

# STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (JK-216) MODAKAFUSP ALFA

PRONUNCIATION moe da' ka fusp al' fa

THERAPEUTIC CLAIM Treatment of multiple myeloma

## CHEMICAL NAMES

1. Immunoglobulin G4 [228-proline], anti-(human antigen CD38) (human-Rattus norvegicus monoclonal TAK-573  $\gamma$ 4-chain) Fc C-terminal fusion protein with human interferon  $\alpha$ 2b [106-alanine, 145-aspartic acid], disulfide with human-Rattus norvegicus monoclonal TAK-573  $\kappa$ -chain, dimer (Source: CAS)
2. Immunoglobulin G4-kappa, anti-[human ADP-ribosyl cyclase/cyclic ADP-ribose hydrolase 1 (EC:3.2.2.6) (ADPRC 1/cADRP hydrolase 1, cell surface antigen CD38)], humanized monoclonal antibody, fused at each C-terminus of the heavy chains (1-447, 1"-447") to attenuated human interferon  $\alpha$ -2b (IFN $\alpha$ 2b) variant (K<sup>23</sup>>R<sup>470</sup>, T<sup>106</sup>>A<sup>553</sup>, A<sup>145</sup>>D<sup>592</sup>) (448-612, 448"-612"); gamma4 heavy chain humanized fused to IFN $\alpha$ 2b (1-612) [VH (*Homo sapiens* IGHV1-69-2\*01 (90.7%) -(IGHD)- IGHJ4\*01 (85.7%)) CDRIMGT [8.8.13] (26-33.51-58.97-109) (1-120)-*Homo sapiens* IGHG4\*01, G4v5 h P10 (CH1 (121-218), hinge 1-12 S<sup>10</sup>>P (228) (219-230), CH2 (231-340), CH3 (341-445), CHS (446-447))(121-447), fused to IFN $\alpha$ 2b K<sup>23</sup>>R (470), T<sup>106</sup>>A (553), A<sup>145</sup>>D (592) (448-612)],(134-214')-disulfide with kappa light chain humanized (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-33\*01 (83.2%) -IGKJ4\*01 (100%)) CDR-IMGT [6.3.9] (27-32.50- 52.89-97) (1'-107') -*Homo sapiens* IGKC\*01 (100%), Km3 A45.1 (153), V<sup>101</sup> (191) (108'-214')]; dimer (226-226":229-229")-bisdisulfide; produced in Chinese hamster ovary (CHO) K1SV cells, glycoform alfa (Source : WHO pINN list 122)

## STRUCTURAL FORMULA

### Heavy chain (anti-CD38 $\gamma$ 4-IFN $\alpha$ 2b)

EVQLVQSGAE	VKKPGATVKI	SCKVSGYTFT	DSVMNWVQQA	PGKGLEWMGW	50
IDPEYGRTDV	AEKFQGRVTI	TADTSTDTAY	MELSSLRSED	TAVYYCARTK	100
YNSGYGFPYW	GQGTTVTVSS	ASTKGPSVFP	LAPCSRSTSE	STAALGCLVK	150
DYFPEPVTVS	WNSGALTSGV	HTFPAVLQSS	GLYSLSSVVT	VPSSSLGTKT	200
YTCNVDHKPS	NTKVDKRVES	KYGGPCPPCP	APEFLGGPSV	FLFPPKPKDT	250
LMISRTPEVT	CVVVDVSEQED	PEVQFNWYVD	GVEVHNAKTK	PREEQFNSTY	300
RVVSVLTVLH	QDWLNGKEYK	CKVSNKGLPS	SIEKTISKAK	GQPREPQVYT	350
LPSSQEEMTK	NQVSLTCLVK	GFYPSDIAVE	WESNGQPENN	YKTPPVVLDL	400
DGSFFLYSRL	TVDKSRWQEG	NVFSCVMHE	ALHNHYTQKS	LSLSLGKCDL	450
PQTHSLGSRR	TLMLLAQMRR	ISLFSCLKDR	HDFGFPQEEF	GNQFQKAETI	500
PVLHEMIQOI	FNLFSTKDSS	AAWDETLLDK	FYTELYQQLN	DLEACVIQGV	550
GVAETPLMKE	DSILAVRKYF	QRITLYLKEK	KYSPCAWEVV	RDEIMRSFSL	600
STNLQESLRS	KE				612

### Light chain

DIQMTQSPSS	LSASVGDRTV	ITCKASQNV	SDVDWYQQK	GKAPKLLIYK	50'
ASNDYTGVP	RFSGSGSGTD	FTFTISSLQP	EDIATYYCMQ	SNTHPRTFGG	100'
GTKVEIKRTV	AAPSVFIFPP	SDEQLKSGTA	SVVCLLNNFY	PREAKVQWKV	150'
DNALQSGNSQ	ESVTEQDSKD	STYLSLSTLT	LSKADYEHK	VYACEVTHQG	200'
LSSPVTKSFN	RGEC				214'

Disulfide bridges

22-96	22''-96''	23'-88'	23'''-88'''	134'-194'	134'''-194'''	134-214'	134''-214'''
147-203	147''-203''	226-226''	229-229''	261-321	261''-321''	367-425	367''-425''
448-545	448''-545''	476-585	476''-585''				

Glycosylation sites (N)

297	297''
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MOLECULAR FORMULA	C <sub>8132</sub> H <sub>12618</sub> N <sub>2152</sub> O <sub>2551</sub> S <sub>66</sub>
MOLECULAR WEIGHT	183.5 kDa
TRADEMARK	None as yet
SPONSOR	Takeda Pharmaceuticals
CODE DESIGNATIONS	TAK-573, TEV-48573
<u>CAS</u> REGISTRY NUMBER	2254522-19-3
UNII	TN8CEX4UT2
WHO NUMBER	11306

gbk