

Biotechnology

### Kite Pharma

**Equity Research** 

June 1, 2015

Price: \$55.15 (05/29/2015)

Price Target: NA

#### **OUTPERFORM (1)**

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#### **Key Data**

Symbol NASDAQ: KITE Market Cap (MM) \$2,374.7

Quick Take: Company Update

# KTE-C19 Heading Into Open Waters, Much More Below The Surface

#### The Cowen Insight

In conjunction with ASCO we hosted a dinner with senior Kite management. KTE-C19 is enrolling patients into a potentially pivotal Phase I/II trial. Management indicates its solid tumor pipeline has generated responses and is set for further expansion. We continue to view Kite as a leader in immune oncology and remain at Outperform.

#### Laying The Foundation To Be A Major Player In IO

Last night we hosted an investor dinner with Kite's CEO Arie Belldegrun, CMO David Chang, and other senior members of the clinical development team. In the past 18 months Kite has raised ~\$500MM, expanded from 6 employees to 100+, signed a collaboration with Amgen, and now begun a potentially pivotal trial on KTE-C19. Management reviewed what it has learned about engineered T cells and where it sees the field heading as it approaches commercialization in 2017. Our discussions included data on the persistence of CARs, KTE-C19's pivotal trial, Kite's engineered T cell programs in solid tumors, and the future direction of Kite's NCI and Amgen collaborations.

#### **Long-Term Persistence Not Required For Durable DLBCL Responses**

Management reviewed the results of a correlative analysis that was presented in a poster session at ASCO. Kite conducted an in-depth analysis of samples from 29 DLBCL patients treated with CD19-CAR T cells at the NCI. Among these patients, 22 responses (11 CRs and 11 PRs) were observed. Responders were divided into two groups. The first representing those with responses lasting <1yr (n=10) and the second representing ongoing responses of at least 1yr (n=11). Both patient groups had median peripheral CD19 CAR T cell persistence of 29 days. In fact, the responder with the longest T cell persistence (184 days) experienced a response lasting <1yr. Conversely the responder with the least persistency (11 days) has an ongoing response of >1yr. In addition, 7/11 long-term responders have experienced B cell recovery and are no longer using prophylactic immunoglobulin therapy. This further indicates that long-term maintenance of a peripheral CD19 CAR population is not necessary for a durable response in DLBCL. Kite's data in DLBCL stands in contrast to statements from Juno and Novartis' collaborators at Penn regarding their datasets in ALL. It is not clear if the disparate conclusions regarding persistency is due to (1) differences in cellular therapies, (2) differences in the indications studied, or (3) the limited size of the datasets.

Kite's presentation also examined serum cytokine levels prior to preconditioning, following preconditioning, and following the infusion of CD19-CAR T cells. This analysis revealed that preconditioning causes the body to produce a number of homeostatic cytokines including IL-7 and IL-15. These cytokines are important regulators of T cell expansion. Importantly, data across all CD19 programs indicates that T cell expansion following infusion is highly correlated with the generation of a clinical response. Furthermore, management reports that its extensive work on perfecting the preconditioning regimen has taught Kite how to generate these **Please see addendum of this report for important disclosures.** 

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homeostatic cytokines. Competitor solid tumor programs have generally struggled to generate T cell expansion following the infusion of T cells. We believe this proprietary dataset could be a key enabler for generating solid tumor efficacy.

#### First Corporate CAR T Cell Trial Now Enrolling.

In May, Kite announced that the Phase I portion of its Phase I/II trial on KTE-C19 for refractory diffuse large B cell lymphoma (DLBCL) had enrolled its first patient. The Phase I lead-in is designed to ensure that T cell production outside of NCI is generating similar efficacy and safety data as that previously reported from the NCI. Management intends to present data from this n=6 patient cohort at ASH 2015. The company will also press release the start of the Phase II portion of the trial. In the meantime, no news from the study is good news as any major safety or efficacy challenges that might merit a change in strategy would need to be disclosed. For competitive reasons, management is not disclosing the chemotherapy conditioning regimen or cell dose, but Kite did say that T cells expanded for six days appear to have optimal properties for transplantation, so where possible (assuming enough T cells can be collected) we assume Kite is employing a six day T cell expansion process. Management noted that enrollment does not appear to be an issue as centers are highly interested in participating. Nonetheless the company will limit the pace of the study to ensure logistics are smooth and protocols are followed closely. Kite remains on track to start Phase II trials of KTE-C19 in MCL, ALL, and CLL in 2015 using the optimized Phase I protocol from DLBCL. As with DLBCL, these studies could potentially support registration. In Europe, the acquisition of T Cell Factory has given Kite the necessary resources to develop KTE-C19 on its own. Discussions with the EMA over regulatory strategy are proceeding and clinical development might begin in

Kite is also in the process of building commercial scale (5000 patients/yr capacity) and clinical scale (300 patients/yr capacity) manufacturing facilities in Los Angeles from which to rapidly move promising preclinical product candidates into the clinic and ultimately market without the need for external tech transfer. This will also form a platform to quickly test emerging engineered T cell technologies (e.g. gene editing, switches, etc.) as needed. Last night Kite reported that the 300 patient clinical scale facility will be online within the next month. The commercial scale facility remains ontrack for completion in Q1:16. This will allow for its FDA approval in advance of or simultaneous to KTE-C19's BLA approval.

## Multiple Constructs Have Now Shown Activity In Solid Tumors; Pipeline Getting Bigger

Under its CRADA with the NCI, Kite is conducting a wide-ranging development program. With five CAR/TCR (EGFRVIII, NY-ESO-1, MAGE A3/A6, MAGE A3, and HPV-16 E6) constructs currently enrolling patients and two additional constructs (HPV-16 E7 and SSX2) set to enter the clinic soon, we believe Kite has the broadest clinical pipeline in the engineered T cell space. Importantly, all of these programs are directed at antigens found on solid tumors. We believe it is simply a matter of time before at least one of Kite's programs bears fruit. Last night, Kite indicated that it has observed responses in at least three solid tumor indications. Kite expects NCI will present data from these programs in 2016 once robust datasets have been accrued. Meanwhile the company continues to guide toward disclosing its first solid tumor-directed corporate IND by year end.

Beyond its CRADA with the NCI, management indicates that its Amgen collaboration is also progressing according to plan. Under this collaboration Kite and Amgen will work together on CAR constructs in pairs. Each CAR pair will consist of one Kiteowned program (with a single-digit Amgen royalty) and one Amgen-owned candidate (with a high single to double-digit royalty to Kite). The collaboration is expected to

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result in its first IND filing within 18 months of it being signed. Therefore, the first Kite:Amgen IND should occur around mid-2016. A steady stream of INDs is expected to follow with programs alternating between the Kite and Amgen pipelines.

#### KITE Also Holds A Leadership Position In Neo-antigens.

Termed the "ultimate personalized therapy" neo-antigen T cell therapy refers to autologous T cells that have been engineered to recognize neo-antigens within a specific patient's tumor cells. At ASH 2014, Dr. Rosenberg presented an initial proof-of-concept for how the NCl can conduct the neo-antigen sequencing, TCR isolation, and T cell production required to deliver such a therapy within 10 weeks, Kite believes that in order for this approach to be commercially viable, turn around times will need to be shortened to 4-6 weeks, The company believes the scientific progress in this field is rapid, and it is now just a matter of time before neo-antigen based TCR therapy becomes a reality. It believes clinical trials might be possible within 3-5 years. By virtue of its association with Dr. Rosenberg and Ton Schumacher (Kite Europe), we believe Kite is far and away the leader in this cutting edge area of immune oncology,

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### Valuation Methodology And Risks

#### **Valuation Methodology**

#### **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**

#### **Biotechnology:**

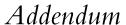
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#### **Risks To The Price Target**

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.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon a 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 it there are any good methodologies for assigning a specific target price to such stocks.

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Ticker	Company Name
KITE	Kite Pharma

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Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

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

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Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

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Buy (a)	450	58.67%	103	22.89%
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Sell (c)	15	1.96%	0	0.00%

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#### Kite Pharma Rating History as of 05/29/2015

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#### 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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