

**Kite Pharma, Inc.**

KITE - BUY - KITE at ASCO 2015; If You Only Read One Note  
Read This THREE

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**FLASH NOTE**

SECTOR: Biopharmaceuticals

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**At ASCO 2015, Kite Pharma (KITE, BUY, \$55.15) presented data from a small cohort of patients illustrating that it may be able to discern functional biomarkers that could be predictive of patient responses to CARs.** Autologous CAR-engineered T cell therapy has been shown promising in relapsed/refractory B cell tumors. Kite has evaluated T cell product characteristics and a number of biomarkers in patients treated with anti-CD19 CAR T cells.

In 29 evaluable patients with non-Hodgkin's lymphoma (NHL) or chronic lymphocytic leukemia (CLL), anti-CD19 CAR T cells induced objective responses. The complete response rate was 38% (76% overall response rate). Clearing of CAR-T cells in blood and recovery of normal B cells was frequent in patients with durable clinical responses. This was an outcome we did not expect. Pre-conditioning with cyclophosphamide and fludarabine induced immune homeostatic cytokines (IL-15, IL-7), chemokines (MCP-1), and pro-inflammatory markers including CRP and PLGF. Clinical responders showed *in vivo* expansion of CAR+ T cells to a considerable range of 15-300 CAR+ PBMC/ $\mu$ L within 14 days post-treatment.

Finally, Kite looked at the composition of T cells but not of CAR-T cells post-treatment to determine if manufacturing time in culture of engineered CAR-T cells influenced outcomes.

**Conclusion:**

- Kite was able to conclude that durable clinical responses could occur without long-lasting CAR-T cells in circulation. This allows for normal B cell recovery.
- The method used for pre-conditioning the patient does affect activation and trafficking of T cells. This can be key in clinical trials.
- A shorter manufacturing process produces CAR T cells with higher CD4+ naïve and central memory T cells. Post infusion CAR-T cells showed a diversified population of differentiating T cell as well as naïve T cells.
- CAR-T cell treatment results in elevation and resolution of circulating cytokines within three weeks after treatment.
- The merit of this functional analysis generates the hypothesis that Kite may be able to prognosticate patients that respond better or best with CAR therapy. Similar analyses are ongoing in the in the 112-patient registrational study.

| KITE Anti-CD19 CAR T induced objective responses in pts with r/r NHL and CLL |      |     |
|--|------|-----|
| Tumor type   | ORR  | CRR |
| Any (n=29)   | 76%  | 38% |
| DLBCL/PMBCL (n=17)   | 65%  | 35% |
| CLL (n=7)  | 86%  | 57% |
| Indolent NHL (n=5)   | 100% | 20% |

Source: ASCO 2015 data, Kochenderfer et al, Blood 2012 and JCO 2015 data

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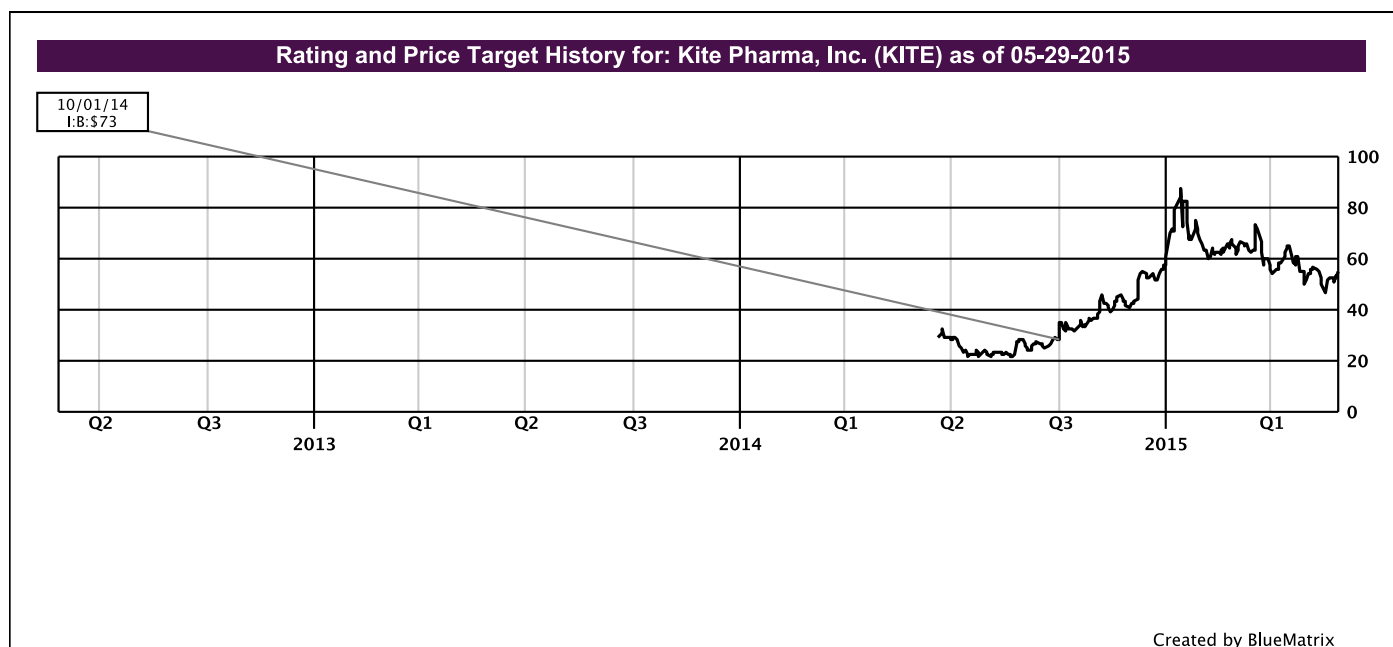
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