STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (JK-169)	PIVEKIMAB SUNIRINE
PRONUNCIATION	pi vek' i mab soo' ni reen
THERAPEUTIC CLAIM	Treatment of cancer

CHEMICAL NAMES

1. Immunoglobulin G1 [446-cysteine], anti-(human interleukin 3 receptor)(human-Mus musculus monoclonal G4723A γ1-chain), disulfide with human-Mus musculus monoclonal G4723A κ-chain, dimer, 446,446'-bis(thioether) with N-[6-[[2-(3-mercapto-2,5-dioxo-1-pyrrolidinyl)ethyl]amino]-1,6-dioxohexyl]-L-alanyl-N-[3-[[[(12aS)-11,12,12a,13-tetrahydro-8-methoxy-6-oxo-6H-indolo[2,1-c][1,4]benzodiazepin-9-yl]oxy]methyl]-5-[[[(12S,12aS)-11,12,12a,13-tetrahydro-8-methoxy-6-oxo-12-sulfo-6H-indolo[2,1-c][1,4]benzodiazepin-9-yl]oxy]methyl]phenyl]-L-alaninamide (Source : CAS)

2. immunoglobulin G1-kappa, anti-[*Homo sapiens* IL3RA (interleukin 3 receptor subunit alpha, interleukin 3 receptor, alpha (low affinity), CD123)], monoclonal antibody, conjugated with sulfonated DGN549-C, a cytotoxic indolobenzodiazepine dimer bonded to a protease-cleavable maleimidoethylamino-adipyl-Ala-Ala linker; gamma1 heavy chain (1-450) [VH (*Homo sapiens* IGHV1-46*01 (80.6%) -(IGHD) -IGHJ4*01 (100%), CDR-IMGT [8.8.14] (26-33.51-58.97-110)) (1-121) -*Homo sapiens* IGHG1*01, G1m17,1 (CH1 K120 (218) (122-219), hinge 1-15 (220-234), CH2 (235-344), CH3 D12 (360), L14 (362), S122>C (446) (345-449), CHS K2>del (450)) (122-450)], (224-214')-disulfide with kappa light chain (1'-214') [V-KAPPA *Musmus/Homsap* (*Mus musculus* IGKV14-111*01 (83.2%) -IGKJ2*03 (83.3%) S120>Q (100), L124>V (104)/*Homo sapiens* IGKV1-16*01 (82.1%) -IGKJ2*01 (91.7%) L124>V (104), CDR-IMGT [6.3.9] (27-32.50-52.89-97)) (1'-107') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (153), V101 (191) (108'-214')]; dimer (230-230'':233-233'')-bisdisulfide, produced in a Chinese hamster ovary (CHO)-K1 cell line, glycoform alfa; conjugated at the sulfur atoms of Cys^{446} and $Cys^{446''}$ with approximately two (3Ξ)-1-[2-(6-{[(2*S*)-1-({(2*S*)-1-[3-({[(12*S*,12a*S*)-8-methoxy-6-oxo-12-sulfo-11,12,12a,13-tetrahydro-6*H*-indolo[2,1-*c*][1,4]benzodiazepin-9-yl]oxy}methyl)-5-({[(12a*S*)-8-methoxy-6-oxo-11,12,12a,13-tetrahydro-6*H*-indolo[2,1-*c*][1,4]benzodiazepin-9-yl]oxy}methyl)anilino]-1-oxopropan-2-yl}amino)-1-oxopropan-2-yl]amino}-6-oxohexanamido)ethyl]-2,5-dioxopyrrolidin-3-yl (*sunirine*) groups (Source: WHO pINN list 125)

STRUCTURAL FORMULA

Heavy chain

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QVQLVQSGAE  VKKPGASVKV  SCKASGYIFT  SSIMHWVRQA  PGQGLEWIGY   50
IKPYNDGTKY  NEKFKGRATL  TSDRSTSTAY  MELSSLRSED  TAVYYCAREG  100
GNDYYDTMDY  WGQGTLVTVS  SASTKGPSVF  PLAPSSKSTS  GGTAALGCLV  150
KDYFPEPVTV  SWNSGALTSG  VHTFPAVLQS  SGLYSLSSVV  TVPSSSLGTQ  200
TYICNVNHKP  SNTKVDKKVE  PKSCDKTHTC  PPCPAPELLG  GPSVFLFPPK  250
PKDTLMISRT  PEVTCVVVDV  SHEDPEVKFN  WYVDGVEVHN  AKTKPREEQY  300
NSTYRVVSVL  TVLHQDWLNG  KEYKCKVSNK  ALPAPIEKTI  SKAKGQPREP  350
QVYTLPPSRD  ELTKNQVSLT  CLVKGFYPSD  IAVEWESNGQ  PENNYKTTPP  400
VLDSDGSFFL  YSKLTVDKSR  WQQGNVFSCS  VMHEALHNHY  TQKSLCLSPG  450
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Light chain

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DIQMTQSPSS  LSASVGDRVT  ITCRASQDIN  SYLSWFQQKP  GKAPKTLIYR   50'
VNRLVDGVPS  RFSGSGSGND  YTLTISSLQP  EDFATYYCLQ  YDAFPYTFGQ  100'
GTKVEIKRTV  AAPSVFIFPP  SDEQLKSGTA  SVVCLLNNFY  PREAKVQWKV  150'
DNALQSGNSQ  ESVTEQDSKD  STYSLSSTLT  LSKADYEKHK  VYACEVTHQG  200'
LSSPVTKSFN  RGEC                                           214'
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Disulfide bridges

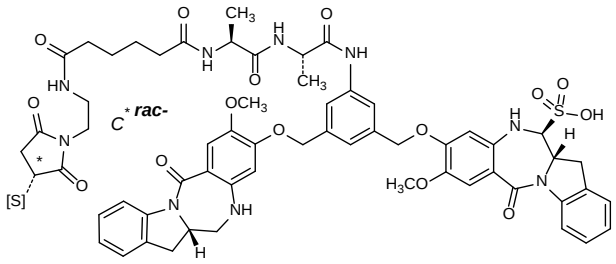
22-96	22''-96''	23'-88'	23'''-88'''	134'-194'	134'''-194'''	148-204	148''-204''
224-214'	224''-214'''	230-230''	233-233''	265-325	265''-325''	371-429	371''-429''

Glycosylation sites (N)

301, 301''

Other modifications

~1.5-2.1 sunirine groups/mAb at the S atoms of Cys C446, C446":



MOLECULAR FORMULA	$C_{6476}H_{10002}N_{1718}O_{2034}S_{46}$. $(C_{60}H_{64}N_9O_{15}S)_n$, $1.5<n>2$
MOLECULAR WEIGHT	~150 kDa
TRADEMARK	None as yet
SPONSOR	ImmunoGen
CODE DESIGNATIONS	IMGN632
CAS REGISTRY NUMBER	2417174-95-7
UNII	L15LO3W1XX
WHO NUMBER	11695

gbk