

# STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (mn-268)  
Formerly (HI-248)

ZANIDATAMAB

PRONUNCIATION

zan" i dat' a mab

THERAPEUTIC CLAIM

Treatment of cancer

## CHEMICAL NAMES

1. Immunoglobulin G1, anti-(human tyrosine kinase receptor HER2) (human-Mus musculus biparatopic monoclonal ZW25 light chain variable region fragment) fusion protein with peptide (synthetic 20-amino acid linker) fusion protein with human-Mus musculus biparatopic monoclonal ZW25 heavy chain variable region fragment fusion protein with peptide (synthetic 20-amino acid linker) fusion protein with human Fc fragment, (261→229'),(264→232')-bis(disulfide) with immunoglobulin G1 anti-(human tyrosine kinase receptor HER2) (human-Mus musculus biparatopic monoclonal ZW25  $\gamma$ 1-chain) disulfide with human-Mus musculus biparatopic monoclonal ZW25  $\kappa$ -chain
2. Immunoglobulin G1-kappa, anti-[*Homo sapiens* ERBB2 (epidermal growth factor receptor 2, receptor tyrosine protein kinase erbB-2, EGFR2, HER2, HER-2, p185c-erbB2, NEU, CD340)], humanized monoclonal antibody, biparatopic (targeting two different non-overlapping epitopes on ERBB2); gamma1 heavy chain humanized (1-449) [VH (*Homo sapiens* IGHV3-66\*01 (78.8%) -(IGHD) - IGHJ4\*01 (100%)) [8.8.12] (1-120) -*Homo sapiens* IGHG1\*01 G1m17,1 (CH1 K120 (217) (121-218), hinge 1-15 (219-233), CH2 (234-343), CH3 T6>V (353), L7>Y (354), D12 (359), L14 (361), F85.1>A (408), Y86>V (410) (344-448), CHS K2>del (449)) (121-449)], (223-215')-disulfide with kappa light chain humanized (1'-215') [V-KAPPA (*Homo sapiens* IGKV1-16\*01 (84.2%) -IGKJ1\*01 (100%)) [6.3.9] (1'-108') -*Homo sapiens* IGKC\*01 (100%) Km3 A45.1 (154), V101 (192) (109'-215')]; gamma1 heavy chain V-KAPPA-VH-CH2-CH3 humanized (1"-481") [V-KAPPA (*Homo sapiens* IGKV1-39\*01 (86.3%) -IGKJ1\*01 (100%)) [6.3.9] (1"-108") -20-mer linker (109"-128") -VH (*Homo sapiens* IGHV3-66\*01 (81.6%) -(IGHD) -IGHJ4\*01 (100%)) [8.8.13] (129"-248") -dialanyl (249"-250") -*Homo sapiens* IGHG1\*01 (hinge 1-15, C5>S (255) (251-265), CH2 (266-375), CH3 T6>V (385), D12 (391), L14 (393), T22>L (401), K79>L (427), T81>W (429) (376-480), CHS K2>del (481)) (251"-481")]; dimer (229-261":232-264")-bisdisulfide, produced in Chinese Hamster Ovary (CHO), glycoform alfa (Source: WHO pINN list 121)

## STRUCTURAL FORMULA

### Heavy chain A

GEVQLVESGG	GLVQPGGSLR	LSCAASGFTF	ADYTMDWVRQ	APGKGLEWVG	50
DVNPNSGGSI	YNQRFKGRFT	FSVDRSKNTL	YLQMNSLRAE	DTAVYYCARN	100
LGPSFYFDYW	GQGTLVTVSS	ASTKGPSVFP	LAPSSKSTSG	GTAALGCLVK	150
DYFPEPTVTS	WNSGALTSKV	HTFPQAVLQSS	GLYSLSSVVT	VPSSSLGTQT	200
YICNVNHHKPS	NTKVDKKEVP	KSCDKHTHTCP	PCPAPPELLGG	PSVFLFPPKP	250
KDTLMISRTP	EVTTCVVVDVS	HEDPEVKFNW	YVDGVEVHNA	KTKPREEQYN	300
STYRVVSVLT	VLHQDWLNGK	EYKCKVSNKA	LPAPIEKTIS	KAKGQPREPQ	350
VYVYPPSRDE	LTKNQVSLTC	LVKGFYPSDI	AVEWESNGQP	ENNYKTTPEV	400
LDSDGSFALV	SKLTVDKSRW	QQGNVFSCSV	MHEALHNHYT	QKSLSLSPG	449

Light chain

GDIQMTQSPS	SLSASVGDV	TITCKASQDV	SIGVAWYQQK	PGKAPKLLIY	50'
SASYRYTGVP	SRFSGSGSGT	DFTLTISLQ	PEDFATYYCQ	QYYIYPATFG	100'
QGTKVEIKRT	VAAPSVFIFP	PSDEQLKSGT	ASVVCLLNNF	YPREAKVQWK	150'
VDNALQSGNS	QESVTEQDSK	DSTYSLSTL	TLISKADYEKH	KVYACEVTHQ	200'
GLSSPVTKSF	NRGEC				215'

Heavy chain B

GDIQMTQSPS	SLSASVGDV	TITCRASQDV	NTAVAWYQQK	PGKAPKLLIY	50"
SASFLYSGVP	SRFSGSRSGT	DFTLTISLQ	PEDFATYYCQ	QHYTTPPTFG	100"
QGTKVEIKGG	SGGSGGGSG	GGSGGGSGEV	QLVESGGGLV	QPGGSLRLSC	150"
AASGFNIKDT	YIHWRQAPG	KGLEWVARIY	PTNGYTRYAD	SVKGRFTISA	200"
DTSKNTAYLQ	MNSLRAEDTA	VYYCSRWGGD	GFYAMDYWGQ	GTLVTVSSAA	250"
EPKSSDKTHT	CPPCPAPELL	GGPSVFLFPP	KPKDTLMISR	TPEVTCVVVD	300"
VSHEDPEVKF	NWYVDGVEVH	NAKTKPREEQ	YNSTYRVVSV	LTVLHQDWLN	350"
GKEYKCKVSN	KALPAPIEKT	ISKAKGQPRE	PQVYVLPSPR	DELTKNQVSL	400"
LCLVKGFYPS	DIAVEWESNG	QPENNYLTWP	PVLDSGGSFF	LYSKLTVDKS	450"
RWQQGNVFSC	SVMHEALHNN	YTQKSLSLSP	G		481"

Disulfide bridges location

23-97	24'-89'	24"-89"	135'-195'	147-203	150"-224"	215'-223
229-261"	232-264"	264-324	296"-356"	370-428	402"-460"	

Glycosylation sites (N)

Asn-300 Asn-332"

**MOLECULAR FORMULA** C<sub>5553</sub>H<sub>8526</sub>N<sub>1482</sub>O<sub>1726</sub>S<sub>36</sub> . (non-glycosylated)

**MOLECULAR WEIGHT** 124.82 kDa (non-glycosylated)

**TRADEMARK** None as yet

**SPONSOR** Jazz Pharmaceuticals Ireland Ltd.

**CODE DESIGNATIONS** JZP598, ZW25

**CAS REGISTRY NUMBER** 2169946-15-8

**UNII** Z20OC92TDI

**WHO NUMBER** 10997

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