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Kite Pharma Presents Ongoing Complete Responses at 9 Months in Phase 1 of ZUMA-1 in Patients with Chemorefractory Non-Hodgkin Lymphoma

CHICAGO--(BUSINESS WIRE)-- Kite Pharma, Inc. (Nasdaq:KITE) ("Kite") today announced updated durability of complete responses in the Phase 1 portion of the ZUMA-1 trial. The study is evaluating KTE-C19 in patients with chemorefractory diffuse large B-cell lymphoma (DLBCL), an aggressive form of non-Hodgkin lymphoma (NHL). KTE-C19 is an investigational therapy in which a patient's T-cells are genetically modified to express a chimeric antigen receptor (CAR) that is designed to target the antigen CD19, a protein expressed on the cell surface of B-cell lymphomas and leukemias. The results will be presented today at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting (abstract #7559).

"Three reported complete remissions in patients with chemorefractory DLBCL after a single treatment with CAR T-cell therapy are still ongoing at nine months. This is remarkable given that single-digit complete response rates are historically observed in patients who do not respond to chemotherapy," said Sattva S. Neelapu, Associate Professor and Director of Translational Research, Department of Lymphoma and Myeloma, The University of Texas MD Anderson Cancer Center. "These results are extremely important as CAR engineered T-cells have the potential to transform the treatment landscape for chemorefractory DLBCL."

The Phase 1 portion of ZUMA-1 treated a total of 7 patients with chemorefractory DLBCL. The results showed that treatment with KTE-C19 achieved rapid and durable responses in patients with chemorefractory disease (objective response rate 71%, complete response rate 57%). Ongoing complete responses were observed in 3 patients after nine months of follow-up. KTE-C19 related adverse events consisted predominantly of cytokine release syndrome (CRS) and neurotoxicity, which were generally reversible. Grade 3 or higher CRS was observed in 14% and neurotoxicity in 57%; all were reversible except in one patient with dose-limiting toxicity.

KTE-C19, currently in Phase 2 clinical studies, has received Breakthrough Therapy Designation and Orphan Drug status from the U.S. Food and Drug Administration for the treatment of patients with chemorefractory DLBCL, primary mediastinal B-cell lymphoma, and transformed follicular lymphoma. The European Medicines Agency has also granted KTE-C19 access to regulatory support under its Priority Medicines (PRIME) initiative for the treatment of DLBCL and Orphan Drug Designation for various hematological indications.

About Diffuse Large B-Cell Lymphoma

According to the American Cancer Society, NHL accounts for about four percent of all cancers in the United States, making it one of the most common cancers diagnosed. DLBCL is the most common form of the disease, accounting for one out of every three cases of NHL.[1] It is estimated that 26,000 people will be diagnosed with DLBCL in the United States in 2016. DLBCL is an aggressive and fast growing lymphoma, but considered curable in patients who respond to initial treatment with a chemotherapy-based regimen. Patients with chemorefractory DLBCL face limited treatment options and historically poor outcomes.

About Kite's ZUMA Clinical Programs for KTE-C19

KTE-C19 is an investigational therapy in which a patient's T-cells are genetically modified to express a CAR that is designed to target the antigen CD19, a protein expressed on the cell surface of B-cell lymphomas and leukemias. Kite is currently enrolling four pivotal studies (also known as ZUMA studies) for KTE-C19 in patients with various B-cell malignancies.

Study	Phase	Indication	Status
ZUMA-1 NCT02348216	Phase 2 Pivotal (N=112)	Chemorefractory DLBCL, PMBCL, TFL	Phase 2 enrolling
ZUMA-2 NCT02601313	Phase 2 Pivotal (N=70)	Relapsed/refractory MCL	Phase 2 enrolling
ZUMA-3 NCT02614066	Phase 1/2 Pivotal (N=75)	Relapsed/refractory Adult ALL	Phase 1/2 enrolling

ZUMA-4 NCT02625480	Phase 1/2 Pivotal (N=75)	Relapsed/refractory Pediatric ALL	Phase 1/2 enrolling

DLBCL = diffuse large B-cell lymphoma
PMBCL = primary mediastinal B-cell lymphoma
TFL = transformed follicular lymphoma
MCL = mantle cell lymphoma
ALL = acute lymphoblastic leukemia

About Kite Pharma

Kite Pharma, Inc. is a clinical-stage biopharmaceutical company engaged in the development of novel cancer immunotherapy products, with a primary focus on engineered autologous cell therapy (eACT™) designed to restore the immune system's ability to recognize and eradicate tumors. Kite is based in Santa Monica, CA. For more information on Kite Pharma, please visit www.kitepharma.com. Sign up to follow @KitePharma on Twitter at www.twitter.com/kitepharma.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the success of KTE-C19 and the ability to advance multiple clinical trials of KTE-C19. Various factors may cause differences between Kite's expectations and actual results as discussed in greater detail in Kite's filings with the Securities and Exchange Commission, including without limitation in its Form 10-Q filed with the SEC on May 9, 2016. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

References:

1. American Cancer Society. Non-Hodgkin Lymphoma.
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Kite Pharma
Greg Mann
VP, Investor Relations
gmann@kitepharma.com
or
For Media:
inVentiv Health
David Polk
310-309-1029
david.polk@inventivhealth.com
or
Anne Cummings
212-845-5632
anne.cummings@inventivhealth.com

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