

July 27, 2016

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (DE-143) ROVALPITUZUMAB TESIRINE

PRONUNCIATION roe val" pi tooz' ue mab tes sir' een

THERAPEUTIC CLAIM Treatment of cancer

CHEMICAL NAMES

1. Immunoglobulin G1, anti-(protein DLL3 (delta-like ligand 3)) (human-*Mus musculus* monoclonal sc0001 heavy chain), disulfide with human-*Mus musculus* monoclonal sc0001 κ -chain, dimer, thioether with *N*-[31-(3-mercapto-2,5-dioxo-1-pyrrolidinyl)-1,29-dioxo-4,7,10,13,16,19,22,25-octaoxa-28-azahentriacont-1-yl]-L-valyl-*N*-[4-[[[(11S,11aS)-8-[[5-[[[(11aS)-5,11a-dihydro-7-methoxy-2-methyl-5-oxo-1*H*-pyrrolo[2,1-*c*][1,4]benzodiazepin-8-yl]oxy]pentyl]oxy]-11,11a-dihydro-11-hydroxy-7-methoxy-2-methyl-5-oxo-1*H*-pyrrolo[2,1-*c*][1,4]benzodiazepin-10(5*H*)-yl]carbonyl]oxy]methyl]phenyl]-L-alaninamide
2. Immunoglobulin G1-kappa, anti-(human delta-like protein 3 (drosophila delta homolog 3, delta 3)); humanized monoclonal antibody: γ 1 heavy chain (1-447) [humanized VH (*Homo sapiens* IGHV1-18*1 (87%) –(IGHD)-IGHJ4*01) [8.8.11] (1-118) -*Homo sapiens* IGHG1*01 {CH3 K¹⁰⁷>del(448)} (119-447)], (221-214')-disulfide with kappa light chain (1'-214') [humanized V-KAPPA (*Homo sapiens* IGKV3-15*01 (87%) –IGKJ2*02) [6.3.9] (1'-107') -*Homo sapiens* IGKC*01 (108'-214')], dimer (227-227":230-230")-bisdisulfide; an average of two cysteine residues involved in inter-chain disulfide bridges are S-substituted with tesirine radical

STRUCTURAL FORMULA

Heavy chain

<u>Q</u> VQLVQSGAE	VKKPGASVKV	SCKASGYTFT	NYGMNWVRQA	PGQGLEWMGW	50
IN Y TGTEPT Y	ADDFKGRVTM	TTDTSTSTAY	MELRSLRSD	TAVYYCARIG	100
DSSPSDYWGQ	GTLVTVSSAS	TKGPSVFPLA	PSSKSTSGGT	AALGCLVKDY	150
FPEPVTVSWN	SGALTSGVHT	FPAVLQSSGL	YSLSSVVTVP	SSSLGTQTYI	200
CNVN H KPSNT	KVDKKVEPKS	<u>C</u> DKTHT <u>C</u> PPC	PAPELLGGPS	VFLFPPKPKD	250
TLMISRTPEV	TCVVVDVSHE	DPEVKFNWYV	DGVEVHNAKT	KPREEQYNST	300
YRVVSVLTVL	HQDWLNGKEY	KCKVSNKALP	APIEKTISKA	KGQPREPQVY	350
TLPPSRDEL T	KNQVSLTCLV	KGFYPSDIAV	EWESNGQPEN	NYKTTTPVLD	400
SDGSFFLYSK	LTVDKSRWQQ	GNVFCSCVMH	EALHNHYTQK	SLSLSPG	447

Light chain

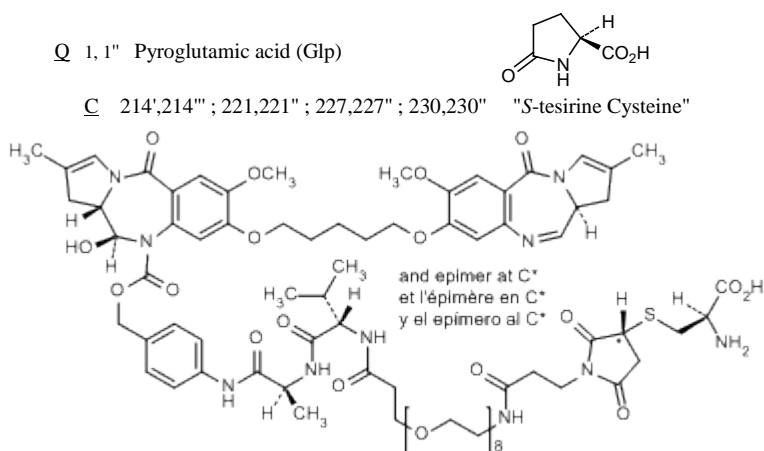
EIVMTQSPAT	LSVSPGERAT	LSCKASQSVS	NDVVWYQQKP	GQAPRLLIYY	50'
ASNRYTGIPA	RFSGSGSGTE	F L T L ISSLQS	EDFAVYYCQQ	DYTSPPWTFGQ	100'
GTKLEIKRTV	AAPSVFIFPP	SDEQLKSGTA	SVVCLLNFFY	PREAKVQWKV	150'
DNALQSGNSQ	ESVTEQDSKD	STYLSSTLT	LSKADYEKHK	VYACEVTHQG	200'
LSSPVTKSFN	RGE <u>C</u>				214'

Disulfide bridges location

22-96	22"-96"	23'-88'	23'''-88'''	134'-194'	134'''-194'''	145-201	145"-201"
214'-221*	214'''-221'''*	227-227**	230-230**	262-322	262'''-322'''	368-426	368"-426"

* an average of one interchain disulfide bond is reduced and the two cysteines S-substituted with tesirine.

Potential modified residues



Glycosylation sites (N)

Asn-298 Asn-298"

MOLECULAR FORMULA

 $C_{6416}H_{9894}N_{1698}O_{2028}S_{46} (C_{75}H_{102}N_9O_{23})_n$ (peptide)

MOLECULAR WEIGHT

147.0 kDa (peptide)

TRADEMARK

None

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CODE DESIGNATIONS

SC0002

CAS REGISTRY NUMBER

1613313-09-9

UNII

P256HB60FF

WHO NUMBER

10141

gbk