

Kite Pharma, Inc.

KITE - BUY - Proof of Concept for Leukemia Necessitates Move into Lymphoma and Leukemia

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FLASH NOTE

SECTOR: Biopharmaceuticals

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Published in the October 13 issue of the *Lancet* (entitled "T cells expressing CD19 chimeric antigen receptors for acute lymphoblastic leukemia in children and adults: a phase I dose-escalation trial"), work in Dr. Crystal Mackall's lab (Division of Pediatric Oncology at the National Cancer Institute) using an anti-CD19 chimeric antigen receptor, or CAR, has demonstrated "proof of concept" in eradicating chemo-resistant leukemia in ALL patients. This is important because KITE (BUY, \$32.56) will be moving forward not only in lymphoma with anti-CD19 T-cell CARs, but also in leukemia. This "proof of concept" broadens KITE's platform and moves a number of programs into clinical development sooner than expected.

Twenty-one heavily pre-treated patients with acute lymphoblastic leukemia or non-Hodgkins lymphoma were enrolled in an intent-to-treat trial and infused with anti-CD19 CAR T cells. Nineteen patients received the prescribed dose whereas two were unable to obtain the required dose assigned. The maximum tolerated dose of anti-CD19 CAR was determined and all patients were assessed for responses.

Response rates were 70 percent, and 60 percent had an MRD-negative complete responses. The patients with MRD-negative responses (ten patients) underwent stem cell transplantation and all ten remain disease free following ten months of follow-up.

While this trial was not a "KITE-sponsored study," it does illustrate that the anti-CD19 construct KITE is using in lymphoma also has utility in leukemia (ALL). Importantly KITE will begin a Phase II study in relapsed/refractory leukemia (ALL) in 2H 2015. This is in addition to other relapsed/refractory lymphoma trials planned for 2015 including DLBCL (diffuse large B-cell lymphoma), PMBCL (Primary Mediastinal Diffuse B-cell lymphoma), TFL (Follicular Lymphoma), and Mantle Cell Lymphoma all in 1H 2015, and CLL (Chronic Lymphocytic Leukemia) in 2H 2015. The overall goal is to address the utility of anti-CD19 CAR T cells not only in lymphoma **but also** in leukemia.

We should see additional data in DLBCL at the American Society of Hematology meetings in December. An IND in DLBCL should be submitted in December as well.

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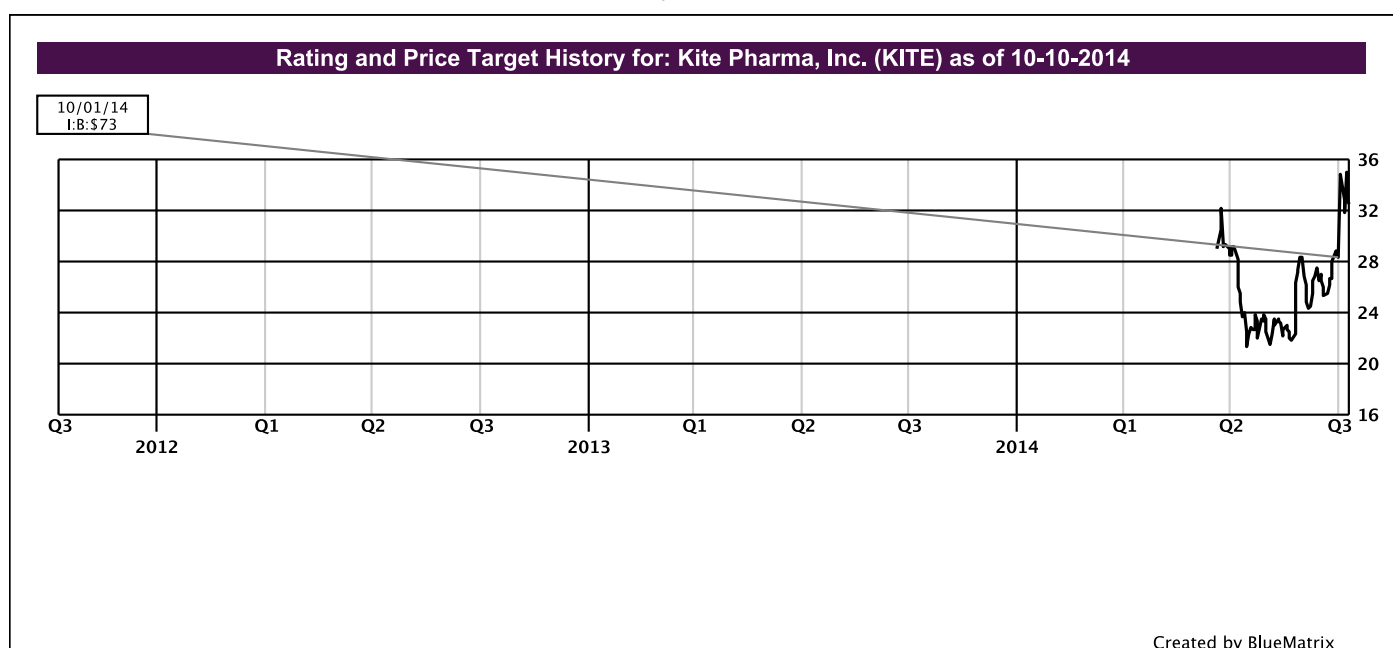
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