LymphomaHub

DLBCL, FL

The FDA grants KTE-C19 Priority Review for the treatment of transplant-ineligible relapsed/refractory Non-Hodgkin Lymphoma

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On 26th May 2017, KTE-C19 (axicabtagene ciloleucel) was granted Priority Review by the U.S. Food and Drug Administration (FDA) for the treatment of patients who are ineligible for transplant with R/R NHL.

Results of the phase II ZUMA-1 trial (NCT02348216) form the basis of this Priority Review. Preliminary data from the ZUMA-1 trial were presented in April during AACR 2017, which the Lymphoma Hub reported on.

As a result of this Priority Review, a decision on Kite Pharma's Biologics License Application (BLA; submitted in March 2017) for KTE-C19 will be reached 4 months earlier than if under standard review.

Kite Pharma also plan to file for potential approval for KTE-C19 in Europe for R/R DLBCL patients; this application is expected to take place in Q3 of this year.

Reference:

1. Targeted Oncology. KTE-C19 Granted Priority Review by FDA for Non-Hodgkin Lymphoma. 2017 May 26. http://www.targetedonc.com/news/ktec19-granted-priority-review-by-fda-for-nonhodgkin-lymphoma. [Accessed 2017 May 30].