STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (DE-33)	AXICABTAGENE CILOLEUCEL
PRONUNCIATION	ax" i kab' ta jeen sye" loe loo' sel
THERAPEUTIC CLAIM	Antineoplastic

PRODUCT DESCRIPTION

KTE-C19 is composed of autologous T cells transduced with a retroviral vector encoding an anti-CD-19 CD28/CD3-zeta chimeric antigen receptor

The retroviral vector (PG13-CD19-H3 Vector) encodes a chimeric antigen receptor (CAR) directed against the B cell antigen, CD19. This retroviral vector utilizes the MSGV1 (murine stem cell virus-based splice-gag vector) retroviral plasmid backbone and consists of 7026 bps including the 5' long terminal repeat (LTR) from the murine stem cell virus (promoter), packaging signal including the splicing donor (SD) and splicing acceptor (SA) sites, FMC63-based CAR sequence containing a signal peptide (human GM-CSF receptor), FMC63 light chain variable region (FMC63 VL), linker peptide, FMC63 heavy chain variable region (FMC63 VH), CD28 (hinge, transmembrane and cytoplasmic region), and CD3-zeta (cytoplasmic region), followed by the murine stem cell virus 3'LTR. The resulting plasmid was named MSGV1-FMC63-CD28z. The retroviral vector is produced from a stably-transduced PG13 cell line.

TRADEMARK	None as yet
SPONSOR	Kite Pharma
CODE DESIGNATIONS	KTE-C19
UNII	U2I8T43Y7R
WHO NUMBER	10518

SCS