

January 28, 2015

STATEMENT ON A NONPROPRIETARY NAME ADOPTED BY THE USAN COUNCIL

USAN (CD-15) IDARUCIZUMAB

PRONUNCIATION eye" da roo siz' ue mab

THERAPEUTIC CLAIM Reversal of anticoagulant effects of dabigatran

CHEMICAL NAMES

- 1-225-Immunoglobulin G1, anti-(dabigatran) (human-*Mus musculus* γ 1-chain) (225→219')-disulfide with immunoglobulin G1, anti-(dabigatran) (human-*Mus musculus* κ -chain)
- Immunoglobulin G1-kappa Fab fragment, anti-(dabigatran); humanized mouse monoclonal antibody: γ 1 heavy chain fragment (1-225) [humanized VH (human IGHV4-59*01 (82%) –(IGHD)-IGHJ4*01) [8.7.16] (1-122) –human IGHG1*01 fragment (CH1-H¹⁻⁵) (123-225)] (225-219')-disulfide with kappa light chain (1'-219') [humanized V-KAPPA (human IGKV2D-30*01 (88%) – IGKJ4*01) [11.3.9] (1'-112') –human IGKC*01 (113'-219')]

STRUCTURAL FORMULA

Heavy chain Fab fragment

QVQLQESGPG	LVKPSSETLSL	TCTVSGFSLT	SYIVDWIRQP	PGKLEWIGV	50
IWAGGSTGYN	SALRSRVSIT	KDTSKNQFSL	KLSSVTAADT	AVYVCASAAY	100
YSYNYDGF	YWGQGLVTV	SSASTKGPSV	FPLAPSSKST	SGGTAALGCL	150
VKDYFPEPVT	VSWNSGALTS	GVHTFPAVLQ	SSGLYSLSSV	VTVPSSSLGT	200
QTYICNVNHNK	PSNTKVDKVV	EPKSC			225

Light chain

DVVMTQSPPLS	LPVTLGQPAS	ISCKSSQSL	YTDGKTYLYW	FLQRPQGSPR	50'
RLIYLVSCLD	SGVPDRFSGS	GSGETDFTLKI	SRVEAEDVGV	YYCLQSTHFP	100'
HTFGGGTKVE	IKRTVAAPSV	FIFPPSDEQL	KSGTASVCL	LNNFYPREAK	150'
VQWKVDNALQ	SGNSQESVTE	QDSKDYSL	SSTLTLSKAD	YEKHKVYACE	200'
VTHQGLSSPV	TKSFNRGEC				219'

Disulfide bridges

22-95	23'-93'	139'-199'	149-205	219'-225
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MOLECULAR FORMULA C₂₁₃₁H₃₂₉₉N₅₅₅O₆₇₁S₁₁

MOLECULAR WEIGHT 47.8 kDa

TRADEMARK None as yet

SPONSOR Boehringer Ingelheim Pharmaceuticals, Inc.

CODE DESIGNATIONS BI 655075

IDARUCIZUMAB

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CAS REGISTRY NUMBER 1362509-93-0

UNII 97RWB5S1U6

WHO NUMBER 9698

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