STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (DE-117)	RIVOGENLECLEUCEL
PRONUNCIATION	riv'' oh jen lek loo' sel
THERAPEUTIC CLAIM	Antineoplastic

PRODUCT DESCRIPTION

Cell source**:** Peripheral blood mononuclear cells from human allogeneic donor chosen by available HLA typing match- may be haploidentical up to fully matched donor.

Cellular identity**:** Product active cells are human T cells that are CD19 positive (CD3+CD19+), CD19 positivity serving as a marker indicating that the inducible Caspase9 transgene is present.

Manipulations or enrichment to the cells**:** Cells are 1) transduced with a retroviral vector (BPZ-1001) carrying the inducible caspase 9 transgene and the CD19 marker gene, along with related sequences described in the genetic map below allowing for responsiveness to the AP1903 small molecule, and 2) selected using a magnetic-bead based selection technology (CliniMACS) allowing for enrichment of CD19 positive cells.

Vector identity (AAV, adenovirus, etc.): BPX-501 drug substance is a suspension of retrovirus (BPZ-1001) transduced, CD19 selected human T cells. The BPZ-1001 (SFG.iCasp9.2A. CD19) is a Gibbon ape leukemia virus (GalV) pseudotyped gamma retrovirus that encodes a synthetic ligand-inducible human caspase 9 eDNA (iCasp9) linked to a truncated form of human CD19(CD19) used as a selectable marker and contains a drug binding domain consisting of human FK506-binding protein (FKBP12) with an F36V mutation. This point mutation increases the binding affinity ofFKBP12 to a non-toxic, membrane-permeable, synthetic homodimerizer, AP1903.

TRADEMARK	None as yet
SPONSOR	Bellicum Pharmaceuticals, Inc.
CODE DESIGNATIONS	BPX-501
UNII	E6349B696W
WHO NUMBER	10567

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