

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (FG-176) CIBISATAMAB
 PRONUNCIATION sye" bi sat' a mab
 THERAPEUTIC CLAIM Treatment of cancer

CHEMICAL NAMES

1. Immunoglobulin G1, humanized bispecific trivalent, anti-(human carcinoembryonic antigen/human CD3 antigen ϵ -chain) bivalent γ -chain, disulfide with anti-(human carcinoembryonic antigen) κ -chain, anti-(human carcinoembryonic antigen) monovalent γ -chain and anti-(human CD3 antigen ϵ -chain) κ -chain
2. Immunoglobulin G1-kappa/lambda with domain crossover, anti-(*Homo sapiens* Carcinoembryonic antigen-related cell adhesion molecule 5 (CD66e antigen)) and anti-(*Homo sapiens* T-cell surface glycoprotein CD3 epsilon chain (CD3e antigen)); humanized monoclonal antibody, bispecific, trivalent; γ - κ heavy chain anti-human Carcinoembryonic antigen and CD3e antigen (VH-CH1-VH-C-kappa-CH2-CH3) (1-694) [humanized VH anti-Carcinoembryonic antigen (*Homo sapiens* IGHV1-18*01 (83%) –(IGHD)-IGHJ4*01 (92%)) [8.8.14] (1-121) -*Homo sapiens* IGHG1*01 {CH1-hinge-(1-6)}(122-225) –bis(tetraglycylseryl) (226-235) humanized VH anti-CD3e antigen (*Homo sapiens* IGHV3-23*03 (87%) –(IGHD)-IGHJ6*01 (91%)) [8.10.16] (236-360) - *Homo sapiens* IGKC*01{R¹>A(361),T²>S(362)} (361-467)- *Homo sapiens* IGHG1*01{hinge-(6-15), CH2[L⁴>A(481),L⁵>A(482),P⁹⁹>G(576)], CH3[S¹⁴>C(601),T²⁶>W(613)]} (468-694)]; (224-215')-disulfide with κ light chain anti-human Carcinoembryonic antigen (1'-215') [humanized V-KAPPA (*Homo sapiens* IGKV1-16*01 (82%) –IGKJ2*02)[6.3.10] (1'-108') -*Homo sapiens* IGKC*01 (109'-215')]; (467-214'')-disulfide with λ - γ light chain and CD3e antigen (1''-214'') [V-LAMBDA (*Mus musculus* IGLV1*01 (81%) –IGKJ1*01)[9.3.9] (1''-109'') –biseryl (110''-111'') –*Homo sapiens* IGHG1*01 {CH1-hinge(1-5)}(112''-214'')]; γ 1 heavy chain anti-human Carcinoembryonic antigen (1'''-451''') [humanized VH (*Homo sapiens* IGHV1-18*01 (83%) –(IGHD)-IGHJ4*01 (92%)) [8.8.14] (1'''-121''') -*Homo sapiens* IGHG1*01 {CH2[L⁴>A(238),L⁵>A(239),P⁹⁹>G(333)], CH3[Y⁹>C(353),T²⁶>S(370),L²⁸>A(372),Y⁶⁷>V(411)]} (122'''-451''')] (224'''-215''')-disulfide with κ light chain anti-human Carcinoembryonic antigen (1''''-215''') [humanized V-KAPPA (*Homo sapiens* IGKV1-16*01 (82%) –IGKJ2*02)[6.3.10] (1''''-108''') -*Homo sapiens* IGKC*01 (109''''-215''')], dimer (230''''-473: 233''''-476: 353''''-601)-trisdisulfide

Heavy chain anti-human Carcinoembryonic antigen and CD3e antigen

QVQLVQSGAE	VKKPGASVKV	SCKASGYTFT	EFGMNWRQA	PGQGLEWMGW	50
INTKTGEATY	VEEFKGRVTF	TTDTSTSTAY	MELRSLRSDD	TAVYICARWD	100
FAYYVEAMDY	WGQGTITVVS	SASTKGPSVF	PLAPSSKSTS	GGTAALGCLV	150
KDYFPEPVTV	SWNSGALTSG	VHTFPAVLQS	SGLYSLSSVV	TVPSSSLGTQ	200
TYICNVNHKP	SNTKVDKQVE	PKSCDGGGGS	GGGGSEVQLL	ESGGGLVQPG	250
GSLRLSCAAS	GFTFTSYAMN	WVRQAPGKGL	EWVSRIRSKY	NNYATYYADS	300
VKGRFTISR	DSKNTLYLQM	NSLRAEDTAV	YYCVRHGNFG	NSYVSWFAYW	350

GQGTLVTVSS	ASVAAPSVFI	FPPSDEQLKS	GTASVVCLLN	NFYPREAKVQ	400
WKVDNALQSG	NSQESVTEQD	SKDSTYSLSS	TLTLSKADYE	KHKVYACEVT	450
HQGLSSPVTK	SFNRGECDKT	HTCPPCPAPE	AAGGPSVFLF	PPKPKDTLMI	500
SRTPEVTCVV	VDVSHEDPEV	KFNWYVDGVE	VHNAKTKPRE	EQYNSTYRVV	550
SVLTVLHQDW	LNGKEYKCKV	SNKALGAPIE	KTISKAKGQP	REPQVYTLPP	600
CRDELTKNQV	SLWCLVKGFY	PSDIAVEWES	NGQPENNYKT	TPPVLDSDSG	650
FFLYSKLTVD	KSRWQQGNVF	SCSVMHEALH	NHYTQKLSLSL	SPGK	694

Light chain anti-human Carcinoembryonic antigen

DIQMTQSPSS	LSASVGDRVT	ITCKASAAVG	TYVAWYQQKP	GKAPKLLIYS	50'
ASYRKRGVPS	RFSGSGSGTD	FLLTISSLQP	EDFATYYCHQ	YYTYPLFTFG	100'
QGTKLEIKRT	VAAPSVFIFP	PSDEQLKSGT	ASVVCLLNMF	YPREAKVQWK	150'
VDNALQSGNS	QESVTEQDSK	DSTYLSLSTL	TLISKADYEKH	KVYACEVTHQ	200'
GLSSPVTKSF	NRGEC				215'

Light chain anti-human CD3e antigen

QAVVTQEPSSL	TVSPGGTVTL	TCGSSTGAVT	TSNYANWVQE	KPGQAFRGLI	50"
GGTNKRAPGT	PARFSGSLLG	GKAALTLSGA	QPEDEAEYYC	ALWYSNLWVF	100"
GGGKLTIVLS	SASTKGPSVF	PLAPSSKSTS	GGTAALGCLV	KDYFPEPVTV	150"
SWNSGALTSG	VHTFPAVLQS	SGLYSLSSVV	TVPSSSLGTQ	TYICNVNHKP	200"
SNTKVDKKE	PKSC				214"

Heavy chain anti-human Carcinoembryonic antigen

QVQLVQSGAE	VKKPGASVKV	SCKASGYTFT	EFGMNWVRQA	PGQGLEWMGW	50"
INTKTGEATY	VEEFKGRVTF	TTDTSTSTAY	MELRSLRSD	TAVYYCARWD	100"
FAYYVEAMDY	WGQGTIVTVS	SASTKGPSVF	PLAPSSKSTS	GGTAALGCLV	150"
KDYFPEPVTV	SWNSGALTSG	VHTFPAVLQS	SGLYSLSSVV	TVPSSSLGTQ	200"
TYICNVNHKP	SNTKVDKKE	PKSCDKTHTC	PPCPAPEAAG	GPSVFLFPPK	250"
PKDTLMI SRT	PEVTCVVDV	SHEDPEVKFN	WYVDGVEVHN	AKTKPREQY	300"
NSTYRVVSVL	TVLHQDWLNG	KEYCKVSNK	ALGAPIEKTI	SKAKQPREP	350"
QVCTLPPSRD	ELTKNQVLSL	CAVKGFYPSD	IAVEWESNGQ	PENNYKTTPP	400"
VLDSGGSFFL	VSKLTVDKSR	WQQGNVFSCS	VMHEALHNHY	TQKLSLSLSPG	450"
K					451"

Light chain anti-human Carcinoembryonic antigen

DIQMTQSPSS	LSASVGDRVT	ITCKASAAVG	TYVAWYQQKP	GKAPKLLIYS	50"
ASYRKRGVPS	RFSGSGSGTD	FLLTISSLQP	EDFATYYCHQ	YYTYPLFTFG	100"
QGTKLEIKRT	VAAPSVFIFP	PSDEQLKSGT	ASVVCLLNMF	YPREAKVQWK	150"
VDNALQSGNS	QESVTEQDSK	DSTYLSLSTL	TLISKADYEKH	KVYACEVTHQ	200"
GLSSPVTKSF	NRGEC				215"

Disulfide bridges location

22"-90"	22-96	22"-96"	23'-88'	23""-88""	135'-195'
135""-195""	138"-194"	148-204	148""-204""	214"-467	215'-224
215""-224""	230""-473	233""-476	257-333	265""-325""	
353""-601	371""-429""	387-447	508-568	614-672	

Glycosylation sites (N)

Asn-301"" Asn-544

MOLECULAR FORMULA C₈₅₆₃H₁₃₁₉₃N₂₂₇₃O₂₆₈₂S₅₉ (non-glycosylated)

MOLECULAR WEIGHT 192.8 kDa

TRADEMARK None as yet

SPONSOR Genentech/Roche

CODE DESIGNATIONS RG7802, RO 6958688

CAS REGISTRY NUMBER 1855925-27-7

UNII ZAM5J1ATF2

WHO NUMBER 10636

gbk