

September 24, 2014

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (BC-157)	SOFITUZUMAB VEDOTIN
PRONUNCIATION	soe" fi tooz' ue mab ve doe' tin
THERAPEUTIC CLAIM	Treatment of ovarian cancer

CHEMICAL NAMES

1. Immunoglobulin G1, anti-(human CA 125 (carbohydrate antigen)) (human-Mus musculus monoclonal MMUC1206A heavy chain), disulfide with human-Mus musculus monoclonal MMUC1206A light chain, dimer, thioether with N-[[[4-[[N-[6-(3-mercapto-2,5-dioxo-1-pyrrolidinyl)-1-oxohexyl]-L-valyl-N5-(aminocarbonyl)-L-ornithyl]amino]phenyl]methoxy]carbonyl]-N-methyl-L-valyl-N-[(1S,2R)-4-[(2S)-2-[(1R,2R)-3-[[[(1R,2S)-2-hydroxy-1-methyl-2-phenylethyl]amino]-1-methoxy-2-methyl-3-oxopropyl]-1-pyrrolidinyl]-2-methoxy-1-[(1S)-1-methylpropyl]-4-oxobutyl]-N-methyl-L-valinamide
2. Immunoglobulin G1-kappa auristatin E conjugate, anti-[*Homo sapiens* MUC16 (mucin 16, MUC-16, cancer antigen 125, CA125)], humanized monoclonal antibody conjugated to auristatin E; gamma1 heavy chain (1-446) [humanized VH (*Homo sapiens* IGHV3-48*03 (79.80%) -(IGHD)-IGHJ4*01) [9.8.9] (1-116) -*Homo sapiens* IGHG1*03 (CH1 R120>K (213) (117-214), hinge (215-229), CH2 (230-339), CH3 (340-444), CHS (445-446)) (117-446)], (219-214')-disulfide with kappa light chain (1'-214') [humanized V-KAPPA (*Homo sapiens* IGKV1-5*01 (87.90%) -IGKJ1*01) [6.3.9] (1'-107') - *Homo sapiens* IGKC*01 (108'-214')]; dimer (225-225":228-228")-bisdisulfide; conjugated, on an average of 3 to 4 cysteinyl, to monomethylauristatin E (MMAE), via a cleavable maleimidocaproylvalyl-citrullinyl-*p*-aminobenzyloxycarbonyl (mc-val-cit-PABC) type linker

STRUCTURAL FORMULA *

Heavy chain

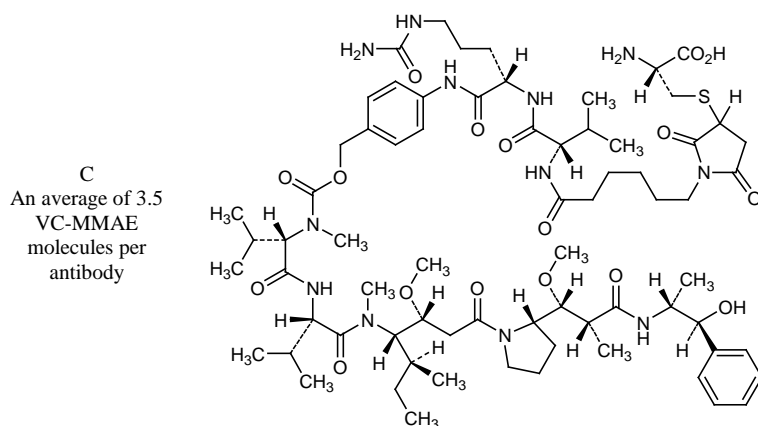
EVQLVESGGG	LVQPGGSLRL	SCAASGYSIT	NDYAWNWVRQ	APGKGLEWVG	50
YISYSGYTTY	NPSLKSFRFTI	SRDTSKNTLY	LQMNSLRAED	TAVYYCARWT	100
SGLDYWGQGT	LVTVSSASTK	GPSVFPLAPS	SKSTSGGTAA	LGCLVKDYFP	150
EPVTVSWNSG	ALTSGVHTFP	AVLQSSGLYS	LSSVVTVPSS	SLGTQTYICN	200
VNHKPSNTKV	DKKVEPKSCD	KTHTCPPCPA	PELGGPSVF	LFPPKPKDTL	250
MISRTPEVTC	VVVDVSHEDP	EVKFNWYVDG	VEVHNAKTKP	REEQYNSTYR	300
VVSVLTVLHQ	DWLNGKEYKC	KVSNKALPAP	IEKTISKAKG	QPREPQVYTL	350
PPSREEMTKN	QVSLTCLVKG	FYPSDIAVEW	ESNGQPENNY	KTTTPPVLDSD	400
GSFFLYSKLT	VDKSRWQQGN	VFSCSVMHEA	LHNHYTQKSL	SLSPGK	446

Light chain

DIQMTQSPSS	LSASVGDVRT	ITCKASDLIH	NWLAWYQQKP	GKAPKLLIYG	50
ATSLETGVPS	RFSGSGSGTD	FTLTISLQP	EDFATYYCQQ	YWTPPFTFGQ	100
GTKVEIKRTV	AAPSVFIFPP	SDEQLKSGTA	SVVCLLNNFY	PREAKVQWKV	150
DNALQSGNSQ	ESVTEQDSKD	STYSLSSTLT	LSKADYEKHK	VYACEVTHQG	200
LSSPVTKSFN	RGEC				214

Disulfide bridges

22-96	22''-96''	23'-88'	23'''-88'''	134'-194'
134'''-194'''	143-199	143''-199''	219-214'	219''-214'''
225-225''	228-228''	260-320	260''-320''	366''-424''
366-424				

Modified residues**Glycosylation sites**

Asn296 Asn296''

*Genentech: please verify the post-translational modifications and the disulfide bridges

MOLECULAR FORMULA	Not determined
MOLECULAR WEIGHT	144.7 kDa
TRADEMARK	None as yet
SPONSOR	Genentech/Roche
CODE DESIGNATIONS	Anti-MUC16 ADC, DMUC5754A
<u>CAS</u> REGISTRY NUMBER	1418200-58-4
UNII	2X3CKG601L
WHO NUMBER	9861