

July 31, 2013

## STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (AB-128)

PINATUZUMAB VEDOTIN

PRONUNCIATION

pin" a tooz' ue mab ve doe' tin

THERAPEUTIC CLAIM

Treatment of B-cell malignancies

## CHEMICAL NAMES

1. Immunoglobulin G1, anti-(human antigen CD22) (human-*Mus musculus* monoclonal MCDT2219A heavy chain), disulfide with human-*Mus musculus* monoclonal MCDT2219A  $\kappa$ -chain, dimer, thioether with maleimidocaproyl-valine-citrulline-*p*-aminobenzyloxycarbonyl monomethylauristatin E
2. Immunoglobulin G1-kappa, anti-(human B-cell receptor CD22 (B-lymphocyte cell adhesion molecule, sialic acid-binding Ig-like lectin 2, T-cell surface antigen Leu-14)), humanized monoclonal antibody (pinatuzumab), which is linked to an average of 3 to 4 molecules of auristatin E by as much cleavable linkers (vedotin): gamma 1 heavy chain (1-449) [humanized VH (*Homo sapiens*IGHV3-66\*04 (79.6%) –IGHJ4\*01 [8.8.13] (1-120) –*Homo sapiens*IGHG1\*03 CH1R<sup>97</sup>>K(217),des-CH3K<sup>107</sup> (121-449)], (223-219')-disulfide with kappa light chain (1'-219') [humanized V-KAPPA (*Homo sapiens*IGKV1-39\*01 (80.0%) –IGKJ1\*01 [11.3.9] (1'-112') –*Homo sapiens*IGKC\*01 (113'-219')]; dimer (229-229':232-232'')-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)acetyl]-8-(1-methylethyl)-6,9,16-trioxo-7,10,15,17-tetraazaheptadecyl]-2,5-dioxo-1H-pyrrolidin-3-yl radicals

## STRUCTURAL FORMULA

## Heavy chain

EVQLVESGGG	LVQPGGSLRL	SCAASGYEFS	RSWMNWRQA	PGKGLEWVGR	50
IYPGDGDTNY	SGKFKGRFTI	SADTSKNTAY	LQMNSLRAED	TAVYYCARDG	100
SSWDWYFDVW	GQGTLLTVSS	ASTKGPSVFP	LAPSSKSTSG	GTAALGCLVK	150
DYFPEPVTVS	WNSGALTSGV	HTFPAVLQSS	GLYSLSSVVT	VPSSSLGTQT	200
YICNVNHHKPS	NTKVDKQVEP	KSCDKTHTCP	PCPAPPELLGG	PSVFLFPPKP	250
KDTLMISRTP	EVTCTVVDVS	HEDPEVKFNW	YVDGVEVHNA	KTKPREEQYN	300
STYRVVSVLT	VLHQDWLNGK	EYCKVSNKA	LPAPIEKTIS	KAKGQPREPQ	350
VYTLPPSREE	MTKNQVSLTC	LVKGFYPSDI	AVEWESNGQP	ENNYKTTTPV	400
LDSGDGSFFLY	SKLTVDKSRW	QQGNVFSCSV	MHEALHNHYT	QKSLSLSPGK	449

## Light chain

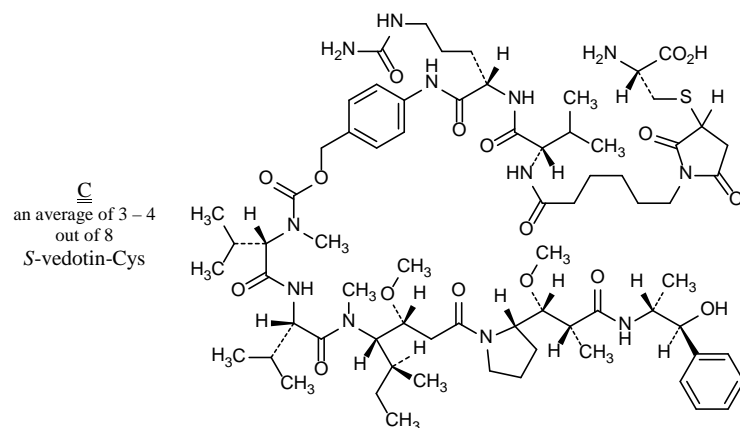
DIQMTQSPSS	LSASVGDRV	ITCRSSQSI	HSVGNFLEW	YQKPGKAPK	50'
LLIYKVSNR	SGVPSRFSG	GSGTDFLTI	SSLQPEDFAT	YYCFQGSQFP	100'
YTFGQGTKVE	IKRTVAAPSV	FIFPPSDEQL	KSGTASVCL	LNNFYPREAK	150'
VQWKVDNALQ	SGNSQESVTE	QDSKDYSL	SSTLTLSKAD	YEKHKVYACE	200'
VTHQGLSSPV	TKSFNRGEC				219'

## Disulfide bridges

22-96	22"-96"	23'-93'	23'''-93'''	139'-199'	139'''-199'''	147-203	147"-203"
219'-223*	219'''-223'''*	229-229**	232-232**	264-324	264'''-324'''	370-428	370"-428"

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

## Modified residues



## Glycosylation sites (N)

Asn-300 Asn-300'

## MOLECULAR FORMULA

$C_{6748}H_{10377}N_{1773}O_{2083}S_{44}$  (with 3.5 VC-MMAE molecules attached; lacking carbohydrate and heavy chain C-terminal lysine)

## MOLECULAR WEIGHT

151.1 KDa

## TRADEMARK

None as yet

## SPONSOR

Genentech/Roche

## CODE DESIGNATIONS

DCDT2980S, RO5541072-000, FCU2703, ACD22-VCMAE

## CAS REGISTRY NUMBER

1313706-14-7

## WHO NUMBER

9713

gbk