

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (HI-166) AMIVANTAMAB

PRONUNCIATION am" i van' ta mab

THERAPEUTIC CLAIM Antineoplastic

CHEMICAL NAME

1. Immunoglobulin G1 [413-lysine], anti-(human epidermal growth factor receptor) (human monoclonal JNJ-61186372  $\gamma$ 1-chain), disulfide with human monoclonal JNJ-61186372  $\kappa$ -chain,(234→228'),(237→231')-bis(disulfide) with immunoglobulin G1 [411-arginine] anti-(human hepatocyte growth factor receptor c-Met) human monoclonal JNJ-61186372  $\gamma$ 1-chain) disulfide with human monoclonal JNJ-61186372  $\kappa$ -chain
2. Immunoglobulin G1-kappa, anti-[*Homo sapiens* EGFR (epidermal growth factor receptor, receptor tyrosine-protein kinase erbB-1, ERBB1, HER1, HER-1, ERBB)] and anti-[*Homo sapiens* MET (met proto-oncogene, hepatocyte growth factor (HGF) receptor, HGFR, scatter factor (SF) receptor, HGF/SF receptor, receptor tyrosine-protein kinase c-met, papillary renal cell carcinoma 2, RCCP2)], *Homo sapiens* monoclonal antibody, bispecific; gamma1 heavy chain *Homo sapiens* anti-EGFR (1-455) [VH (*Homo sapiens* IGHV3-33\*01 (95.9%) -(IGHD) -IGHJ4\*01 (100%)) [8.8.18] (1-125) -*Homo sapiens* IGHG1\*03 G1m3, nG1m1 (CH1 R120 (222) (126-223), hinge 1-15 (224-238), CH2 (239-348), CH3 E12 (364), M14 (366), F85.1>L (413) (349- 453), CHS (454-455)) (126-455)], (228-214')-disulfide with kappa light chain *Homo sapiens* anti-EGFR (1'-214') [V-KAPPA (*Homo sapiens* IGKV1-13\*02 (96.8%) -IGKJ4\*01 (100%)) [6.3.9] (1'-107') -*Homo sapiens* IGKC\*01 (100%) Km3 A45.1 (153), V101 (191) (108'-213')]; gamma1 heavy chain *Homo sapiens* anti-MET (1"-449") [VH (*Homo sapiens* IGHV1-18\*01 (95.9%) -(IGHD) -IGHJ4\*01 (100%)) [8.8.12] (1"-119") -*Homo sapiens* IGHG1\*03 G1m3, nG1m1 (CH1 R120 (216) (120-217), hinge 1-15 (218-232), CH2 (233-342), CH3 E12 (358), M14 (360), K88>R (411) (343- 447), CHS (448-449)) (119"-449")], (222"-214'")-disulfide with kappa light chain *Homo sapiens* anti-MET (1'"-214'") [V-KAPPA (*Homo sapiens* IGKV1- 12\*01 (95.8%) -IGKJ5\*01 (100%)) [6.3.9] (1'"-107'") -*Homo sapiens* IGKC\*01 (100%) Km3 A45.1 (153), V101 (191) (108'"-214'")]; dimer (234-228":237-231")-bis(disulfide), produced in Chinese Hamster Ovary (CHO) cells, glycoform alfa

STRUCTURAL FORMULA

Heavy chain (anti-EGFR)

QVQLVESGGG	VYQPGRSLRL	SCAASGFTFS	TYGMHWVRQA	PGKGLEWVAV	50
IWDDGSYKYY	GDSVKGRFTI	SRDNSKNTLY	LQMNSLRAED	TAVYYCARDG	100
ITMVRGVMKD	YFDYWGQGTL	VTVSSASTKG	PSVFPPLAPSS	KSTSGGTAAL	150
GCLVKDYFPE	PVTVSWNSGA	LTSGVHTFPA	VLQSSGLYSL	SSVVTVPSSS	200
LGTQTYICNV	NHKPSNTKVD	KRVEPKSCDK	THTCPPCPAP	ELLGGPSVFL	250
FPPKPKDTLM	ISRTPEVTCV	VVDVSHEDPE	VKFNWYVDGV	EVHNAKTKPR	300
EEQYNSTYRV	VSVLTVLHQD	WLNGKEYKCK	VSNKALPAPI	EKTISKAKGQ	250

PREPQVYTLF	PSREEMTKNQ	VSLTCLVKGF	YPSDIAVEWE	SNGQPENNYK	300
TTPPVLDSDG	SFLLYSKLTV	DKSRWQQGNV	FSCSVMHEAL	HNHYTQKSLS	350
LSPGK					455

#### Light chain (anti-EGFR)

AIQLTQSPSS	LSASVGDRVT	ITCRASQDIS	SALVWYQQKP	GKAPKLLIYD	50'
ASSLESGVPS	RFGSGESGTD	FTLTISLQP	EDFATYYCQQ	FNSYPLTFGG	100'
GTKVEIKRTV	AAPSVFIFPP	SDEQLKSGTA	SVVCLLNNFY	PREAKVQWKV	150'
DNALQSGNSQ	ESVTEQDSKD	STYLSLSTLT	LSKADYEKHK	VYACEVTHQG	200'
LSSPVTKSFN	RGEC				214'

#### Heavy chain (anti-MET)

QVQLVQSGAE	VKKPGASVKV	SCETSGYTFT	SYGISWVRQA	PGHGLEWMGW	50"
ISAYNGYTNY	AQKLQGRVTM	TTDTSTSTAY	MELRSLRSDD	TAVYYCARDL	100"
RGNTNYFDYWG	QGTLTVVSSA	STKGPSVFPL	APSSKSTSGG	TAALGCLVKD	150"
YFPEPVTVSW	NSGALTSGVH	TFPAVLQSSG	LYSLSSVTV	PSSSLGTQTY	200"
ICNVNHNKPSN	TKVDKRVPEK	SCDKTHTCPP	CPAPELLGGP	SVFLFPPKPK	250"
DTLMISRTPE	VTCVVVDVSH	EDPEVKFNWY	VDGVEVHNAK	TKPREEQYNS	300"
TYRVVSVLTV	LHQDWLNGKE	YKCKVSNKAL	PAPIEKTISK	AKGQPREPQV	350"
YTLPPSREEM	TKNQVSLTCL	VKGFYPSDIA	VEWESNGQPE	NNYKTTPPVL	400"
DSDGSFFLYS	RLTVDKSRWQ	QGNVFSCSVM	HEALHNHYTQ	KSLSLSPGK	449"

#### Light chain (anti-MET)

DIQMTQSPSS	VSASVGDRVT	ITCRASQGIS	NWLAWFQHKP	GKAPKLLIYA	50'''
ASLLSGVPS	RFGSGSGTD	FTLTISLQP	EDFATYYCQQ	ANSFPITFGQ	100'''
GTRLEIKRTV	AAPSVFIFPP	SDEQLKSGTA	SVVCLLNNFY	PREAKVQWKV	150'''
DNALQSGNSQ	ESVTEQDSKD	STYLSLSTLT	LSKADYEKHK	VYACEVTHQG	200'''
LSSPVTKSFN	RGEC				214'''

#### Disulfide bridges

22-96	22''-96''	23'-88'	23'''-88'''	134'-194'	134'''-194'''	146''-202''
152-208	214'-228	214'''-222''	234-228''	237-231''	263''-323''	269-329
369''-427''	375-433					

#### Glycosylation sites

305 299''

#### MOLECULAR FORMULA

$C_{6472}H_{10040}N_{1730}O_{2020}S_{46}$

#### MOLECULAR WEIGHT

145.9 KDa

#### TRADEMARK

None as yet

#### SPONSOR

Janssen Research & Development

#### CODE DESIGNATIONS

JNJ-6372, JNJ 61186372, CNTO4424

#### CAS REGISTRY NUMBER

2171511-58-1

#### UNII

OJSR7Z0NB6

#### WHO NUMBER

11030

gbk