Kite Pharma Receives Positive Opinion for Orphan Drug Designation in the European Union for KTE-C19, Kite's Lead Cancer T-Cell Immunotherapy

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SANTA MONICA, Calif., Sept. 11, 2015 (GLOBE NEWSWIRE) -- Kite Pharma, Inc. (Kite) (Nasdaq:KITE) announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products(COMP) has adopted a positive opinion recommending KTE-C19 for designation as an orphan medicinal product for the treatment of PMBCL and MCL. KTE-C19 is an investigational therapy in which a patient's T cells are genetically engineered to express a chimeric antigen receptor (CAR) designed to target the antigen CD19, a protein expressed on the cell surface of B-cell lymphomas and leukemias. No other product candidate currently has orphan drug designation for the treatment of PMBCL in the EU. Kite previously received orphan drug designation for KTE-C19 for the treatment of diffuse large B-cell lymphoma (DLBCL) in both the US and the EU.

"The positive opinion for EU orphan designation for PMBCL and for MCL aligns with Kite's leadership in and broad commitment to delivering innovative therapies that have the potential to transform the lives of cancer patients around the world," said Arie Belldegrun, M.D., FACS, Chairman, President and Chief Executive Officer of Kite. "We are conducting a Phase 1/2 clinical trial of KTE-C19 in patients with refractory, aggressive non-Hodgkin lymphoma, including DLBCL and PMBCL, and plan to report initial topline results from the Phase 1 portion of the trial later this year."

The COMP adopts an opinion on the granting of orphan drug designation, after which the opinion is submitted to the European Commission for endorsement of the opinion. Orphan drug designation by the European Commission provides regulatory and financial incentives for companies to develop and market therapies that treat a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the EU, and where no satisfactory treatment is available. In addition to a 10-year period of marketing exclusivity in the EU after product approval, orphan drug designation provides incentives for companies seeking protocol assistance from the EMA during the product development phase, and direct access to the centralized authorization procedure.

About Kite Pharma, Inc.

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.

Kite Pharma, Inc. 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. The press release 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 intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the progress of Kite's product development programs, including of its lead candidate, KTE-C19, and the timing of data disclosure. 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 for the quarter ended June 30, 2015. Any forward-looking statements that are made in this press release speak only as of the date of this press release. Kite assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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