

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (HI-117) SIMLUKAFUSP ALFA
 PRONUNCIATION sim loo' ka fusp al fa
 THERAPEUTIC CLAIM Antineoplastic

CHEMICAL NAMES

Immunoglobulin G1, anti-(human seprase) (human monoclonal FAP-IL-2v heavy chain) fusion protein with peptide (synthetic linker) fusion protein with interleukin 2 (human mutant qm IL-2), disulfide with human monoclonal FAP-IL-2v light chain, dimer with immunoglobulin G1, anti-(human seprase) (human monoclonal FAP-IL-2v heavy chain), disulfide with human monoclonal FAP-IL-2v light chain immunoglobulin G1-kappa, anti-(*Homo sapiens* Prolyl endopeptidase FAP (Fibroblast activation protein alpha; Surface-expressed protease; Seprase; EC=3.4.21.26)); ω mono-linked to modified (*Homo sapiens* Interleukin-2 (T-cell growth factor, IL-2, aldesleukin)); fusion protein: γ1 heavy chain (1-446) [*Homo sapiens* VH (IGHV3-23*01 (98%) –(IGHD)-IGHJ4*01 (93%)) [8.8.10] (1-117) -*Homo sapiens* IGHG1*01 {CH2[L⁴>A(234),L⁵>A(235),P⁹⁹>G(329)], CH3[S¹⁴>C(354),T²⁶>W(366),K¹⁰⁷>del(447)]} (118-446)] fusion protein with tris(tetraglycylseryl) (linker 447-461) and with -*Homo sapiens* Interleukin-2 [T³>A(464),F⁴²>A(503),Y⁴⁵>A(506),L⁷²>G(533),C¹²⁵>A(586)] (462-594) (220-215')-disulfide with κ light chain (1'-215') [*Homo sapiens* V-KAPPA (IGKV3-20*01 (95%) –IGKJ1*01)[7.3.9] (1'-108') -*Homo sapiens* IGKC*01 (109'-215')], (226-226":229-229":354-349")-trisdisulfide with γ1 heavy chain (1"-447") [*Homo sapiens* VH (IGHV3-23*01 (98%) –(IGHD)-IGHJ4*01 (93%)) [8.8.10] (1"-117") -*Homo sapiens* IGHG1*01 {CH2[L⁴>A(234"),L⁵>A(235"),P⁹⁹>G(329")], CH3[Y⁹>C(349"),T²⁶>S(366"),L²⁸>A(368"),Y⁶⁷>V(407")]} (118"-447")] (220"-215'")-disulfide with κ light chain (1'"-215'") [*Homo sapiens* V-KAPPA (IGKV3-20*01 (95%) –IGKJ1*01)[7.3.9] (1'"-108'") -*Homo sapiens* IGKC*01 (109'"-215'")]; produced in CHO K1 cells, glycoform alfa.

STRUCTURAL FORMULA

Heavy chain A

EVQLLESGGG	LVQPGGSLRL	SCAASGFTFS	SYAMSWVRQA	PGKGLEWVSA	50
IIGSGASTYY	ADSVKGRFTI	SRDNSKNTLY	LQMNSLRAED	TAVYYCAKGW	100
FGGFNYWQQG	TLVTVSSAST	KGPSVFPLAP	SSKSTSGGTA	ALGCLVKDYF	150
PEPVTVSWNS	GALTSVHTF	PAVLQSSGLY	SLSSVVTVPS	SSLGTQTYIC	200
NVNHKPSNTK	VDKVKVEPKSC	DKTHTCPPCP	APEAAGGPSV	FLFPPKPKDT	250
LMISRTPEVT	CVVVDVSHED	PEVKFNWYVD	GVEVHNAKTK	PREEQYNSTY	300
RVVSVLTVLH	QDWLNGKEYK	CKVSNKALGA	PIEKTISKAK	GQPREPQVYCT	350
LPPCRDELTK	NQVSLWCLVK	GFYPSDIAVE	WESNGQPENN	YKTTTPVLDS	400
DGSFFLYSKL	TVDKSRWQQG	NVFSCVMHE	ALHNHYTQKS	LSLSPGGGGG	450
SGGGSGGGG	SAPASSSTKK	TQLQLEHLLL	DLQMILNGIN	NYKNPKLTRM	500
LTAKFAMPKK	ATELKHLQCL	EEELKPLEEV	LNGAQSKNFH	LRPRDLISNI	550
NVIVLELKGK	ETTFMCEYAD	ETATIVEFLN	RWITFAQSII	STLT	594

Light chain B' and D''

EIVLTQSPGT	LSLSPGERAT	LSCRASQSVT	SSYLAWYQQK	PGQAPRLLIN	50'
VGSRRATGIP	DRFSGSGSGT	DFTLTISRLE	PEDFAVYYCQ	QGIMLPPTFG	100'
QGTKVEIKRT	VAAPSVFIFP	PSDEQLKSGT	ASVVCLLNMF	YPREAKVQWK	150'
VDNALQSGNS	QESVTEQDSK	DSTYLSSTL	TLSKADYEKH	KVYACEVTHQ	200'
GLSSPVTKSF	NRGEC				215'

Heavy chain C

EVQLLESGGG	LVQPGGSLRL	SCAASGFTFS	SYAMSWVRQA	PGKGLEWVSA	50"
IIGSGASTYY	ADSVKGRFTI	SRDNSKNTLY	LQMNSLRAED	TAVYYCAKGW	100"
FGGFNYWQQG	TLVTVSSAST	KGPSVFPLAP	SSKSTSGGTA	ALGCLVKDYF	150"
PEPVTVSWNS	GALTSVHTF	PAVLQSSGLY	SLSSVVTVPS	SSLGTQTYIC	200"
NVNHKPSNTK	VDKVKVEPKSC	DKTHTCPPCP	APEAAGGPSV	FLFPPKPKDT	250"
LMISRTPEVT	CVVVDVSHED	PEVKFNWYVD	GVEVHNAKTK	PREEQYNSTY	300"
RVVSVLTVLH	QDWLNGKEYK	CKVSNKALGA	PIEKTISKAK	GQPREPQVCT	350"
LPPCRDELTK	NQVSLSCAVK	GFYPSDIAVE	WESNGQPENN	YKTTTPVLDS	400"
DGSFFLVSKL	TVDKSRWQQG	NVFSCVMHE	ALHNHYTQKS	LSLSPGK	447"

Disulfide bridges location

22-96	22"-96"	23'-89'	23'''-89'''	135'-195'	135'''-195'''
144-200	144"-200"	215'-220'	215'''-220'''	226-226"	229-229"
261-321	261"-321"	349'-354'	367-425	367"-425"	519-566

Glycosylation sites (N)

Asn-297 Asn-297"

MOLECULAR FORMULA C₇₀₈₀H₁₁₀₂₆N₁₉₀₄O₂₂₀₃S₅₀ (non-glycosylated)

MOLECULAR WEIGHT 159.7 kDa (non-glycosylated)

TRADEMARK None as yet

SPONSOR Genentech

CODE DESIGNATIONS FAP-IL2v; RO6874281; RG7461

CAS REGISTRY NUMBER 1776942-10-9

UNII FL08SGO9XA

WHO NUMBER 11116

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