STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (GH-165)	BREXUCABTAGENE AUTOLEUCEL
PRONUNCIATION	brex u kab' ta jeen au toe loo' sel
THERAPEUTIC CLAIM	Antineoplastic

PRODUCT DESCRIPTION

KTE-X19 is composed of engineered autologous peripheral blood T cells selected with anti-CD4 and anti-CD8 coated particles, activated with anti-CD3 and anti-CD28 antibodies, and transduced with retroviral vector (PG13-CD19-H3 Vector) expressing anti-CD19 CD28/CD3- zeta chimeric antigen receptor. This product is designed to exhibit anti-tumoral activities in patients with CD19-expressing B cells malignancies that may have circulating tumor cells.

The retroviral vector (PG13-CD19-H3 Vector) encodes a 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, Inc.
CODE DESIGNATIONS	KTE-X19
UNII	4MD2J2T8SJ

SCS