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Fosun Kite gains first CAR T-cell therapy approval in China

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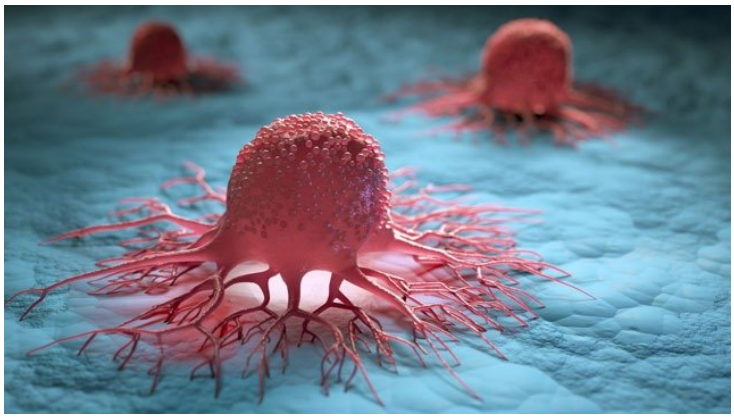
Approval Supported by Positive Results of Multi-center Trial in Chinese Patients



Kite, a Gilead Company, has announced that Fosun Kite Biotechnology Co., Ltd., a joint venture between Kite and Shanghai Fosun Pharmaceutical (Group) Co., Ltd, has received approval from the China National Medical Products Administration (NMPA) for axicabtagene ciloleucel for the treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma (PMBCL), high-grade B-cell lymphoma and DLBCL arising from follicular lymphoma.

Axicabtagene ciloleucel is the first and only commercially available chimeric antigen receptor (CAR) T-cell therapy approved in China.

“In relapsed or refractory LBCL, current standard-of-care is associated with poor long-term outcomes, so we are pleased to offer this new hope of survival for patients in China who are in need of new therapeutic options,” said Terence O’Sullivan, Vice President, International Region at Kite. “Thank you to the dedicated healthcare professionals, patients and caregivers who worked with the team at Fosun Kite to make this treatment option available in China.”

Axicabtagene Ciloleucel, FKC876, is an autologous CD19-directed CAR T-cell therapy manufactured in China under a license to YESCARTA® (Axicabtagene Ciloleucel) from Kite.