Kite Pharma

Equity Research

Quick Take: Company Update

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Price: $62.72 (06/23/2015)
Price Target: NA

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: KITE
Market Cap (MM)	$2,700.7

Depth Of Scientific Expertise Highlighted At Investor Day

The Cowen Insight

At yesterday's analyst day in NYC, Kite unveiled new technologies, reviewed its scientific foundation and aspirations, and provided a pipeline update. Kite's Phase I/II DLBCL trial continues to enroll patients and an ongoing HPV E6 TCR trial has generated responses in solid tumors. We continue to view Kite as the leader in engineered T cells and remain at Outperform.

Much Progress Has Been Made, But Kite Isn't Resting

Yesterday, Kite hosted an analyst event in New York. Management reviewed the significant progress it has made over the past year since its IPO. Kite has transitioned chimeric antigen receptor (CAR) T cell manufacturing outside of NCI, initiated a potentially pivotal program in DLBCL, begun construction of commercial manufacturing facilities, and significantly expanded its scientific expertise via the acquisition of T Cell Factory, a broadened CRADA with NCI, and collaborations with Amgen and bluebird bio. In addition, Kite set out its vision for the future of engineered T cell therapy. This vision includes new methods for manipulating the activation/ inhibition of T cells, a significant focus on T cell receptor (TCR) -based therapies for shared antigens, and ultimately TCRs specific for an individual patient's neo-antigens.

Kite Is Leading On The Science

There are three major approaches to cancer immunotherapy, (1) nonspecific activation of immune cells via stimulation (e.g. IL-2) or blocking inhibitory signals (e.g. PD-1), (2) immunization (e.g. Provenge, T-Vec), or (3) the transfer of *ex vivo* activated immune cells (eg. TILs, CAR T cells). Kite is focused on developing therapies belonging to the last category of immunotherapies. Specifically, Kite is developing engineered T cells that express CARs or TCRs specific for cancer antigens. Kite highlighted the immense depth of scientific experience in engineered T cells, immunology, oncology, and product development represented across the organization both through internal employees (Drs. Chang, Roberts, and Schumacher) and key external advisors/ collaborators (Drs. Levy, Rosenberg, and Witte). Together these individuals were instrumental in the creation of the first CAR administered to humans (Dr. Roberts), the first successful cancer immunotherapy (Dr. Rosenberg), and multiple revolutionary cancer drugs including Rituxan (Dr. Levy) and Gleevec (Dr. Witte). Kite and others have presented data indicating significant efficacy with CD19 CARs and NY-ESO-1 TCRs. We believe Kite has assembled the team required to make engineered T cells applicable to a broad portion of oncology. To accomplish this goal, Kite's efforts are focused on two primary methods to increase the breadth of tumors addressable by engineered T cells. First is identifying the appropriate cancer specific antigens to attack and second is developing secondary technologies to improve the activity of engineered T cells.

First Generation CARs Are Great But More Is Needed

Kite's collaborators discussed that CD19 is a nearly perfect antigen given its uniform expression across multiple tumor types and restriction to a healthy cell type (B cells) that can live without. Kite and its collaborators believe additional attractive antigens exist. One such antigen is EGFRvIII. Working with NCI, Kite has treated ~15 patients (GBM and head and neck cancers) at NCI using an EGFRvIII CAR construct. Dr. Rosenberg reported that dose escalation has just now reached the level where one could imagine seeing efficacy but that as of now no responses have been observed. Kite's collaboration with Amgen should provide additional attractive CAR candidates. This collaboration is directed at converting Amgen's library of antigen targets and antibody sequences into CAR constructs for the treatment of AML, multiple myeloma, kidney, and lung cancers. The first IND from this collaboration is expected in H2:16. While hopeful for these efforts, Kite and its collaborators noted that 20+ years of antibody development had likely identified the few targets that fit the CD19-like expression criteria. Therefore, Kite is pursuing two mechanisms to broaden the list of potential tumor targets.

Second Generation CAR Therapies Bring Intelligence To The T Cell

First, Kite is working preclinically to develop second generation "logic gated" CAR therapies that require a targeted cell to either simultaneously express two antigens or perhaps more significantly express one antigen but not a second. These engineered T cells will simultaneously express two CAR constructs. In order to introduce an "and" operator the constructs will separately contain the primary stimulation (e.g. CD3) and secondary stimulation (e.g. CD28) signaling domains. Conversely, an "and not" operator can be introduced by using a traditional CAR construct containing both the primary and secondary stimulation domains in combination with a second CAR construct that contains an inhibitory domain. Consequently, if an off-target cell expresses the target antigen but also the inhibitory antigen it will be spared whereas a tumor cell that only expresses the target antigen will be killed. Kite believes second generation CAR therapies are 2-3 years away from the clinic.

TCRs Triple The Potentially Addressable Antigens

Second, Kite is using T cell receptors to pursue the ~75% of proteins that are expressed intracellularly and are therefore inaccessible to antibody recognition. Kite currently has four TCR constructs (NY-ESO-1, MAGE A3/A6, MAGE A3. and HPV-16 E6) in the clinic and plans to initiate clinical trials on at least three additional constructs (HPV-16 E7, SSX2, and KRAS) within the next 18 months.

Kite acquired Dr. Ton Schumacher's T Cell Factory (TCF) to further expand the TCR pipeline. TCF's core TCR GENErator technology allows for the rapid isolation of high-affinity TCR sequences. Since TCR based therapies' target populations are restricted by MHC expression (ex. HLA-A2 is only expressed by ~50% of Caucasians) the TCF technology will be deployed to identify TCR sequences that utilize alternative MHC sequences to target the same antigen. Kite believes three TCR sequences per antigen are sufficient to cover >80% of the global population and approximately five sequences can cover >90% of the global population. In addition, the TCR GENErator will be deployed to identify TCRs specific for neo-antigens being identified under the NCI CRADA. Dr. Rosenberg reports that his lab is able to complete exome sequencing of tumor samples within 48 hours of receiving the sample. Within an additional 48 hours Dr. Rosenberg's group is able to identify the subset of peptides that are actually presented on MHC molecules within the tumor. Dr. Rosenberg has now performed this protocol using samples from >25 melanoma and 16 GI cancer patients. Published data on the melanoma patients indicates that neo-antigens were presented universally, but each patient contained unique neo-antigens. Dr. Rosenberg disclosed that he has since found at least one melanoma patient with shared neo-antigens. Among the GI cancer patients, 15 were found to present neo-antigens.

These neo-antigen profiles have not been published yet. With the TCR GENErator, Kite now possesses a high-throughput manner by which high-affinity TCRs specific to neo-antigen peptides can be isolated. Drs. Rosenberg and Schumacher believe that experience with TIL therapy indicates the simultaneous use of two to three neo-antigen TCR specificities should be sufficient to control many tumors. Kite has previously indicated that this ultimate in personalized medicine could be ready for clinical trials in 3-5 years.

HPV E6 TCR Shows Efficacy In Solid Tumors

Human papilloma virus (HPV) is associated with numerous cancers including anal, head and neck, and the majority of cervical cancers. These cancers lead to ~15,000 deaths/yr in the U.S. Dr. Rosenberg recently published proof of concept data showing durable responses in two out of nine patients treated with HPV specific tumor infiltrating lymphocytes (TILs). Kite and Dr. Rosenberg have followed up these findings with an HPV E6 specific TCR product. Dr. Rosenberg disclosed for the first time that using this construct he has observed "multiple responses". As a result, Kite plans to transition the HPV-16 E6 program from an NCI held IND to a Kite held IND in early 2016.

Kite Is Also Working To Increase T Cell Activity

Beyond expanding the list of antigen targets, Kite is also developing methods by which it can make its T cells more potent. Preclinical studies have shown that IL-7 and IL-15 expression is vital for the engraftment and efficacy of CAR T cells. Working with NCI, Kite has conducted work to optimize the preconditioning regimen for among other parameters the generation of IL-7 and IL-15 expression. Preclinical work has also demonstrated that engineered T cells that have undergone less *ex vivo* differentiation generate superior efficacy. Kite and NCI have developed a small molecule (KTE-SM01) that is capable of decoupling T cell proliferation and differentiation. The identity of KTE-SM01's target was not disclosed, but based upon a literature review we believe it to be an AKT kinase inhibitor. Using KTE-SM01, Kite hopes to generate T cell products that are skewed towards a stem cell memory phenotype. Kite is now working to include KTE-SM01 in its next generation T cell manufacturing protocol.

Kite is also pursuing strategies to combine engineered T cells with additional therapeutic manipulations including checkpoint inhibition and/or coexpression of cytokines. Kite intends to develop a second generation HPV E6 TCR therapy that contains an additional modification(s). Earlier this week, Kite signed a collaboration with bluebird bio for this project. Under the collaboration Kite and bluebird bio will develop an engineered T cell product using (1) Kite's HPV E6 TCR sequence, (2) bluebird's lentiviral delivery system and (3) bluebird's gene editing platform to modify activating/inhibitory pathways. Kite indicated that this project could result in clinical trials in 2-3 years.

KTE-C19's Pivotal DLBCL Trial Progressing Well; More Trials Starting In H2:15

Kite has successfully transitioned production of KTE-C19 from NCI to its contract manufacturer (PTC). Last month, PTC produced cells were used to dose the first patient in Kite's potentially pivotal Phase I/II trial of KTE-C19 in DLBCL. For the Phase I portion, Kite is currently enrolling patients at four clinical sites. If no more than two dose limiting toxicities are observed among the first six patients, Kite will progress to the Phase II portion and enroll 50 patients from 20-25 clinical sites. This is expected to occur in H2:15. Data from the Phase I portion, including the trial's cell dose and preconditioning regimen will be presented at ASH 2015. Phase II data is expected to be released in 2016. Kite believes historical data indicates a <20% ORR and 4-5 month mOS would be expected. Therefore, an ORR of at least 40% with a mOS of at least 6 months is expected to be approvable. Simultaneous to beginning the Phase II

portion of the DLBCL trial, Kite intends to initiate a Phase II trial of KTE-C19 in MCL. Also in H2:15, Kite plans to initiate a Phase I/II ALL trial and a Phase II CLL trial.

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:

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

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.

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Addendum

Stocks Mentioned In Important Disclosures

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

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

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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)	450	58.67%	103	22.89%
Hold (b)	302	39.37%	8	2.65%
Sell (c)	15	1.96%	0	0.00%

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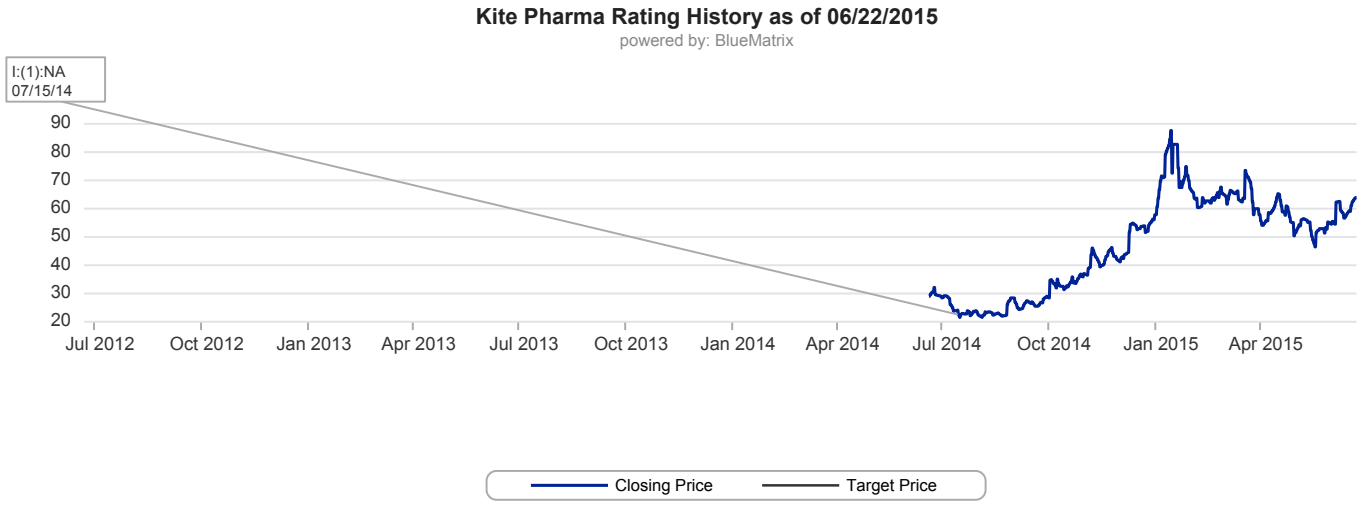

Legend for Price Chart:

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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