

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (JK-194)	RUNIMOTAMAB
PRONUNCIATION	run" i moe' ta mab
THERAPEUTIC CLAIM	Treatment of cancer

CHEMICAL NAMES

1. Immunoglobulin G1 [300-glycine,369-tryptophan], anti-(human epidermal growth factor receptor HER2) (human monoclonal KTRC5520 γ 1-chain), disulfide with human monoclonal KTRC5520 κ -chain, (229→228'),(232→231')-bis(disulfide) with immunoglobulin G1 [299-glycine,368-serine,370-alanine,409-valine] anti-(human CD3 antigen) (human monoclonal HTHR4765 γ 1-chain) disulfide with human monoclonal HTHR4765 κ -chain (Source: CAS)
2. Immunoglobulin G1-kappa, anti-[*Homo sapiens* ERBB2 (epidermal growth factor receptor 2, receptor tyrosine protein kinase erbB-2, EGFR2, HER2, HER-2, p185cerbB2, NEU, CD340)] and anti-[*Homo sapiens* CD3E (CD3 epsilon, Leu-4)], monoclonal antibody, bispecific; gamma1 heavy chain anti-ERBB2 (1-450) [VH anti-ERBB2 (*Homo sapiens* IGHV3-66*01 (81.6%) - (IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.13] (26-33.51-58.97-109) (1-120) - *Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1, G1v30 CH2 G84.4, G1v32 CH3 W22 (CH1 R120>K (217) (121-218), hinge 1-15 (219-233), CH2 N84.4>G (300) (234-343), CH3 E12 (359), M14 (361), T22>W (369) (344-448), CHS (449-450)) (121-450)], (223-214')-disulfide with kappa light chain anti-ERBB2 (1'-214') [V-KAPPA anti-ERBB2 (*Homo sapiens* IGKV1-39*01 (86.3%) -IGKJ1*01 (100%)) 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')]; gamma1 heavy chain anti-CD3E (1"-449") [VH anti-CD3E (*Mus musculus* IGHV1-66*01 (82.7%) - (IGHD) -IGHJ2*01 (86.7%)/*Homo sapiens* anti-CD3E IGHV1-3*01 (82.7%) - (IGHD) -IGHJ4*01 (100%)) CDR-IMGT [8.8.12] (26-33.51-58.97-108) (1"-119") -*Homo sapiens* IGHG1*03v, G1m3>G1m17, nG1m1, G1v30 CH2 G84.4, G1v33 CH3 S22, A24, V86 (CH1 R120>K (216) (120"-217"), hinge 1-15 (218"-232"), CH2 N84.4>G (299) (233-342), CH3 E12 (358), M14 (360), T22>S (368), L24>A (370), Y86>V (409) (343"-447"), CHS (448"-449") (120"-449")], (222"-219")-disulfide with kappa light chain anti-CD3E (1'''-219''') [V-KAPPA anti-CD3E (*Homo sapiens* IGKV4-1*01 (91.8%) - IGKJ1*01 (100%)) CDR-IMGT [12.3.8] (27-38.56-58.95-102) (1'''-112''') -*Homo sapiens* IGKC*01 (100%), Km3 A45.1 (158), V101 (196) (113'''-219''')]; dimer (229-228":232-231")-bisdisulfide, produced in Chinese hamster ovary (CHO) cells, non-glycosylated (Source: WHO pINN list 124)

STRUCTURAL FORMULA

Heavy chain (anti-ERBB2)

EVQLVESGGG	LVQPGGSLRL	SCAASGFNIK	DTYIHWVRA	PGKLEWVAR	50
IYPTNGYTRY	ADSVKGRFTI	SADTSKNTAY	LQMNSLRAED	TAVYYCSRWG	100
GDGFYAMDYW	GQGTLVTVSS	ASTKGPSVFP	LAPSSKSTSG	GTAALGCLVK	150
DYFPEPVTVS	WNSGALTSGV	HTFPAVLQSS	GLYSLSSVVT	VPSSSLGTQT	200
YICNVNHKPS	NTKVDKKEVP	KSCDKTHTCP	PCPAPELLGG	PSVFLFPPKP	250
KDTLMISRTP	EVTCVVVDVS	HEDPEVKFNW	YVDGVEVHNA	KTKPREEQYG	300
STYRVVSVLT	VLHQDWLNGK	EYKCKVSNKA	LPAPIEKTIS	KAKGQPREPQ	350
VYTLPPSREE	MTKNQVSLWC	LVKGFYPSDI	AVEWESNGQP	ENNYKTTTPV	400
LDSDGSFFLY	SKLTVDKSRW	QQGNVFSQSV	MHEALHNHYT	QKSLSLSPGK	450

Light chain (anti-ERBB2)

DIQMTQSPSS	LSASVGDRVV	ITCRASQDVN	TAVAWYQQKP	GKAPKLLIYS	50'
ASFLYSGVPS	RFSGSRSGTD	FTLTISSLQP	EDFATYYCQQ	HYTTPPTFGQ	100'
GTKVEIKRTV	AAPSVFIFPP	SDEQLKSGTA	SVVCLLNIFY	PREAKVQWKV	150'
DNALQSGNSQ	ESVTEQDSKD	STYLSLSTLT	LSKADYKHKH	VYACEVTHQG	200'
LSSPVTKSFN	RGEC				214'

Heavy chain (anti-CD3E)

EVQLVQSGAE	VKPKGASVKV	SCKASGYTFT	NYIHWVRA	PGGLEWIGW	50''
IYPGDGNTKY	NEKFKGRATL	TADTSTSTAY	LELSLRSED	TAVYYCARDS	100''
YSNYYPDYWG	QGTLLVTVSSA	STKGPSVFPL	APSSKSTSGG	TAALGCLVKD	150''
YFPEPVTVSW	NSGALTSGVH	TFFPAVLQSSG	LYSLSSVVTV	PSSSLGTQTY	200''
ICNVNHKPSN	TKVDKKEPK	SCDKTHTCPP	CPAPELLGGP	SVFLFPPKPK	250''
DTLMISRTP	VTCVVVDVSH	EDPEVKFNWY	VDGVEVHNAK	TKPREEQYGS	300''
TYRVVSVLTV	LHQDWLNGKE	YKCKVSNKAL	PAPIEKTISK	AKGQPREPQV	350''
YTLPPSREEM	TKNQVSLSCA	VKGFYPSDIA	VEWESNGQPE	NNYKTTTPVL	400''
DSDGSFFLVS	KLTVDKSRWQ	QGNVFSQSV	HEALHNHYTQ	KSLSLSPGK	449''

Light chain (anti-CD3E)

DIVMTQSPDS	LAVSLGERAT	INCKSSQSL	NSRTRKNYLA	WYQQKPGQPP	50'''
KLLIYWASTR	ESGVDRFSG	SGSGTDFTLT	ISLQAEDVA	VYYCTQSFIL	100'''
RTFGQGTKVE	IKRTVAAPSV	FIFPPSDEQL	KSGTASVCL	LNNFYPREAK	150'''
VQWKVDNALQ	SGNSQESVTE	QDSKSTYSL	SSTLTLSKAD	YEKHKVYACE	200'''
VTHQGLSSPV	TKSFRGEC				219'''

Disulfide bridges

22-96	22''-96''	23'-88'	23'''-94'''	134'-194'	139'''-199'''	147-203	146''-202''
223-214'	222''-219''	229-228''	232-231''	264-324	263''-323''	370-428	369''-427''

Glycosylation sites (N)

None

MOLECULAR FORMULA

C₆₄₉₈H₁₀₀₂₄N₁₇₂₈O₂₀₂₅S₄₂

MOLECULAR WEIGHT

146.1 kDa

TRADEMARK

None as yet

SPONSOR

Genentech, Inc./Hoffmann-La Roche Inc.

CODE DESIGNATIONS

BTRC4017A, RO7227780

CAS REGISTRY NUMBER

2361325-98-4

UNII

F8Z9VSZ0K1

WHO NUMBER

11496

gbk