

# STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (KL-138) ZOLBETUXIMAB

PRONUNCIATION zol" be tux' i mab

THERAPEUTIC CLAIM Antineoplastic

## CHEMICAL NAMES

Immunoglobulin G1, anti-(human claudin-18.2) (human-Mus musculus monoclonal IMAB362 heavy chain), disulfide with human-Mus musculus monoclonal IMAB362 κ-chain, dimer (Source: CAS)

Immunoglobulin G1-kappa, anti-[*Homo sapiens* CLDN18 (claudin 18, claudin-18, SFTPJ, surfactant associated protein J) isoform 2, extracellular domain 1 (EC1)], chimeric monoclonal antibody; gamma1 heavy chain (1-448) [*Mus musculus* VH (IGHV1-61\*01 (92.90%) -(IGHD) -IGHJ2\*01) [8.8.11] (1-118) -*Homo sapiens* IGHG1\*03, G1m3, nG1m1 (CH1 R120 (215) (119-216), hinge (217-231), CH2 (232-341), CH3 E12 (357), M14 (359) (342-446), CHS (447-448)) (119-448)], (221-220')-disulfide with kappa light chain (1'-220') [*Mus musculus* V-KAPPA (IGKV8-19\*01 (100.00%) -IGKJ4\*01) [12.3.9] (1'-113') -*Homo sapiens* IGKC\*01, Km3 A45.1 (159), V101 (197) (114'-220')]; dimer (227-227":230-230")-bisdisulfide (Source: WHO pINN list 117)

## STRUCTURAL FORMULA

### Heavy chain X, X''

QVQLQQPGAE	LVRPGASVKL	SCKASGYTFT	SYWINWVKQR	PGQGLEWIGN	50
IYPSDSYTNV	NQKFKDKATL	TVDKSSSTAY	MQLSSPTSSED	SAVYYCTRSW	100
RGNSFDYWGQ	GTTLTVSSAS	TKGPSVFPLA	PSSKSTSGGT	AALGCLVKDY	150
FPEPVTVSWN	SGALTSGVHT	FPAVLQSSGL	YSLSSVVTVP	SSSLGTQTYI	200
CNVNHKPSNT	KVDKRVEPKS	CDKTHTCPPC	PAPELLGGPS	VFLFPPKPKD	250
TLMISRTPEV	TCVVVDVSHE	DPEVKFNWYV	DGVEVHNAKT	KPREEQYNST	300
YRVVSVLTVL	HQDWLNGKEY	KCKVSNKALP	APIEKTISKA	KGQPREPQVY	350
TLPPSREEMT	KNQVSLTCLV	KGFYPSDIAV	EWESNGQPEN	NYKTTTPVLD	400
SDGSFFLYSK	LTVDKSRWQQ	GNVFSCSVHM	EALHNHYTQK	SLSLSPGK	448

### Light chain X', X''

DIVMTQSPSS	LTVTAGEKVT	MSCKSSQSL	NSGNQKNYLT	WYQQKPGQPP	50'
KLIIYWASTR	ESGVPDRFTG	SGSGTDFTLT	ISSVQAEDLA	VYYCQNDYSY	100'
PFTFGSGTKL	EIKRTVAAPS	VFIFPPSDEQ	LKSGTASVVC	LLNNFYPREA	150'
KVQWKVDNAL	QSGNSQESVT	EQDSKDYSTYS	LSSTLTLSKA	DYEKHKVYAC	200'
EVTHQGLSSP	VTKSFNRGEC				220'

### Disulfide bridges

22-96	22''-96''	23'-94'	23'''-94'''	140'-200'	140'''-200'''	145-201	145''-201''
221-220'	221''-220''	227-227''	230-230''	262-322	262'''-322'''	368-426	368''-426''

### Glycosylation sites (N)

298 298''

MOLECULAR FORMULA C<sub>6534</sub>H<sub>10092</sub>N<sub>1726</sub>O<sub>2053</sub>S<sub>44</sub>

MOLECULAR WEIGHT 149.6 kDa

TRADEMARK	None as yet
SPONSOR	Astellas Pharma US, Inc.
CODE DESIGNATIONS	IMAB362
<u>CAS</u> REGISTRY NUMBER	1496553-00-4
UNII	TF5MPQ8WGY
WHO NUMBER	10473

gbk