

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (JK-54)

AFAMITRESGENE AUTOLEUCEL

PRONUNCIATION

a" fam i tres' jeen aw" toe loo' sel

THERAPEUTIC CLAIM

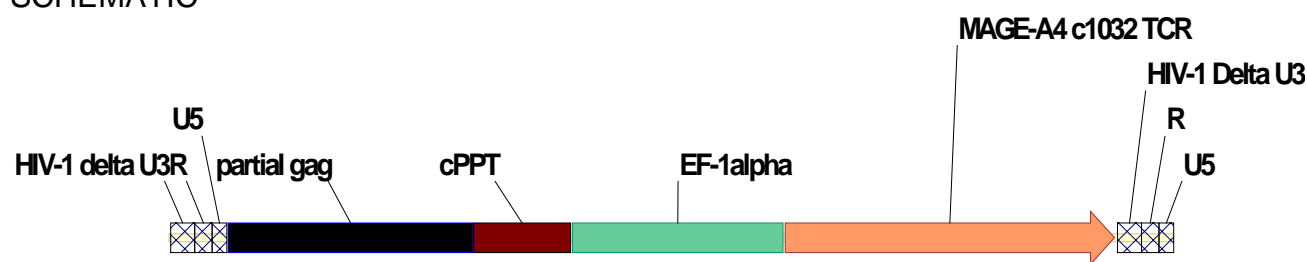
Antineoplastic

PRODUCT DESCRIPTION

MAGE-A4c1032T is an autologous CD4- and CD8-positive T cell product that has been transduced with a self-inactivating lentiviral vector expressing a high affinity MAGE-A4 specific T cell receptor

Autologous CD4+ and CD8+ T cells obtained by leukapheresis, transduced with an HIV-derived selfinactivating (SIN) lentiviral vector, encoding an enhanced-affinity T cell receptor (TCR) specific for the human melanoma antigen A4 (MAGE family member A4, antigen MAGE A4) HLA-A*02 peptide driven by the elongation factor 1 alpha (EF1α) promoter. Cells express lymphonode-homing markers CCR7 and CD62L, CD45 isoforms CD45RA and CD45R0, costimulatory markers CD27 and CD28, IL-7 receptor CD127, and chemokine receptor CXCR3. Cells secrete interleukin 2 (IL-2), tumor necrosis factor (TNF-alpha, TNFα), interferon gamma (interferon γ, IFN-gamma), granzyme, interleukin 4 (IL-4), interleukin 13 (IL-13) and interleukin 17 (IL-17) upon activation. genetically modified cell (Source: INN proposed List #122)

SCHEMATIC



MAGE-A4 c1032 integrated vector genome

5646bp

Feature	Description	Position	Color Code
HIV-1 Delta U3	Truncated HIV-1 LTR U3 region	1, 8	White lattice
R	HIV-1 LTR R region	2, 9	White lattice
U5	HIV-1 LTR U5 region	3, 10	White lattice
Partial gag	Partial region of HIV-1 gag	4	Black
cPPT	Central Polypurine tract	5	Burgundy
EF-1alpha	EF-1 alpha promoter	6	Green
MAGE-A4 c1032 TCR	MAGE-A4 c1032 TCR	7	Beige

TRADENAME	None as of yet
SPONSOR	Adaptimmune, LLC
CODE DESIGNATIONS	MAGE-A4 ^{c1032T}
UNII	CUY18BJ7BP
WHO NUMBER	11286

SCS