

Kite Pharma (KITE)

Updates On NCI CAR-T Programs

BUY

Price target \$35.00

Price \$25.56

Key Takeaway

The NCI recently announced in a public forum w/ key oncology experts its plans to publish from its 20-patient CD19 CAR-T trial in pediatric ALL in Lancet (we est around ASH '14). At last year's ASH, the NCI presented data in 16-patients observing a CR of 67%. Additionally, given KITE's ongoing research collaboration w/ NCI, we want to highlight a new PI CAR-T trial targeting CD22 in pediatric ALL w/ a subgroup that have relapsed on KTE-C19.

Updated Pediatric ALL Data Slated For Lancet: The National Cancer Institute (NCI) plans to publish 20-patients data of CD19 CAR-T (KTE-C19) in Lancet later this year, and we think will coincide w/ ASH (American Society of Hematology). The research group at NCI has disclosed CR's of ~70% and in-line w/ the 67% CR rate observed in 16-patients reported at last year's ASH. The PI/II NCI trial enrolled pts btwn 1-30 years old w/ median age of 13 reported at ASH. Each pt received background therapy of cyclophosphamide/ fludarabine for lymphodepletion and treated pts w/ 1x10 to log6/kg and 3x10 to log6/kg doses.

NCI Plans To Initiate Separate CAR-T In Pediatric ALL: Due to observations from the CD19 CAR-T trial in which approximately 10% of patients relapse w/ CD19 negative leukemia, the NCI has decided to pursue development of a CAR-T targeting CD22 (expressed in >90% of cells in pts w/ ALL), and w/ CD19 negative pts still retaining CD22 expression. As a result, NCI plans to initiate a CD22 CAR-T w/ a similar design as the pediatric ALL PI/II study. The NCI would utilize a second-generation CAR-T w/ CD3zeta/CD28/41BB co-stimulatory domains. The trial will target a std dose-escalation regimen across four doses starting at 1 x 10 to log5/kg and escalating to 3 x 10 to log6/kg. The NCI has modified its production process, which allows it to reduce mfr by 1 day over the previous 10-day process. NCI plans to stratify patients based on receiving prior CD19 CAR-T therapy and believe a subgroup of patients in its ongoing PI/II CD19 ALL trial could be eligible to receive CD22 CAR-T. Given CD22 is highly expressed on B-lineage cells and B-cell lymphoma/leukemia, NCI would hope to observe > 30% CR to move forward into dose expansion phase of the trial. We believe the trial could enroll between 20-30 patients w/ preliminary data by YE '15 and potential KITE license in 2016-2017. We are currently not aware of any other CAR-T companies that have focused on the CD22 target.

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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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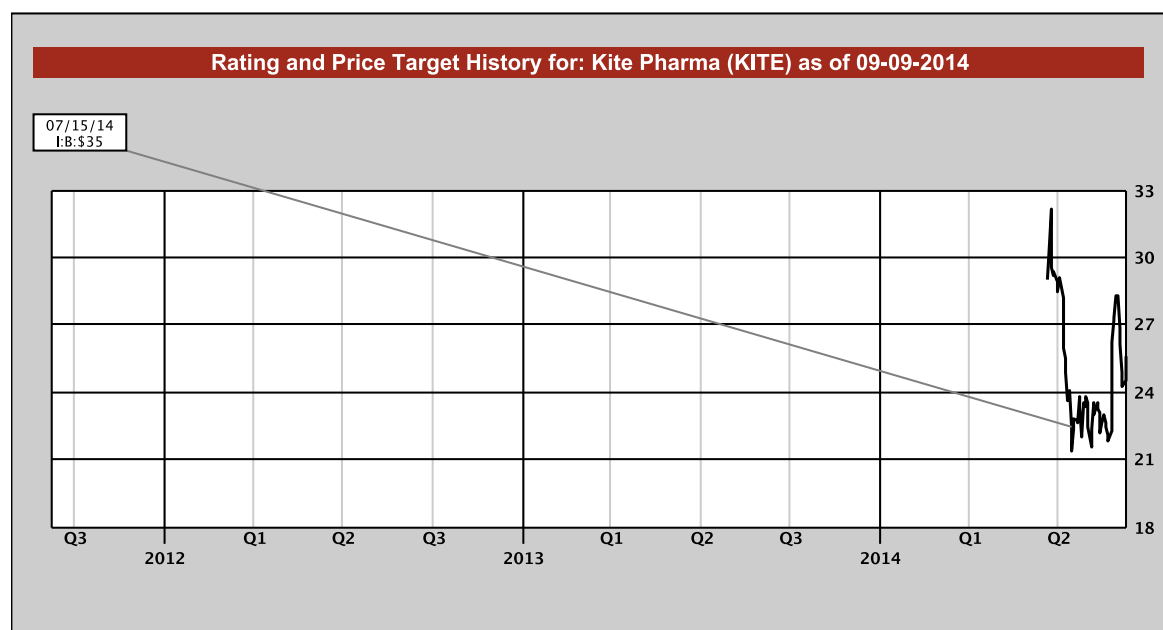
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