

Kite Pharma (KITE)

Kite Shares Its Vision At Analyst Day

BUY

Price target \$83.00

Price \$62.72

Key Takeaway

KITE hosted an analyst day where it reiterated its clinical development plan for KTE-C19, plans to move add'l CAR/TCR targets to clinical trials, and pot'l new strategies to improve T-cell expansion and the introduction of a pot'l CAR to prevent off-target effects on healthy cells. The company is on track to disclosing topline data from the pilot trial enrolling patients with diffuse large B-cell lymphoma (DLBCL) at ASH '15.

KTE-C19 Data At ASH '15: KITE has started enrolling pts in its pilot study with KTE-C19, a CD19 CAR-T in DLBCL this quarter with pivotal trial initiating in Q4. The company acknowledged that it is testing a new lymphodepletion regimen which falls btwn the NCI regimen and the "low" dose regimen presented at ASH '14. Based on data from the pilot study, KITE could modify the lymphodepletion regimen for the pivotal studies and the add'l PII studies evaluating KTE-C19. The company will be requiring all patients in the PII trial to enroll in the hospital for the 1st 7 days after infusion as a pre-cautionary measure and a req't similar to the NCI PI/II study. We think this is a prudent measure which may help address any pot'l toxicity issue(s) that may arise in the DLBCL trial. Based on learnings from this trial, the company may reduce/eliminate this req't longer-term. Interim data from the 1st 50 patients in the pivotal trial would drive a BLA filing by YE '16. KITE expects to complete patient enrollment by YE '16. The 1 EP is ORR with data expected in 2016. KITE also plans to initiate trials in acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL) which would initiate by YE '15.

Pipeline Programs Advance: The National Cancer Institute (NCI) has currently five ongoing trials with various targets with KITE having rights to the following cancer antigen targets - NY-ESO1 and HPV-16 E6 w/ KITE anticipating on filing an IND in 1H '16. The company announced NCI plans to initiate clinical testing w/ a KRAS TCR in pancreatic/colorectal cancer and HPV-16 E7 TCR in cervical cancer in '15. We gained further insights into these programs from NCI's Chief of Surgery Branch, Dr. Steven Rosenberg, who provided his opinions into pot'l optimal targets for solid tumors. Rosenberg believes HPV-16 E6 is de-risked given data in 9 refractory cervical cancer patients treated with TIL therapy and observing 2 CRs and 1 PR with duration of response lasting 22, 15, and 3 mos, respectively (at end of April). Dr. Rosenberg believes EGFRviii could observe activity given the target resides on the tumor cell surface and could be targeted by CAR technology. A trial is currently ongoing evaluating EGFRviii in glioblastoma and have treated 15 patients to date in a slow dose escalation. NCI has not observed any clinical responses however the trial may be somewhat premature given patients have not been treated w/ therapeutic doses. The NCI is also evaluating NY-ESO1 TCR in various tumors and 4 patients have been treated, however, Dr. Rosenberg is less sanguine about the prospects of NY-ESO1 given less than 2% of all patients express the target at less than 50%. In comparison, MAGE A3 could be a better target given it is more commonly expressed. Lastly, Dr. Rosenberg also commented on the UPenn study at AACR evaluating 6 patients w/ mesothelin CAR-T and believes mesothelin may not be an appropriate target given it also is expressed in healthy tissues.

Next Gen Technologies Focused On Improving T Cell Expansion and Preventing Off-Target Effects: KITE introduced two concepts - one focused on generating T cells utilizing pharmacological molecules which may yield younger T cells w/ greater persistence. We think this technology is based on NCI research which focused on Akt inhibition (Crompton et al, Cancer Research 2015) leading to enhanced cell persistence of memory T cells. KITE is also developing a control CAR which at the presence of a healthy cell could signal the self-destruction of the CAR-T cell.

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Company Description

Kite Pharma, Inc. operates as a clinical stage biotechnology company which engages in the development of novel cancer immunotherapeutic products with focus on engineered autologous T cell therapeutics targeted to different tumor types. In addition, the company is advancing a novel therapeutic cancer vaccine aimed to trigger potent and specific immunity against multiple epithelial cancers, which has the potential to complement its eACT programs.

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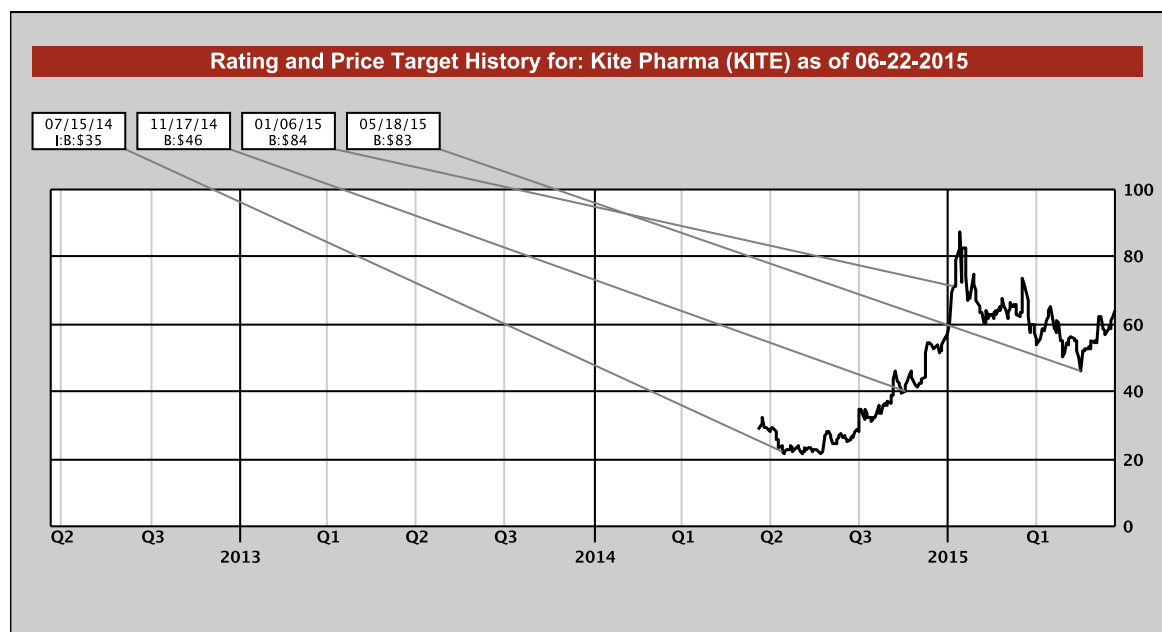
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