

May 29, 2013

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (AB-73)

DARATUMUMAB

PRONUNCIATION

dar" a toom' ue mab

THERAPEUTIC CLAIM

Treatment of malignancies that express CD38, including Multiple Myeloma

CHEMICAL NAMES

1. Immunoglobulin G1, anti-(human CD38 (antigen)) (human monoclonal 3003-005 heavy chain), disulfide with human monoclonal 3003-005 κ -chain, dimer
2. Immunoglobulin G1-kappa, anti-[*Homo sapiens* ADP-ribosyl cyclase 1 (CD38, cyclic ADP-ribose hydrolase 1, cADPr hydrolase 1, T10)], *Homo sapiens* monoclonal antibody; gamma1 heavy chain (1-452) [*Homo sapiens* VH (IGHV3-23*01 (94.90%) -(IGHD)-IGHJ4*01) [8.8.15] (1-122) -IGHG1*03 (123-452)], (225-214')-disulfide with kappa light chain (1'-214') [*Homo sapiens* V-KAPPA (IGKV3-11*01 (100.00%) -IGKJ1*01) [6.3.9] (1'-107') -IGKC*01 (108'-214')]; (231-231":234-234")-bisdisulfide dimer

STRUCTURAL FORMULA

Heavy chain

EVQLLESGGG	LVQPGGSLRL	SCAVSGFTFN	SFAMSWVRQA	PGKGLEWVSA	50
ISGSGGGTY	ADSVKGRFTI	SRDNSKNTLY	LQMNSLRAED	TAVYFCAKDK	100
ILWFGEPEVFD	YWGQGTLLTV	SSASTKGPSV	FPLAPSSKST	SGGTAALGCL	150
VKDYFPEPVT	VSWNSGALTS	GVHTFPAVLQ	SSGLYSLSV	VTVPSSSLGT	200
QTYICNVNHNK	PSNTKVDKRV	EPKSCDKTHT	CPPCPAPELL	GGPSVFLFPP	250
KPKDTLMISR	TPEVTCVVVD	VSHEDPEVKF	NWYVDGVEVH	NAKTKPREEQ	300
YNSTYRVVSV	LTVLHQDWLN	GKEYCKVSN	KALPAPIEKT	ISKAKQPRE	350
PQVYTLPPSR	EEMTKNQVSL	TCLVKGFYPS	DIAVEWESNG	QPENNYKTTT	400
PVLDSDSGSAF	LYSKLTVDKS	RWQQGNVFSC	SVMHEALHNN	YTQKSLSLSP	450
GK					452

Light chain

EIVLTQSPAT	LSLSPGERAT	LSCRASQSVS	SYLAWYQQKP	GQAPRLLIYD	50
ASNRATGIPA	RFGSGSGTD	FRTLTISSELP	EDFAVYYCQQ	RSNWPPTFGQ	100
GTKVEIKRTV	AAPSVFIFPP	SDEQLKSGTA	SVVCLLNNFY	PREAKVQWKV	150
DNALQSGNSQ	ESVTEQDSKD	STYLSLSTLT	LSKADYEKHK	VYACEVTHQG	200
LSSPVTKSFN	RGEC				214

Disulfide bridges

22-96	22"-96"	23"-88"	23""-88""	134'-194'	134""-194""	149-205	149"-205"
225-214'	225"-214""	231-231"	234-234"	266-326	266"-326"	372-430	372-430"

Glycosylation sites (N)

Asn302 Asn302"

MOLECULAR FORMULA

 $C_{6466}H_{9996}N_{1724}O_{2010}S_{42}$

MOLECULAR WEIGHT

145.4 kDa

DARATUMUMAB

N13

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TRADEMARK

None as yet

SPONSOR

Janssen Global Services LLC/Johnson & Johnson

CODE DESIGNATIONS

HuMax-CD38, 3003-005

CAS REGISTRY NUMBER

945721-28-8

WHO NUMBER

9128

gbk