

July 31, 2013

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (AB-130) POLATUZUMAB VEDOTIN

PRONUNCIATION poe" la tooz' ue mab ve doe' tin

THERAPEUTIC CLAIM Treatment of cancer

CHEMICAL NAMES

1. Immunoglobulin G1, anti-(human antigen CD79b) (human-*Mus musculus* monoclonal MCDS4409A heavy chain), disulfide with human-*Mus musculus* monoclonal MCDS4409A κ -chain, dimer, thioether with maleimidocaproyl-valine-citrulline-*p*-aminobenzyloxycarbonyl monomethylauristatin E
2. Immunoglobulin G1-kappa, anti-(human B-cell antigen receptor complex-associated protein beta chain (B-cell-specific glycoprotein B29, Ig-beta, immunoglobulin-associated B29 protein, CD79b antigen)), humanized monoclonal antibody (polatuzumab), which is linked to an average of 3 to 4 molecules of auristatin E by as much cleavable linkers (vedotin): gamma 1 heavy chain (1-446) [humanized VH (*Homo sapiens*IGHV3-23*04 (76.5%) –IGHJ4*01) [8.8.10] (1-117) –*Homo sapiens*IGHG1*03 CH1R⁹⁷>K(214), des-CH3K¹⁰⁷ (118-446)], (220-218')-disulfide with kappa light chain (1'-218') [humanized V-KAPPA (*Homo sapiens*IGKV1-39*01 (85.9%) –IGKJ1*01) [10.3.9] (1'-111') –*Homo sapiens*IGKC*01 (112'-218')]; dimer (226-226":229-229")-bisdisulfide; some of the interchain disulfide bridges are cleaved and their cysteines are S-substituted by (3RS)-1-[(8S,11S)-11-[(4-[(5S,8S,11S,12R)-14-[(2S)-2-[(1R,2R)-3-[(1R,2S)-2-hydroxy-1-methyl-2-phenylethyl]amino]-1-methoxy-2-methyl-3-oxopropyl]pyrrolidin-1-yl)-12-methoxy-4,10-dimethyl-5,8-bis(1-methylethyl)-11-[(1S)-1-methylpropyl]-3,6,9,14-tetraoxo-2-oxa-4,7,10-triazatetradecyl]phenyl)carbamoyl]-8-(1-methylethyl)-6,9,16-trioxo-7,10,15,17-tetraazaheptadecyl]-2,5-dioxo-pyrrolidin-3-yl radicals

STRUCTURAL FORMULA

Heavy chain

EVQLVESGGG	LVQPGGSLRL	SCAASGYTFS	SYWIEWVRQA	PGKGLEWIGE	50
ILPGGGDTNY	NEIFKGRATF	SADTSKNTAY	LQMNSLRAED	TAVYYCTRRV	100
PIRLDYWGQG	TLVTVSSAST	KGPSVFPLAP	SSKSTSGGTA	ALGCLVKDYF	150
PEPVTVSWNS	GALTSGVHTF	PAVLQSSGLY	SLSSVVTVPS	SSLGTQTYIC	200
NVNHKPSNTK	VDKKVEPKSC	DKTHTCPPCP	APELLGGPSV	FLFPPKPKDT	250
LMISRTPEVT	CVVVDVSHED	PEVKFNWYVD	GVEVHNAKTK	PREEQYNSTY	300
RVVSVLTVLH	QDWLNGKEYK	CKVSNKALPA	PIEKTISKAK	GQPREPQVYT	350
LPPSREEMTK	NQVSLTCLVK	GFYPSDIAVE	WESNGQPENN	YKTTTPVLDS	400
DGSFFLYSKL	TVDKSRWQQG	NVFSCSVMHE	ALHNHYTQKS	LSLSPGK	446

Light chain

DIQLTQSPSS	LSASVGRVTV	ITCKASQSV	YEGDSFLNWF	QQKPGKAPKL	50'
LIYAASNLES	GVPSRFRSGG	SGTDFTLTIS	SLQPEDFATY	YCQQSNEDPL	100'

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N13
90

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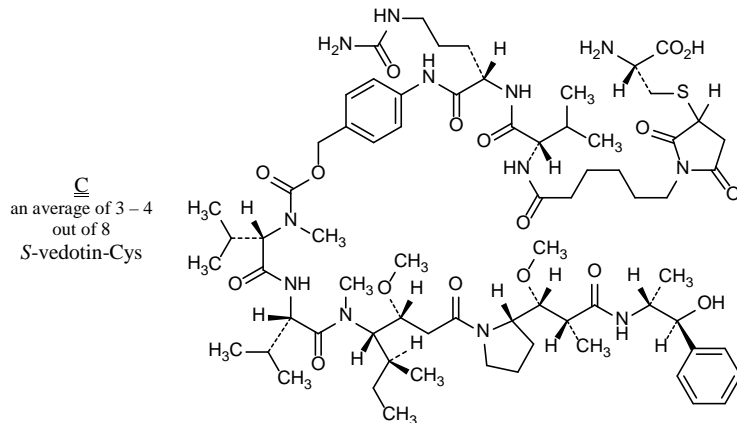
TFGQGTKVEI	KRTVAAPSVF	IFPPSDEQLK	SGTASVVCLL	NNFYPREAKV	150'
QWKVDNALQS	GNSQESVTEQ	DSKDYSTYLSL	STLTLSKADY	EKKHKVYACEV	200'
THQGLSSPVT	KSFNRGE <u>C</u>				218'

Disulfide bridges

22-96	22"-96"	23'-92'	23'''-92'''	138'-198'	138'''-198'''	144-200	144"-200"
218'-220*	218'''-220'''*	226-226**	229-229**	261-321	261"-321"	367-425	367"-425"

* Some are not present and their cysteines are modified (C)

Modified residues

Glycosylation sites (N)

Asn-297 Asn-297"

MOLECULAR FORMULA

 $C_{6670}H_{10317}N_{1745}O_{2087}S_{40}$ (with 3.5 VC-MMAE molecules attached; lacking carbohydrate and heavy chain C-terminal lysine)

MOLECULAR WEIGHT

149.6 kDa

TRADEMARK

None as yet

SPONSOR

Genentech/Roche

CODE DESIGNATIONS

DCDS4501A, RO5541077-000, FCU2711, ACD79B-VCMAE

CAS REGISTRY NUMBER

1313206-42-6

WHO NUMBER

9714

gbk