

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (HI-163) ROZIBAFUSP ALFA
 PRONUNCIATION roe zib' a fusp al' fa
 THERAPEUTIC CLAIM Treatment of inflammatory disease

CHEMICAL NAMES

1. Immunoglobulin G2, anti-(human inducible costimulator ligand protein) (human monoclonal AMG 557 γ 2-chain) fusion protein with protein (synthetic human B cell-activating factor-binding peptide-containing), disulfide with human monoclonal AMG 557 κ -chain, dimer
2. Immunoglobulin G2-kappa, anti-[human inducible costimulator (ICOS) ligand protein] human monoclonal antibody, fused with two copies of a tumor necrosis factor ligand superfamily member 13B (TNFSF13B, B-cell activating factor, BAFF)-binding peptide, glycoform alfa: γ 2 heavy chain [*Homo sapiens* VH (*Homo sapiens* IGHV3-7*01 (98%)-(IGHD)-IGHJ1*01) [8.8.14] [CDRKabatH1: SYWMS (31-35); CDRKabatH2: YIKQDGNEKYYVDSVKG (50-66); CDRKabatH3: EGILWFGDLPTF (99-110)] (1-121) - *Homo sapiens* IGHG2*01 (CH1 (122-219), hinge (220-231), CH2 (232-340), CH3 (341-445), CHS (446-447))] (1-447) fused by a G₅ linker (448-452) and a (GS)₂ATG(GS)₂VASS(GS)₂ATHL linker (471-493) with two copies of a synthetic human tumor necrosis factor ligand superfamily member 13B (TNFSF13B, B cell-activating factor, BAFF)-binding peptide (453-470, 494-511), (135-214')-disulfide with κ light chain [V-KAPPA (*Homo sapiens* IGKV1D-16*01 (98%) -IGKJ1*01) [6.3.9] [CDRKabatL1: RASQGISNWLA (24-34); CDRKabatL2: ASSLQS (50-56); CDRKabatL3: QQYDSYPRT (89-97)] (1'-107') - *Homo sapiens* IGKC*01 (108'-214')] (1'-214'), (223-223'',224-224'',227-227'',230-230'')-tetrakisdisulfide dimer, produced in Chinese hamster ovary (CHO) cells, glycoform alfa

STRUCTURAL FORMULA

Heavy chains X & X''

EVQLVESGGG	LVQPGGSLRL	SCAASGFTFS	SYWMSWVRQA	PGKGLEWVAY	50
IKQDGNKYY	VDSVGRFTI	SRDNAKNSLY	LQMNSLRAED	TAVYICAREG	100
ILWFQDLPTF	WGQGLVTVS	SASTKGPSVF	PLAPCSRSTS	ESTAALGCLV	150
KDYFPEPVTV	SWNSGALTSG	VHTFPAVLQS	SGLYSLSSVV	TVPSSNFSTQ	200
TYTCNVDHKP	SNTKVDKTV	RKCCVECPPC	PAPPVAGPSV	FLFPPKPKDT	250
LMISRPEVTV	CVVVDVSHED	PEVQFNWYVD	GVEVHNAKTK	PREEQFNSTF	300
RVVSVLTIVVH	QDWLNGKEYK	CKVSNKGLPA	PIEKTISKTK	GQPREPQVYV	350
LPPSREEMTK	NQVSLTCLVK	GFYPSDIAVE	WESNGQPENN	YKTPPPMLDS	400
DGSFFLYSKL	TVDKSRWQQG	NVFSCSVMHE	ALHNHYTQKS	LSLSPGKGGG	400
GGLPGCKWDL	LIIKQWVCDPL	SGSATGSGS	SVASSGSGSA	THLLPGCKWD	400
LLIKQWVCDP	L				511

Light chains X' & X'''

DIQMTQSPSS	LSASVGDRTV	ITCRASQGIS	NWLAWYQQKP	EKAPKSLIYA	50'
ASSLQSGVPS	RFSGSGSGTD	FLLTISSLQP	EDFATYYCQQ	YDSYPRTFGQ	100'
GTKVEIKRTV	AAPSVFIFPP	SDEQLKSGTA	SVVCLLNNFY	PREAKVQWKV	150'
DNALQSGNSQ	ESVTEQDSKD	STYLSLSTLT	LSKADYEKHK	VYACEVTHQG	200'
LSSPVTKSFN	RGEC				214'

Disulfide bridges location

22-96	22"-96"	23'-88'	23'''-88'''	134'-194'	134'''-194'''	135-214'	135"-214"
148-204	148"-204"	223-223"	224-224"	227-227"	230-230"	261-321	261"-321"
367-425	367"-425"	456-467	456"-467"	497-508	497"-508"		

Glycosylation sites (N)

Asn-297 Asn-297"

MOLECULAR FORMULA C₇₀₂₀H₁₀₇₉₃N₁₈₆₈O₂₁₈₂S₅₈ . (non glycosylated)

MOLECULAR WEIGHT 158.1 kDa

TRADEMARK None as yet

SPONSOR Amgen Inc.

CODE DESIGNATIONS AMG 570

CAS REGISTRY NUMBER 2143449-47-0

UNII O9YF5SN7KL

WHO NUMBER 10975

gbk