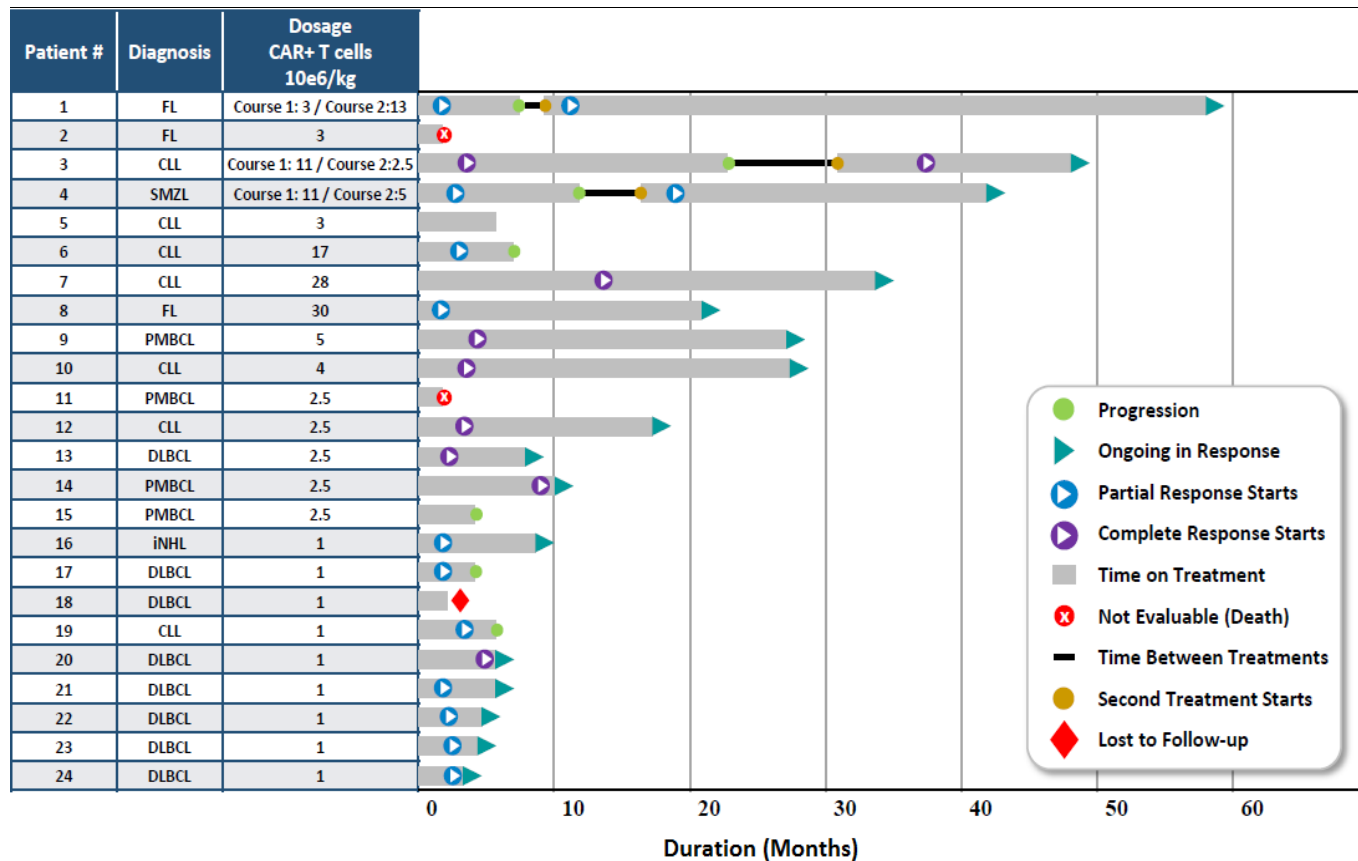
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Kite is funding an ongoing NCI Phase I/II trial using anti-CD19 CAR T cells in CD19 positive B cell malignancies. 24 patients from 3 cohorts have been treated as of March 2014. Cohort 1 consisted of 8 patients that received a conditioning regimen of cyclophosphamide for two days followed by fludarabine for five days. Following conditioning patients were treated with varying doses of anti-CD19 CAR T cells along with IL-2 to stimulate proliferation of the CAR T cells. Cohort 2 consisted of 15 patients (including 3 retreatments from cohort 1) who were treated as in cohort 1 except no IL-2 was given. NCI is currently enrolling a cohort 3 which is receiving lower doses of the conditioning regimen and no IL-2. As of March 2014, 5 patients (including 2 compassionate use subjects) have been enrolled.

Of the 24 trial patients, 2 died before a response could be evaluated. Within the 22 evaluable patients (including 3 who were retreated), 19 experienced an objective response (ORR) of 86%. An objective response was defined as either a complete response (disappearance of all detectable disease) or a partial response (>50% regression of measurable disease and no new sites of disease). When present, responses were generally observed at 1 month post-dosing, which was the time of the first follow-up exam.



## Anti-CD19 CAR T Cell Response Durability



Source: Kite Pharma

In addition to impressive response rates, anti-CD19 CAR T cell responses have been durable. 16 of the 24 treated patients were in remission as of March 13, 2014. Three of these patients had experienced breakthrough disease, but retreatment with anti-CD19 CAR T cells allowed remission to be reestablished in all three. This indicates that breakthrough is likely due to a loss of anti-CD19 CAR T cells and not the ability of the tumor to develop resistance to the synthetic immune response. In fact, patient 1 (follicular lymphoma) experienced an initial remission of less than 1 year, but upon retreatment has maintained remission beyond 50 months from trial entry.

Across all cohorts eight patients with DLBCL have been treated. One patient was lost to follow-up. Among the remaining seven patients, two complete responses and five partial responses have been observed (ORR of 88%). As of March 13, 2014, one of the partial responders has subsequently progressed while six patients remained responsive to therapy. Additional efficacy updates are expected at ASH 2014.



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**DLBCL Patient With A Complete Response Following KTE-C19 Treatment**

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Source: Kite Pharma

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Upon recognition of its cognate antigen, CAR T cells undergo rapid expansion and generate a cytokine storm. As expected, the most common side effects of therapy reported in the NCI trials were fever, low blood pressure, and kidney dysfunction, all of which can result from an excessive cytokine storm. These effects are termed cytokine release syndrome (CRS). To slow the expansion of CAR T cells and therefore reduce the chance of CRS, NCI and Kite have removed IL-2 coadministration from the treatment protocol for cohorts 2 and beyond. Management reports that with this protocol amendment CRS has been largely eliminated. Some patients also experienced transient neurologic dysfunction in the form of aphasia, confusion, neuropathy, and somnolence. It is unclear what causes this dysfunction, but two proposed causes are that it is an effect of the cytokine storm, or alternatively the result of T cells trafficking to the brain and killing lymphoma cells residing in the brain. Importantly, unlike the classic symptoms of a cytokine storm, neurologic dysfunction is not ameliorated by anti-IL-6 antibodies. Nonetheless, all cases of neurologic dysfunction have been transient. As mentioned previously, two patients died after receiving anti-CD19 CAR T cells. Neither death was attributed to therapy. One patient died of influenza-related pneumonia believed to have been allowed by the patients conditioning regimen. The second patient had an autopsy performed but no cause of death was determined. It is presumed that the patient died of a heart arrhythmia as a result of the pre-treatment presence of extensive lymphoma in the chest area surrounding the heart. At autopsy, this patient had no evidence of lymphoma just 16 days after anti-CD19 CAR T cell administration. Consistent with its design, therapy also resulted in B cell aplasia. Management reports that typically the CAR T cells become undetectable in the blood within 2-3 months; it is unclear if this clearance of detectable CD19 CAR T cells will ultimately allow for the return of a healthy B cell compartment. Sustained B cell aplasia could lead to long-term increases in the risk of infections as well as an increased need for antibiotics and/or immunoglobulin supplementation. However, it is notable that physicians currently induce B cell aplasia

during clinical practice when they administer CD20 targeting antibodies such as Rituxan.

#### Anti-CD19 CAR Phase I/II 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: Kite Pharma

#### Kite Is Ready To Advance KTE-C19 In DLBCL

DLBCL is a subtype of non-Hodgkin's lymphoma (NHL) which accounts for approximately 30% of the 70,000 annual NHL diagnoses in the U.S. This makes it the most common form of NHL. First-line therapy of R-CHOP is reasonably effective and cures 50-60% of patients. If R-CHOP fails, platinum-based chemotherapy along with continued rituximab is usually offered to patients. In the event that a response is achieved with second-line therapy, patients may be given a hematopoietic stem cell transplant. If second-line therapy or the transplant fails, patients are left with few options and little hope of a curative therapy. Given the impressive Phase I/II results in seven DLBCL patients, Kite decided to advance the product in this indication. Kite is transitioning manufacturing from NCI to a new more scalable process (described in greater detail below). The output of this new manufacturing process will be referred to by the Kite moniker KTE-C19 as it represents a slightly different product from the anti-CD19 CAR employed by the NCI. Upon certification of the new process Kite plans to file its own IND and initiate a Phase I/II single-arm multicenter trial of KTE-C19 in 3<sup>rd</sup> line DLBCL. Approximately 40 patients will be enrolled who have either failed R-CHOP followed by a platinum-containing regimen or relapsed within 12 months of an autologous transplant. Kite plans to use both the KTE-C19 dosage (1x10<sup>6</sup> KTE-C19 cells/kg) and the low-dose conditioning regimen NCI is currently using in cohort 3. Enrollment is anticipated to begin in H1:15 and continue through Q1:16, with preliminary data available during 2015. Simultaneous to the IND application, Kite plans to use the NCI Phase I/II DLBCL patient data to apply for breakthrough status.

3<sup>rd</sup> line DLBCL patients have few treatment options and are generally only given palliative care. Consequently, these patients have a median survival of approximately 6 months. In the NCI trial, five of seven DLBCL patients (71%) had responses lasting at least as long the expected median survival. Therefore, Kite believes it may be able to file for accelerated approval if the NCI's efficacy data can be replicated. Management believes a 30% response rate may be sufficient for accelerated approval in 3<sup>rd</sup> line DLBCL. If this is achieved in the Kite Phase II trial, accelerated approval could come as early as late 2017. In order to facilitate a potential accelerated approval, Kite plans to initiate a randomized study in second line DLBCL, which would be sufficient for regular approval, in 2016. Kite also plans to expand the KTE-C19 development program to include trials in other B cell malignancies including follicular lymphoma, MCL, PMBCL, CLL, and/or ALL beginning in 2015.

#### **A Potentially Curative 3<sup>rd</sup> Line DLBCL Therapy Is A \$1B+ Opportunity**

Based upon mortality figures, Kite believes there are 8,000 3<sup>rd</sup> line DLBCL patients in the U.S. As a result, the FDA has granted the indication orphan status. While the potential for a cure would be extremely attractive to these patients, many will be unable to withstand the conditioning therapy. As a result, we model a peak penetration of 37% within this market. Given the complexity of a CAR product and the orphan indication, we model premium initial pricing for KTE-C19 of \$250K. These assumptions generate U.S. sales of \$978MM in 2027, for patients receiving their initial dose of KTE-C19.

The NCI has shown that responders that subsequently relapse are capable of being retreated. In addition, Kite believes that its manufacturing process will generate excess transduced T cells which can be frozen and stored for subsequent retreatments. Given the less technically involved nature of retreatment, we assume Kite will offer secondary doses at a discounted initial price of \$150K. We believe that retreatment will only be attempted in patients that initially experience a response on KTE-C19. In order to calculate a pool of potential retreatment patients, we assumed that KTE-C19 will generate a 65% ORR and that ~10% of responders will die of alternative causes or decide not to pursue further KTE-C19 therapy. Based upon the NCI trial, Kite believes that each year ~10% of these patients will experience a relapse. Therefore, we calculate the potential for retreatments as an incremental \$128MM opportunity by 2027. Given the potential for rapid approval, need for complex manufacturing facilities and the intricacies of securing reimbursement in ex-U.S. markets, we assume Kite will license KTE-C19 to a partner for limited upfront cash and tiered royalties in the mid-20%<sup>s</sup>. We model ex-U.S. royalties to provide an additional \$174MM to Kite. In total, this brings the 3<sup>rd</sup> line DLBCL market opportunity to \$1.28B by 2027.

### 3<sup>rd</sup> Line DLBCL Revenue Model

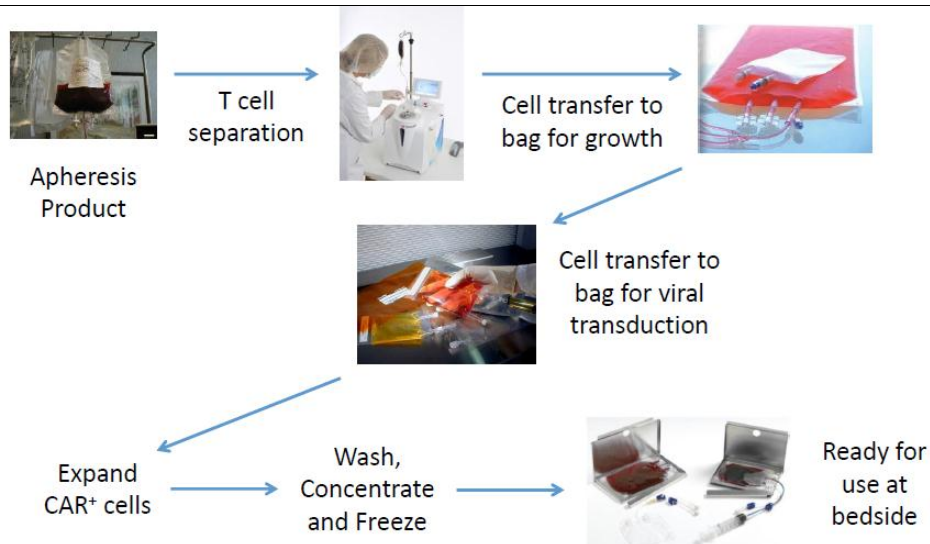
U.S.	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
# of new DLBCL cases	23,562	23,798	24,036	24,276	24,519	24,764	25,012	25,262	25,514	25,769
% on Third Line Therapy	34%	34%	34%	34%	34%	34%	34%	34%	34%	34%
# on Third Line Therapy	8,011	8,091	8,172	8,254	8,336	8,420	8,504	8,589	8,675	8,762
% of Patients Treated with KTE-CD19 Cells	2%	5%	10%	18%	25%	30%	33%	35%	37%	37%
# of Patients Treated with KTE-CD19 Cells	200	397	800	1,465	2,068	2,505	2,799	2,988	3,187	3,273
Price per Initial Dose (\$000)	\$250	\$255	\$260	\$265	\$271	\$276	\$282	\$287	\$293	\$299
U.S. KTE-CD19 Revenue (\$MM) from Initial Dosing	\$50.0	\$101.2	\$208.0	\$388.7	\$559.7	\$691.5	\$788.1	\$858.1	\$933.6	\$977.7
# of Continuing DLBCL KTE-CD19 Patients		117	334	760	1,524	2,552	3,721	4,931	6,117	7,288
% of Patients in Need of Redosing		10%	10%	10%	10%	10%	10%	10%	10%	10%
# of Repeat Doses		12	33	76	152	255	372	493	612	729
Price per Repeat Dose (\$000)		\$150	\$153	\$156	\$159	\$162	\$166	\$169	\$172	\$176
U.S. KTE-CD19 Revenue (\$MM) from Redosing		\$1.8	\$5.1	\$11.9	\$24.3	\$41.4	\$61.6	\$83.3	\$105.4	\$128.1
Total DLBCL U.S. KTE-CD19 Revenue (\$MM)	\$50.0	\$102.9	\$213.1	\$400.6	\$583.9	\$732.9	\$849.7	\$941.4	\$1,039.0	\$1,105.8
R.O.W.										
R.O.W. KTE-CD19 Sales (\$MM)	\$0.0	\$10.29	\$59.7	\$172.2	\$280.3	\$395.8	\$501.3	\$574.3	\$644.2	\$696.7
As a % of U.S. Sales	0%	10%	28%	43%	48%	54%	59%	61%	62%	63%
Kite Royalty	20%	20%	20%	20%	20%	22%	22%	25%	25%	25%
R.O.W. KTE-CD19 Revenue (\$MM)	\$0.0	\$2.1	\$11.9	\$34.4	\$56.1	\$87.1	\$110.3	\$143.6	\$161.0	\$174.2
Total WW KTE-CD19 Revenue (\$MM)	\$50.0	\$105.0	\$225.0	\$435.0	\$640.0	\$820.0	\$960.0	\$1,085.0	\$1,200.0	\$1,280.0
% growth Y/Y		110%	114%	93%	47%	28%	17%	13%	11%	7%

Source: Cowen and Company

### Manufacturing KTE-C19 Is Not Simple

NCI developed the initial multistep process by which lymphocytes are isolated from a patient and converted into an anti-CD19 CAR T cell therapy ready for reintroduction into the patient. In general terms, this process begins by apheresing a patient. The apheresis product is then sent from the clinic to the manufacturing facility where a ficol separation is performed to enrich for lymphocytes. The T cells are then activated *in vitro* by anti-CD3 antibodies. Activated T cells are subsequently transduced using a gammaretrovirus expressing the CAR construct of interest. Transduced cells are then expanded, washed and concentrated. Concentrated CAR T cells can then be sent to the clinic for immediate use or potentially frozen for future use.

### CAR T Cell Production Schematic

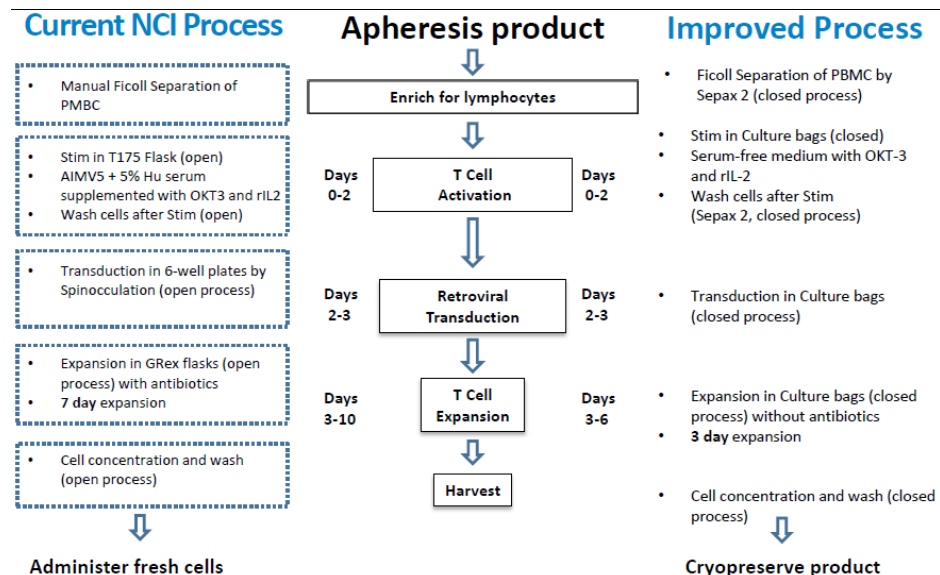


Source: Kite Pharma

Kite believes the current NCI production process contains multiple inefficiencies and/or steps containing unnecessary risk factors. First, NCI currently performs the initial lymphocyte enrichment using a manual ficoll separation. Kite and NCI have worked together to transition this step to an automated machine. The initial T cell activation is currently performed in undefined culture media containing human serum. Kite believes that this introduces reproducibility risks which can be eliminated by transitioning to defined serum-free media. In addition, the current protocol performs all tissue culture procedures in flasks and plates which require an open system subject to contamination. Kite has improved this process by utilizing tissue culture bags, which close off the tissue culture from the surrounding environment and reduce the risk of contamination. As a result, Kite believes it is also able to remove antibiotics from the post-transduction growth media. The post-transduction T cell expansion step has also been optimized to shorten it from up to 10 days down to as few as 3 days. Finally, Kite has developed a cryopreservation protocol that it believes will allow for long term storage of CAR T cell products. While all of these improvements should shorten production timelines and generate a more reliable product yield, it is possible an unrecognized component of the existing protocol is required to generate the efficacy signal observed in the NCI trial. As such, a manufacturing protocol transition does introduce risk to the program. Nonetheless, many of these improvements are likely to be required to generate a commercially viable production line. Therefore, it is best that Kite addresses these hurdles early on. In addition, these process improvements have allowed Kite to generate intellectual property surrounding the manufacturing process in addition to the product itself.

Significantly, Kite is not altering the gene construct or the expression vector from the NCI trial. Therefore, as long as Kite can demonstrate that the end products are consistent the FDA should accept the NCI trial data in conjunction with the Kite trial data in DLBCL. To reach this goal, Kite has defined the KTE-C19 product as CD19 specific CAR T cells exhibiting a defined ratio of naïve, T<sub>CM</sub>, T<sub>EM</sub>, and T<sub>EFF</sub> cells. The frequency of each T cell subset is determined by using flow cytometry to identify CD3<sup>+</sup>CD45RA<sup>+</sup>CCR7<sup>+</sup> cells. Kite and NCI have extensively characterized the improved “Kite” process, but its end products have not been administered to patients.

## CAR T Cell Production Schematic



Source: Kite Pharma

Kite is developing a relationship with the CMO Progenitor Cell Therapy (PCT) to conduct the manufacturing of KTE-C19 using the Kite process. Manufacturing and documentation training is expected to be completed by August 2014. Following this step, the engineering and process qualification for GMP certification is expected to be completed by November 2014. This will allow for Kite to file its own IND for KTE-C19 in Q4:14. In the meantime Kite is working with NCI to deploy this process under the auspices of the NCI's IND. This will allow the Stanford and UCLA medical centers to begin enrolling patients into NCI's cohort 3. Successful expansion of the NCI IND will provide Kite with experience organizing the shipment of cellular products and streamline the site opening process for Kite's planned DLBCL trial.

Given the complexity of the manufacturing process we conservatively model Kite's future COGS as approximately 30%. However, management believes it can achieve COGS as low as 15%. On the positive side, we expect the complexity of the production process and the regulatory hurdles created by such complexity are likely to keep biosimilar competition at bay well after KTE-C19's patents expire. For this reason, we think KTE-C19 is best valued on an NPV basis that credits the drug for its longer-term terminal value. Using a discount rate of 15%, a terminal growth rate of -5%, and assuming KTE-C19 revenues are only achieved in the above outlined opportunity in 3<sup>rd</sup> line DLBCL, we model a NPV of \$43/share.

3<sup>rd</sup> Line DLBCL DCF

Financial Year End	12/31/2014
Valuation Date	7/9/2014
Discount Rate	15.0%
Terminal Growth Rate	-5.0%

KTE-C19: NPV Valuation

Wednesday, July 09, 2014

\$MM	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
<b>KTE-CD19 Revenue</b>	0	0	0	0	2	50	105	225	435	640	820	960	1,085	1,200	1,280
<i>Growth (%)</i>									93%	47%	28%	17%	13%	25%	20%
<b>Collaborative and Grant Revenue</b>	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
<i>Growth (%)</i>															
<b>Total Revenues</b>	0	0	0	0	2	50	105	225	435	640	820	960	1085	1200	1280
<i>Growth (%)</i>						2400%	110%	114%	93%	47%	28%	17%	13%	11%	7%
<b>COGS</b>	0	0	0	0	1	15	32	68	131	192	246	288	326	360	384
<i>COGS as a % of sales</i>					35%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
<b>R&amp;D</b>	5	8	37	58	60	64	79	90	109	115	82	77	65	48	38
<i>R&amp;D as a % of Revenues</i>						128%	75%	40%	25%	18%	10%	8%	6%	4%	3%
<b>SG&amp;A</b>	1	8	12	14	70	80	95	113	131	147	156	163	168	174	179
<i>SG&amp;A as a % of Revenues</i>						160%	90%	50%	30%	23%	19%	17%	16%	15%	14%
<b>Operating Income</b>	(6)	(16)	(49)	(72)	(129)	(109)	(100)	(45)	65	186	336	432	526	618	678
NOL Balance	(10)	(27)	(76)	(148)	(276)	(384)	(484)	(529)	(529)	(464)	(278)				
NOL/Tax Assets Utilized	0	0	0	0	0	0	0	0	65	186	275				
Taxable Income	0	0	0	0	0	0	0	0	0	0	61	432	526	618	678
<i>Tax rate</i>	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%	35%
<b>Taxes Paid</b>	0	0	0	0	0	0	0	0	0	0	21	151	184	216	237
<i>Effective Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	6%	35%	35%	35%	35%
<b>Approx Free Cash Flow</b>	(6)	(16)	(49)	(72)	(129)	(109)	(100)	(45)	65	186	315	281	342	402	441
Years	-0.52	0.48	1.47	2.48	3.48	4.48	5.47	6.48	7.48	8.48	9.47	10.48	11.48	12.47	13.47
Discount Factor	1.08	0.94	0.81	0.71	0.62	0.53	0.47	0.40	0.35	0.31	0.27	0.23	0.20	0.17	0.15
<b>NPV of Cash flows</b>	(6)	(16)	(49)	(72)	(129)	(109)	(100)	(45)	65	186	315	281	342	402	441

Terminal Value Calculation

Final year FCF	441
Perpetual Growth Rate	-5%
<b>Terminal Value</b>	<b>2095</b>
Discount Factor	0.15
<b>Present Value of Terminal Value</b>	<b>319</b>
<b>Present Value of Cash Flows</b>	<b>1,512</b>
<b>Enterprise Value</b>	<b>1,830</b>
Add: Net cash	201
<b>Market Value</b>	<b>2,031</b>
Fully Diluted Shares Outstanding	47.0
<b>Value per Fully Diluted Share</b>	<b>\$43.21</b>

Source: Cowen and Company.



## Additional eACTs Ready For Takeoff

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In addition to KTE-C19, Kite has partnered with NCI to generate a number of candidate eACTs. Most advanced of the CAR programs is an EGFRvIII CAR which is in an NCI-led Phase I/II trial for glioblastoma. Kite and NCI are also developing TCR product candidates specific for NY-ESO-1, MAGE, and SSX2. The NY-ESO-1 product is currently in an NCI-led Phase I/II trial for synovial carcinoma.

### EGFRvIII CAR

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EGFRvIII is an oncogenic mutation of the epidermal growth factor receptor (EGFR) that causes it to be constitutively active. In addition to causing excessive proliferation within EGFRvIII expressing cells, the mutation confers resistance to radiation and chemotherapy. EGFRvIII also causes IL-6 to be produced. IL-6 is believed to lead to excessive proliferation in bystander cells, which do not contain the EGFRvIII mutation. Due to all of these factors, expression of EGFRvIII has been associated with poor outcomes for glioblastoma patients. Kite and NCI have developed a CAR construct specific for EGFRvIII. This CAR is considered a third-generation CAR because in addition to the CD28 costimulatory domain it also contains a 4-1BB costimulatory domain. Kite is funding an NCI-sponsored Phase I/II trial utilizing this construct in glioblastoma patients. In this trial, patients are being pretreated with a non-myeloablative but lymphoid depleting conditioning regimen of cyclophosphamide and fludarabine. Following the conditioning regimen patients are treated with autologous EGFRvIII CAR T cells plus IL-2. Management reports that the NCI has enrolled 14 patients, and Kite expects to file its own IND in 2016. Kite has already obtained an exclusive license for the use of the CAR in brain cancer, head and neck cancer, and melanoma. Kite also obtained a co-exclusive license from NIH to develop the EGFRvIII CAR against additional cancers. Management believes it may also need to acquire additional IP from a third party regarding the EGFRvIII CAR's scFv target binding site on EGFRvIII.

### NY-ESO-1 TCR

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NY-ESO-1 is a testis antigen which is also expressed in 80% of synovial cell sarcomas and 10-50% of metastatic melanomas, breast, prostate, thyroid, and ovarian cancers. While healthy testis express NY-ESO-1 they do not express MHC class I molecules. Therefore, T cells expressing TCRs specific for NY-ESO-1 presented by MHC class I molecules should not be capable of recognizing and attacking the testes. Kite and NCI have collaborated on developing a murine derived TCR construct which recognizes NY-ESO-1 when presented within the context of the MHC molecule. Kite is funding a Phase II trial which will administer autologous T cells expressing the murine NY-ESO-1 TCR along with IL-2 to approximately 43 HLA-A2 positive patients with NY-ESO-1 positive metastatic cancers. Prior to infusing the T cells, patients will be treated with a non-myeloablative lymphodepleting conditioning regimen of cyclophosphamide and fludarabine. Management reports that as of March 2014, NCI has enrolled 2 patients and initial data is expected in 2015. NCI has granted Kite an exclusive license for the use of this construct in any NY-ESO-1 expressing cancer.

### NCI CRADA Is A Clinical Pipeline Generator

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Under the auspices of the CRADA, Kite has also developed additional TCR based products which have been publicly disclosed. The most advanced of these products are a pair of TCR constructs which target melanoma associated antigen (MAGE) in HLA-A1 and HLA-DP4 positive patients. NCI is currently conducting a Phase I/II trial

and has enrolled one patient. Initial data from this trial is expected in 2015. Under the CRADA an earlier MAGE TCR was produced that unexpectedly targeted healthy brain tissue as well. Consequently, Kite and the NCI have cancelled development of this construct.

A TCR product targeting SSX2 in HLA-A2 positive patients is also being developed. Greater than 95% of synovial sarcoma tumors contain a chromosomal translocation that links SYT with either SSX1 or SSX2. Mouse models indicate that these translocations are oncogenic. Kite has acquired an exclusive license for the use of this construct in head and neck cancer, hepatocellular carcinoma, melanoma, prostate cancer, and sarcoma. Kite plans to fund a Phase I/II trial at NCI but this trial has not yet begun enrolling patients.

### Competitor eACT Franchises Being Built

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In recent years the development of methods to harness the power of the immune system to kill tumors has become one of the most active areas of pharmaceutical development. Hence it is not surprising that Kite has a number of small and large competitors in the eACT space. While each approach differs and there are overlaps between players in terms of antigen selection and/or IP, we believe eACT represents such a broad and wide-open opportunity across a number of cancers and potentially other areas of medicine (infectious disease and autoimmunity) that each company is more likely to succeed or fail on its own merits rather than as a result of the actions of other players.

### Adaptimmune/GSK

Adaptimmune is a private company based in the UK focused on developing T cell therapies for cancer and infectious diseases. Adaptimmune uses Immunocore's TCR affinity selection methods to develop engineered TCRs with high affinity for antigens of interest. Adaptimmune's lead candidate is a human TCR specific for NY-ESO-1 which has been developed under a non-exclusive license from NCI. We believe NCI's studies using Adaptimmune's product provide validation of the NY-ESO-1 antigen as a clinically relevant target within both synovial cell sarcoma and melanoma. Robbins et al.'s 2011 paper in the Journal of Clinical Oncology reports results of NCI studies using Adaptimmune's product in synovial cell carcinoma and melanoma. At this time, the NCI observed objective responses in 4 out of 6 (67%) synovial cell sarcoma and 5 out of 11 (45%) melanoma patients treated with autologous cells expressing Adaptimmune's human NY-ESO-1 TCR construct. No treatment-related adverse events were observed. At AACR 2014, Dr. Steven Rosenberg provided an update to the efficacy data from this trial. In this larger data set, objective responses were seen in 10 out of 15 (67%) synovial cell sarcoma patients as well as in 10 out of 19 (53%) metastatic melanoma patients. Kite management reports that its murine NY-ESO-1 TCR construct demonstrates comparable or enhanced efficacy in preclinical studies. Adaptimmune is currently conducting proof of concept trials of the human NY-ESO-1 TCR in multiple myeloma, melanoma, sarcoma, and ovarian cancer.

In June 2014, GSK entered into a collaboration agreement with Adaptimmune to co-develop Adaptimmune's NY-ESO-1 product and additional unspecified TCR products. Under the agreement GSK will fund development work over the next 7 years with payments in excess of \$350MM. In addition, GSK possesses options on all funded programs which would lead to royalties of single to double digits on net sales.

### bluebird bio/Celgene/Baylor

In March 2013, bluebird entered into research collaborations with Baylor College of Medicine and Celgene to develop CAR T cells. This partnership brings together Celgene's oncology drug development experience, bluebird's expertise working with lentiviral vectors, and the CAR T cell experience of Baylor's Dr. Malcolm Brenner and colleagues. The partners are currently deciding on indications, and plan to attack both liquid and solid tumors. Details on the development plan are expected in 2015, with an initial candidate expected to enter the clinic by H1:16. Under the terms of the deal, bluebird received a \$75MM upfront fee and will be responsible for funding and developing candidates through the end of Phase I. Celgene then has the option, on a per-candidate basis, to license the product. The option fee plus future milestones total up to \$225MM per program, and bluebird is also entitled to mid-single digit to mid-teens royalties on sales, though bluebird retains the right to opt in to a 50/50 U.S. co-development, co-promotion and profit share. The deal was signed for an initial three year term (until March 2016). Celgene has the right to extend the term twice, for an initial further two years, and then for one additional year, in each case for an additional payment.

Details of bluebird and Celgene's CAR construct design and manufacturing approach are largely lacking. However, Baylor's Dr. Brenner is at the forefront of developing inducible caspase systems for modified T cells so that apoptosis can be triggered on command. In addition, Dr. Brenner has published data showing that CAR co-stimulation can also be provided by native TCRs specific for chronic viral infections such as EBV. Therefore, it is possible that bluebird/Celgene's CAR products will be designed quite differently from Kite's and include elements such as a suicide gene and/or be restricted to T cells with particular preexisting specificities.

### Collectis/Servier/Pfizer

Collectis (ALCLS) is a preclinical French company developing allogeneic CAR T cells. By utilizing allogeneic cells, Collectis could ultimately provide an off-the-shelf solution to physicians thereby avoiding the complication of shipping patient samples back and forth between the clinic and manufacturing facility and potentially providing economies of scale. However, using allogeneic cells also creates complications once the cells are inside a patient. First, the donor T cells could utilize their native TCR to recognize and attack the patient's healthy cells, causing graft versus host disease. Consequently, Collectis intends to use gene editing to knock out the native TCR from donor cells. CD52 is also knocked out simultaneously so that campath (alemtuzumab) can be used as a selection marker. Finally, as an added safety measure a portion of the CD20 gene is added as a suicide gene. This allows clinicians to treat a patient with rituxan to kill off any allogenic T cells present within the patient.

Collectis' lead pipeline candidate is an anti-CD19 CAR construct. Management expects to initiate a Phase I trial in 2015. In February 2014, Collectis entered into a partnership agreement with Servier for this construct along with 5 undisclosed targets. Collectis received an upfront payment of \$10MM, with development and commercialization milestone payments of up to \$140MM for each product as well as a royalty.

In June 2014, Collectis signed a collaboration agreement with Pfizer to develop CAR T cell therapies for up to 15 oncology targets selected by Pfizer. For these 15 targets Pfizer has the exclusive rights to Collectis' constructs. In addition, Pfizer has a right of first refusal on an additional 4 targets which Collectis is independently developing. In return for these rights, Collectis received an \$80MM upfront fee, full research and development funding for all 19 targets, development, regulatory, and commercial

milestones of up to \$185MM per Pfizer target, and tiered royalties on any product Pfizer commercializes. Finally, Pfizer also plans to take an approximately 10% equity position in Collectis.

### Juno Therapeutics

Juno is a privately held, clinical stage eACT company that (like Kite) has the goal of developing both CAR and TCR based autologous eACTs. Juno was founded with intellectual property from Memorial Sloan Kettering Cancer Center, Fred Hutchinson Cancer Research Center, and Seattle Children's Research Institute. In addition to contributing intellectual property, each of these institutions formed research collaborations with the company at its founding. Currently, each collaborating institution performs its own manufacturing and while all are developing a CD19 CAR T cell there are differences between each institution's product. Additionally, Juno has added intellectual property from St. Jude Children's Research Hospital which covers the use of the 4-1BB costimulatory domain in CAR constructs. This patent is the subject of a lawsuit between St. Jude (and now Juno) and the University of Pennsylvania (and now Novartis).

Memorial Sloan Kettering Cancer Center isolates CD3+ cells from peripheral blood and then transfects these with a CD19 CAR containing the CD28 costimulatory domain. This is similar to Kite's process in that specific T cell subsets are not isolated before transfection. As a result, the transfected T cell subsets infused into a patient resemble the preexisting populations within that patient. Juno refers to this product as JCAR15. JCAR15 is in Phase I/II trials for ALL where it has generated 16 complete responses in 21 evaluable patients (76%). JCAR15 is being used in Phase I/II trials for NHL generally and CLL specifically.

Dr. Stan Riddell at The Fred Hutchinson Cancer Center has published work that suggests specific T cell subsets are the key to generating an anti-tumor response. In particular, his work advocates that CD8 central memory T cells ( $T_{CM}$ ;  $CD8^+CD62L^+CD7^+$ ) and helper T cells ( $T_H$ ;  $CD4^+CD25^-$ ) are most important. Therefore, the Fred Hutchinson manufacturing process isolates just  $T_{CM}$  and  $T_H$  cells from a patient. The isolated T cells are transfected with a CAR construct which utilizes the 4-1BB costimulatory domain. In addition to the CAR protein, the Fred Hutchinson construct also contains a suicide gene to mitigate the risk of excessive CAR T cell expansion and/or allow for the eventual return of B cells to a patient's peripheral blood. Juno refers to this product as JCAR14. JCAR14 is in Phase I/II trials for NHL and ALL. Data from 6 patients has been reported from the NHL trial. Of these 6 patients, 5 experienced complete responses (83%) and management reports that the single non-responder self-administered steroids the night prior to receiving JCAR14. These steroids may have blunted the expansive potential of the JCAR14 cells.

Seattle Children's is utilizing a third approach to generating CD19 specific CAR T cells. Seattle Children's isolates all CD4 and CD8 T cells from peripheral blood. Following isolation, the T cells are transfected with a CAR construct containing the 4-1BB costimulatory domain. Juno refers to this product as JCAR17. JCAR17 is currently in Phase I/II trials for pediatric CD19+ tumors and ALL.

Juno is also developing TCR-based eACTs in collaboration with Dr. Phillip Greenberg at Fred Hutchinson. This work focuses on identifying TCRs capable of binding antigens of interest and then modifying the epitope binding domain to maximize target recognition. Dr. Greenberg has brought forward a WT1 specific TCR construct for a Phase I/II trial in relapsed AML, myelodysplastic syndrome or CML.

### Novartis/Penn

In 2012, Novartis formed an R&D partnership with the University of Pennsylvania to develop CAR based T cell therapies. Under the terms of this partnership Novartis received rights to CART-19 (a CD19 specific CAR) and any subsequent products developed under the partnership. Novartis has since renamed the CART-19 product CTL-019. To manufacture CTL-019, CD4 and CD8 T cells are isolated and transfected with the CAR construct of interest. The CTL-019 construct contains a costimulatory domain from 4-1BB. CTL-019 has generated impressive Phase I/II results in CLL and ALL. In refractory CLL, Novartis has reported a response rate of 47% among 32 patients. Meanwhile, in ALL Novartis has observed a response rate of 90% among 30 patients. This has led to the FDA granting CTL-019 a breakthrough therapy designation in ALL. Novartis plans to begin a pivotal trial in ALL in 2014, with an NDA targeted for 2016.

Novartis/Penn is also developing CARs directed against Mesothelin (MesoCART) and EGFRvIII. MesoCART is currently enrolling Phase I trials in mesothelioma and pancreatic cancer. The EGFRvIII CAR is expected to begin a Phase I trial in glioma during Q3:14.

## *Valuation Methodology And Risks*

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### **Valuation Methodology**

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#### **Biotechnology:**

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

### **Investment Risks**

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#### **Biotechnology:**

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

### **Risks To The Price Target**

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Kite Pharma is unprofitable, has no approved products, and will likely need to raise additional capital from the public markets prior to turning profitable. There is limited clinical trial experience on lead candidate KTE-C19, and eACT's more broadly. Moreover, KTE-C19 faces a number of clinical, regulatory, and commercial hurdles prior to becoming successful, and projecting any future sales for KTE-C19 is inherently difficult.

# Addendum

## Stocks Mentioned In Important Disclosures

Ticker	Company Name
KITE	Kite Pharma
RLYP	Relypsa
SNSS	Sunesis Pharmaceuticals

## Analyst Certification

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**Market Perform (2):** The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

**Underperform (3):** Stock is expected to achieve a total negative return of at least 10% over the next 12 months

**Assumption:** The expected total return calculation includes anticipated dividend yield

### Cowen and Company Rating System until May 25, 2013

**Outperform (1):** Stock expected to outperform the S&P 500



**Neutral (2):** Stock expected to perform in line with the S&P 500

**Underperform (3):** Stock expected to underperform the S&P 500

**Assumptions:** Time horizon is 12 months; S&P 500 is flat over forecast period

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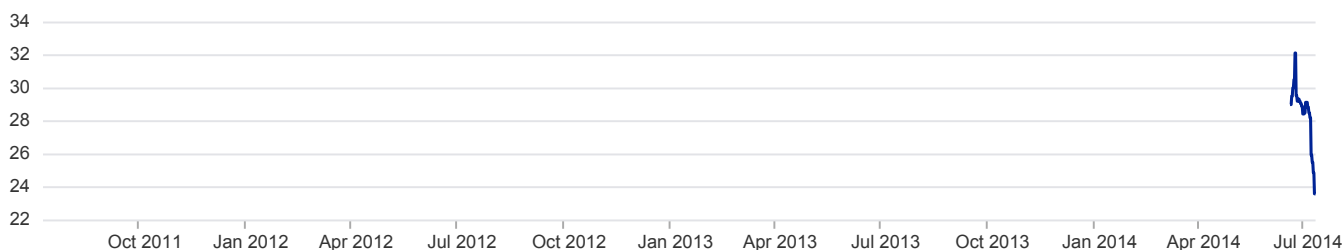
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	417	58.57%	94	22.54%
Hold (b)	279	39.19%	7	2.51%
Sell (c)	16	2.25%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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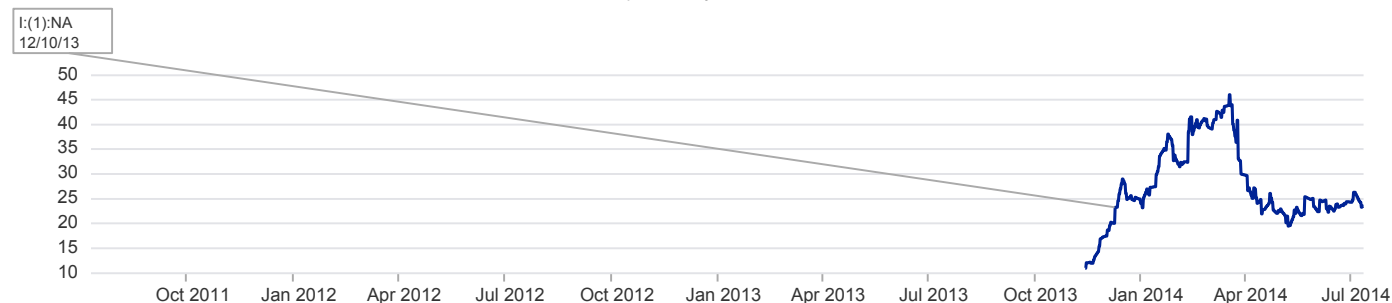
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— Closing Price — Target Price

### Relypsa Rating History as of 07/11/2014

powered by: BlueMatrix



— Closing Price — Target Price

### Sunesis Pharmaceuticals Rating History as of 07/11/2014

powered by: BlueMatrix



— Closing Price — Target Price

Rating Change - 2/21/2006 - Outperform Rating

#### Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available | S=Suspended

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