

2007	01	15
2008	03	26
2008	04	17
2009	01	09
2009	09	21
2010	04	01
2012	07	03
2014	02	10
2014	03	04
2014	05	05
2014	05	18
2015	02	09
2015	07	23
2016	06	07
2016	07	05
2016	08	24
2017	10	09
2018	01	14
2018	03	06
2019	01	08
2019	07	18
2020	08	10

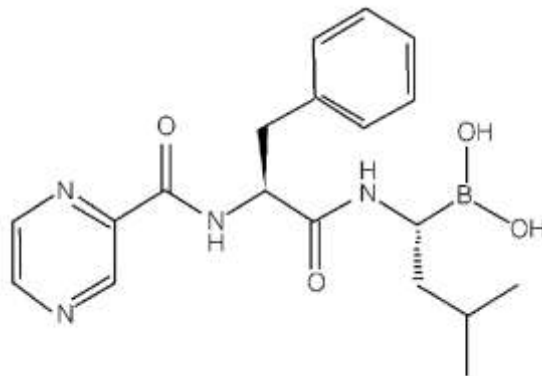
注射用硼替佐米说明书

®

Bortezomib for Injection

Zhusheyong Pengtizuomi

[1R -3- -1-[[2S -1- -3- -2-[]]]]
]



$C_{19}H_{25}BN_4O_4$

384.24

MP

1.0mg

1 9 1~4 3~5 6
22 25 29 32 5~9 1 2 1 4 8 11
72 1 8 22 29

1

2 (1~4)												
	1				2		3	4		5		6
(1.3mg/m ²)	1	--	--	4	8	11		22	25	29	32	

(9mg/m ²)	1	2	3	4	--	--			--	--	--	--		
(60mg/m ²)														
(5~9)														
	1				2		3		4		5		6	
(1.3mg/m ²)	1	--	--	--	8				22		29			
(9mg/m ²)	1	2	3	4	--				--		--			
(60mg/m ²)														

- $\geq 70 \times 10^9/L$ ANC $\geq 1.0 \times 10^9/L$

- 1

2

<ul style="list-style-type: none"> • 4 25% • 1 $\leq 30 \times 10^9/L$ ANC $\leq 0.75 \times 10^9/L$ • 2 ≥ 3 1 1.3mg/m² ≥ 2 1mg/m² 1mg/m² 0.7mg/m² 	
3	1 1.3mg/m ²

*	NCI	CTCAE v 4.0
**	ADL	
***	ADL	

2
 3 1 1 375 mg/m²
 750 mg/m² 50 mg/m² 1 2 3 4 5 100
 mg/m²

- 1
 $\geq 100 \times 10^9 / L$ ANC $\geq 1.5 \times 10^9 / L$
- $\geq 8g / dL$ $\geq 4.96 \text{ mmol} / L$
- 1
 3 3
 4

--	--

<ul style="list-style-type: none"> • ≥ 3 $< 10 \times 10^9/L$ • $< 25 \times 10^9/L$ 	<p style="text-align: right;">2</p> <p>ANC $\geq 0.75 \times 10^9/L$ $\geq 25 \times 10^9/L$</p> <ul style="list-style-type: none"> • • <p>ANC $\geq 0.75 \times 10^9/L$ $\geq 25 \times 10^9/L$</p> <p style="text-align: center;">1.3mg/m² 1mg/m² 1mg/m² 0.7mg/m²</p>
<p>≥ 3</p>	<p style="text-align: right;">2</p> <p style="text-align: center;">1.3 mg/m² 1 mg/m² 1 mg/m² 0.7 mg/m²</p> <p style="text-align: center;">3 / /</p>

0.7mg/m²
1.0mg/m² 0.5mg/m²
5

		SGOT (AST)	1.3mg/m² 2
--	--	-------------------	--

	≤ 1.0x ULN	> ULN	
	> 1.0x 1.5x ULN		
	> 1.5x 3x ULN		0.7mg/m ² 1.0mg/m ² 0.5mg/m ²
	> 3x ULN		
: SGOT = AST = ULN =			

3~5

0.9%

III M34101-039 669 1~3 1.3mg/m²
II 202 2
M34100-025 - II
1.0mg/m² 1.3mg/m² M34100-024

6

II III

MedDRA		
	M34100-039 (N=331)	M34100-024/025 (N=228 ^a)
	115 (35%)	97 (43%)
	87 (26%)	74 (32%)

MedDRA		
	M34100-039 (N=331)	M34100-024/025 (N=228 ^a)
	62 (19%)	55 (24%)
	24 (7%)	15 (7%)
	15 (5%)	11 (5%)
	2 (<1%)	6 (3%)
	1 (<1%)	1 (<1%)
	4 (1%)	2 (<1%)
	9 (3%)	17 (7%)
	6 (2%)	2 (<1%)
	5 (2%)	4 (2%)
	7 (2%)	8 (4%)
	6 (2%)	3 (1%)
^b	1 (<1%)	-
	1 (<1%)	-
	1 (<1%)	-
	3 (<1%)	1 (<1%)
	1 (<1%)	1 (<1%)
	9 (3%)	25 (11%)
	14 (4%)	7 (3%)
	140 (42%)	97 (43%)
	190 (57%)	116 (51%)

MedDRA		
	M34100-039 (N=331)	M34100-024/025 (N=228 ^a)
	190 (57%)	145 (64%)
	117 (35%)	82 (36%)
	80 (24%)	48 (21%)
	32 (10%)	30 (13%)
	25 (8%)	19 (8%)
	10 (3%)	1 (<1%)
	2 (<1%)	4 (2%)
	14 (4%)	13 (6%)
	24 (7%)	10 (4%)
	4 (1%)	5 (2%)
b	7 (2%)	3 (1%)
	7 (2%)	3 (1%)
	2 (<1%)	1 (<1%)
	3 (<1%)	2 (<1%)
	1 (<1%)	-
	1 (<1%)	-
	3 (<1%)	-
	1 (<1%)	2 (<1%)
	201 (61%)	149 (65%)
-	40 (12%)	44 (19%)
-	140 (42%)	118 (52%)
-	12 (4%)	9 (4%)
-	13 (4%)	22 (10%)

MedDRA		
	M34100-039 (N=331)	M34100-024/025 (N=228 ^a)
	116 (35%)	82 (36%)
	37 (11%)	27 (12%)
	35 (11%)	27 (12%)
	21 (6%)	5 (2%)
	26 (8%)	16 (7%)
	1 (<1%)	1 (<1%)
	1 (<1%)	1 (<1%)
	1 (<1%)	-
	3 (<1%)	2 (<1%)
	2 (<1%) M34101-040 ^c	-
	1 (<1%)	1 (<1%)
	26 (8%)	41 (18%)
	45 (14%)	17 (7%)
	48 (15%)	29 (13%)
^b	21 (6%)	23 (10%)
	42 (13%)	26 (11%)
	25 (8%)	13 (6%)
	26 (8%)	6 (3%)
	4 (1%)	1 (<1%)
	14 (4%)	15 (7%)

MedDRA		
	M34100-039 (N=331)	M34100-024/025 (N=228 ^a)
	6 (2%)	2 (<1%)
	6 (2%)	3 (1%)
	13 (4%)	14 (6%)
	10 (3%)	6 (3%)
^b	9 (3%)	9 (4%)
	7 (2%)	-
	7 (2%)	8 (4%)
ALT	3 (<1%)	10 (4%)
AST	5 (2%)	12 (5%)
	6 (2%)	8 (4%)
GGT	1 (<1%)	4 (2%)
	112 (34%)	99 (43%)
	24 (7%)	42 (18%)
	5 (2%)	16 (7%)
	7 (2%)	4 (2%)
	8 (2%)	18 (8%)
	50 (15%)	59 (26%)
	39 (12%)	32 (14%)
	45 (14%)	60 (26%)
()		

MedDRA		
	M34100-039 (N=331)	M34100-024/025 (N=228 ^a)
	2 (<1%) M34101-040 c	-
d	120 (36%)	84 (37%)
	91 (27%)	53 (23%)
	45 (14%)	48 (21%)
	85 (26%)	63 (28%)
	17 (5%)	29 (13%)
	9 (3%)	1 (<1%)
	8 (2%)	17 (7%)
	4 (1%)	-
	2 (<1%)	-
	2 (<1%)	-
	31 (9%)	32 (14%)
	21 (6%)	21 (9%)
	2 (1%)	3 (1%)
	5 (2%)	4 (2%)
	21 (6%)	23 (10%)
	70 (21%)	39 (17%)
	65 (20%)	50 (22%)
	21 (6%)	18 (8%)

MedDRA		
	M34100-039 (N=331)	M34100-024/025 (N=228 ^a)
	4 (1%)	9 (4%)
	4 (1%)	14 (6%)
	3 (<1%)	2 (<1%)
	61 (18%)	47 (21%)
	7 (2%)	5 (2%)
	20 (6%)	27 (12%)
/	14 (4%)	8 (4%)
	6 (2%)	7 (3%)
^b	1 (<1%)	-
^a 228	1.3mg/m ²	
^b		
^c	1.3mg/m ²	4
	M34101-039	
^d	MedDRA HLT	

III

1.3mg/m²

222

7

III

10%

	N=74			N=147		
MedDRA	, n %		, n %		, n %	
	n %	3	≥ 4	n %	3	≥ 4
	26 35	6 8	0	53 36	14 10	4 3
	16 22	4 5	1 1	29 20	9 6	0
	20 27	10 14	3 4	42 29	22 15	4 3
	27 36	8 11	6 8	52 35	12 8	7 5
	8 11	0	0	5 3	1 1	0
	8 11	0	0	3 2	0	0
	11 15	1 1	0	21 14	1 1	0
	27 36	3 4	1 1	35 24	2 1	1 1
	14 19	0	0	27 18	0	0
	12 16	0	1 1	17 12	3 2	0
	14 19	4 5	0	23 16	3 2	0
	15 20	3 4	0	17 12	3 2	0
	12 16	0	0	28 19	0	0
	7 9	1 1	0	16 11	2 1	0

	7 9	0	0	14 10	0	0
	8 11	2 3	0	8 5	1 1	0
	8 11	0	0	5 3	0	0
	17 23	7 9	0	35 24	5 3	0
	36 49	10 14	1 1	51 35	7 5	0
	8 11	0	0	18 12	0	0
	9 12	2 3	0	11 7	2 1	0

10%

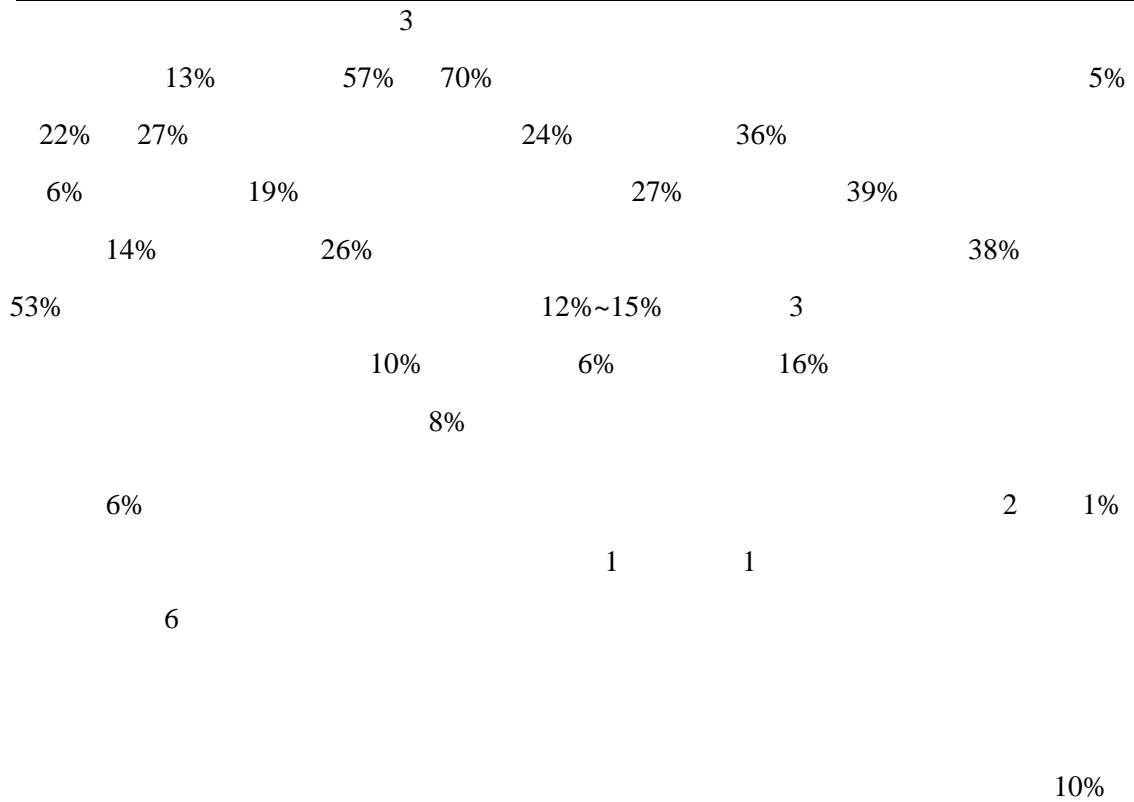
8

III

>10%

	N=74			N=147		
MedDRA	n %			n %		
MedDRA	TEAE	G ≥ 3	Disc	TEAE	G ≥ 3	Disc
TEAE	73 99	52 70	20 27	140 95	84 57	33 22

	27 36	4 5	1 1	35 24	3 2	1 1
	14 19	0	0	9 6	1 1	0
	29 39	7 9	1 1	40 27	6 4	2 1
	19 26	2 3	0	20 14	0	0
^a	39 53	12 16	10 14	56 38	9 6	9 6
^a TEAE G ≥ 3 ≥ 3 Disc						



MMY-2036

9 ≥ 10%

(MMY-2036)

	(MMY-2036)		
		3	≥4
	130		
n (%)	126 (97)		
MedDRA			
	71 (55)	19 (15)	14 (11)
	48 (37)	5 (4)	1 (1)
	23 (18)	9 (7)	0
	20 (15)	5 (4)	0
	45 (35)	9 (7)	0
	36 (28)	0	0
	14 (11)	0	0
	31 (24)	2 (2)	0
	29 (22)	6 (5)	0
	21 (16)	0	0
	15 (12)	0	0
	17 (13)	3 (2)	1 (1)
	13 (10)	1 (1)	0
	22 (17)	4 (3)	0
	13 (10)	3 (2)	0

	(MMY-2036)		
		3	≥4
	15 (12)	1 (1)	0
	14 (11)	1 (1)	0
<p>MedDRA 14.1</p> <p>MMY-2036 NCI CTCAE</p> <p style="margin-left: 150px;">3</p>			

MMY-2045

DOXIL-MMY-3001

10%

10

10%

DOXIL-MMY-3001

MMY-

2045

			+		+	
	n (%)	≥3 n (%)	n (%)	≥3 n (%)	n (%)	≥3 n (%)
	318		318		163	
	301 (95)		314 (99)		154 (94)	
MedDRA						

			+		+	
	n (%)	≥ 3 n (%)	n (%)	≥ 3 n (%)	n (%)	≥ 3 n (%)
	124 (39)	16 (5)		23 (7)	51 (31)	7 (4)
	126 (40)	3 (1)	154 (48)			

			+		+	
	n (%)	≥ 3	n (%)	≥ 3	n (%)	≥ 3
		n (%)		n (%)		n (%)
	33 (10)	3 (1)	33 (10)	2 (1)	15 (9)	3 (2)
	39 (12)	6 (2)	39 (12)	4 (1)	25 (15)	2 (1)
	48 (15)	8 (3)	34 (11)	1 (< 1)	16 (10)	2 (1)
	27 (8)	5 (2)	34 (11)	1 (< 1)	14 (9)	1 (1)
	38 (12)	0	58 (18)	0	26 (16)	1 (1)
	28 (9)	10 (3)	34 (11)	3 (1)	13 (8)	3 (2)
	50 (16)	1 (< 1)	83 (26)	8 (3)	9 (6)	0
	29 (9)	3 (1)	48 (15)	2 (1)	8 (5)	0
	12 (4)	0	37 (12)	0	3 (2)	0
	43 (14)	2 (1)	35 (11)	0	18 (11)	1 (1)

a

MedDRA 14.1

MMY-2045

NCI CTCAE

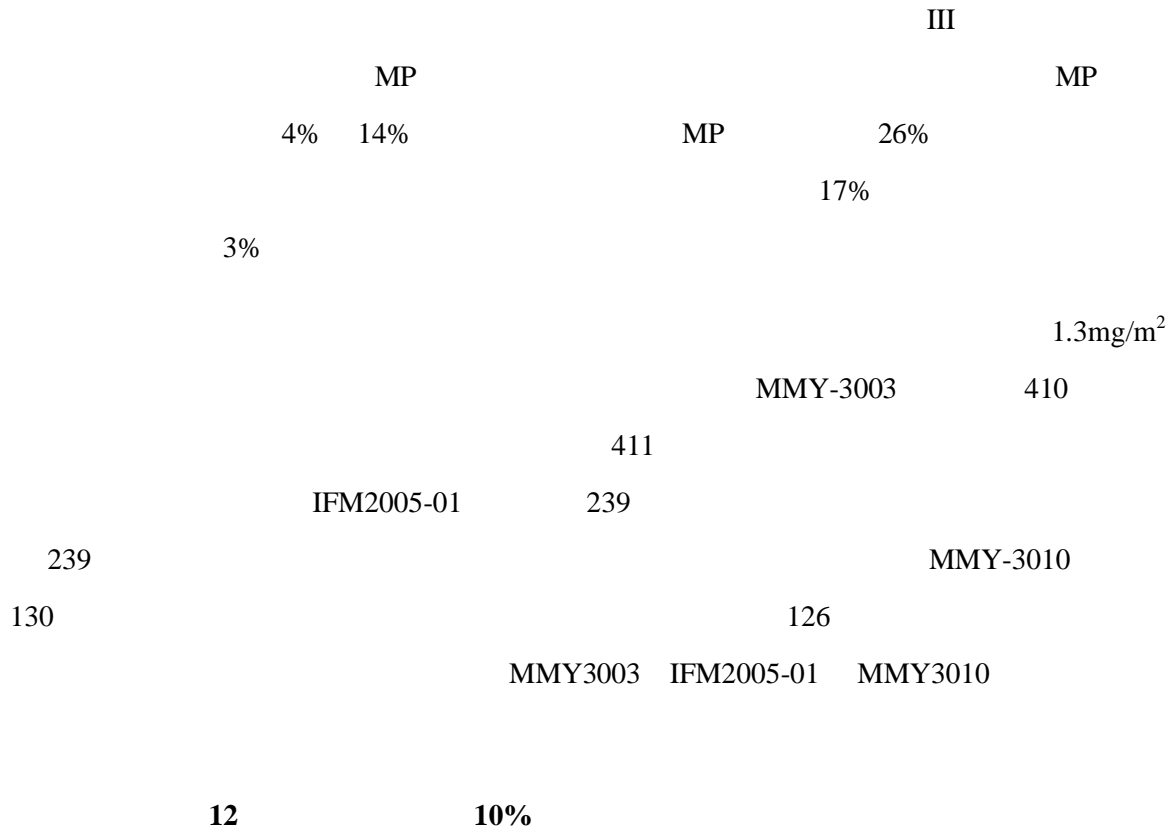
III 340

1.3 mg/m² MP [9mg/m² 60mg/m²]

11 MP 10%

	MP (n=340)			MP (n=337)		
MedDRA	n (%)					
	n (%)	3	≥4	n (%)	3	≥4
	164 (48)	60 (18)	57 (17)	140 (42)	48 (14)	39 (12)
	160 (47)	101 (30)	33 (10)	143 (42)	77 (23)	42 (12)
	109 (32)	41 (12)	4 (1)	156 (46)	61 (18)	18 (5)
	108 (32)	64 (19)	8 (2)	93 (28)	53 (16)	11 (3)
	78 (23)	46 (14)	17 (5)	51 (15)	26 (8)	7 (2)
	134 (39)	10 (3)	0	70 (21)	1 (<1)	0
	119 (35)	19 (6)	2 (1)	20 (6)	1 (<1)	0
	87 (26)	13 (4)	0	41 (12)	2 (1)	0
	77 (23)	2 (1)	0	14 (4)	0	0
	34 (10)	1 (<1)	0	20 (6)	0	0
	156 (46)	42 (12)	2 (1)	4 (1)	0	0
	117 (34)	27 (8)	2 (1)	1 (<1)	0	0
	42 (12)	6 (2)	0	4 (1)	0	0
	85 (25)	19 (6)	2 (1)	48 (14)	4 (1)	0
	54 (16)	18 (5)	0	23 (7)	3 (1)	0
	53 (16)	4 (1)	0	19 (6)	1 (<1)	1 (<1)
	39 (11)	11 (3)	0	9 (3)	4 (1)	0
	64 (19)	6 (2)	0	19 (6)	0	0
	38 (11)	2 (1)	0	7 (2)	0	0

	MP (n=340)			MP (n=337)		
MedDRA	n (%)			n (%)		
	n (%)	3	≥4	n (%)	3	≥4
	35 (10)	1 (<1)	0	21 (6)	0	0



	(N=779)			(N=776)		
MedDRA	n (%)			n (%)		
	n (%)	2	≥ 3	n (%)	2	≥ 3
	715 (92)			679 (88)		
	242 (31)	89 (11)	10 (1)	214 (28)	67 (9)	8 (1)
	215 (28)	71 (9)	22 (3)	206 (27)	77 (10)	9 (1)
	133 (17)	29 (4)	23 (3)	110 (14)	26 (3)	6 (1)
	95 (12)	30 (4)	18 (2)	87 (11)	35 (5)	6 (1)

	147 (19)	53 (7)	20 (3)	54 (7)	11 (1)	4 (1)
	101 (13)	24 (3)	11 (1)	80 (10)	15 (2)	2 (<1)
	101 (13)	41 (5)	19 (2)	55 (7)	13 (2)	1 (<1)
	64 (8)	23 (3)	4 (1)	76 (10)	23 (3)	1 (<1)
	158 (20)	50 (6)	21 (3)	161 (21)	68 (9)	21 (3)
	153 (20)	56 (7)	25 (3)	159 (20)	40 (5)	36 (5)
	110 (14)	33 (4)	16 (2)	91 (12)	33 (4)	10 (1)
	239 (31)	54 (7)	63 (8)	171 (22)	27 (3)	27 (3)
	211 (27)	95 (12)	55 (7)	222 (29)	108 (14)	77 (10)
	196 (25)	51 (7)	109 (14)	206 (27)	53 (7)	120 (15)
	86 (11)	50 (6)	24 (3)	18 (2)	9 (1)	5 (1)
	122 (16)	46 (6)	26 (3)	138 (18)	46 (6)	31 (4)
	100 (13)	2 (<1)	29 (4)	82 (11)	6 (1)	12 (2)
	96 (12)	32 (4)	6 (1)	82 (11)	30 (4)	6 (1)
MedDRA 13.1						

MP

21

MP

41

20

n(%)	21 100	326 97	20 100	338 99
	18 86	259 77	20 100	279 82
	3 14	48 14	3 15	59 17
	0	0	0	1 <1
	0	18 5	0	38 11
	0	2 1	1 5	10 3
	0	28 8	1 5	73 21
	9 43	185 55	18 90	262 77
	8 38	199 59	16 80	239 70
	2 10	27 8	5 25	31 9
	1 5	6 2	0	5 1
	10 48	182 54	13 65	234 69
	0	40 12	0	40 12
	2 10	21 6	1 5	32 9
	6 29	124 37	10 50	159 47
	5 24	151 45	7 35	172 51
()	0	4 1	0	7 2
	4 19	122 36	13 65	253 74
	4 19	76 23	0	112 33
	4 19	62 18	2 10	54 16
	1 5	15 4	1 5	21 6
	5 24	123 36	8 40	133 39
	1 5	80 24	8 40	140 41
	0	3 1	0	7 2
	1 5	69 20	6 30	112 33

II (M34103-053) 155
 1.3mg/m²

14 240
 mg/m² 1.3 mg/m² 375 mg/m² 750
 50 mg/m² 100 mg/m² VcR-CAP
 ≥3 VcR-CAP 4 R-CHOP 3 VcR-CAP
 ≥3
 VcR-CAP 31% R-CHOP 23%
 VcR-CAP 8% R-CHOP
 5%
 VcR-CAP R-CHOP 4.6% 0.8%

14 VcR-CAP R-CHOP
 5% 3 4

LYM-3002 N=482

		VcR-CAP			R-CHOP		
		n=240			n=242		
		3	≥4		3	≥4	
	n %	n %	n %	n %	n %	n %	n %

	VcR-CAP			R-CHOP		
	n=240			n=242		
		3	≥4		3	≥4
	n %	n %	n %	n %	n %	n %
	209 (87)	32 (13)	168 (70)	172 (71)	31 (13)	125 (52)
	116 (48)	34 (14)	69 (29)	87 (36)	39 (16)	27 (11)
	106 (44)	27 (11)	4 (2)	71 (29)	23 (10)	4 (2)
	172 (72)	59 (25)	76 (32)	42 (17)	9 (4)	
	41 (17)	24 (10)	12 (5)	33 (14)	17 (7)	15 (6)

	VcR-CAP			R-CHOP		
	n=240			n=242		
	3		≥ 4	3		≥ 4
	n	%	n	%	n	%
	20 (8)	8 (3)	5 (2)	11 (5)	5 (2)	3 (1)
	31 (13)	1 (< 1)	1 (< 1)	33 (14)	4 (2)	0
	10 (4)	1 (< 1)	0	17 (7)	10 (4)	0
	36 (15)	2 (1)	0	15 (6)	1 (< 1)	0
	11 (5)	3 (1)	1 (< 1)	6 (2)	1 (< 1)	0
	15 (6)	1 (< 1)	0	3 (1)	0	0
	16 (7)	1 (< 1)	0	8 (3)	0	0

R-CHOP=
VcR-CAP=

15

$\geq 1/10$ $\geq 1/100$ $< 1/10$ $(\geq 1/1000$ $< 1/100)$
 $(\geq 1/10000$ $< 1/1000)$ $(< 1/10000$ $)$

15:

--	--	--

PN

≥ 3

	III		2	2
24%	41%	p=0.0124	3	3
6%	16%	p=0.0264	8	

				III
51%	2	2		
	II		2	3
73%				

•

	II	III
11%	12%	

/

•

/

		III		
15%	13%	5%	4%	QT

•

•

ARDS

2

2g/m²

ARDS

•

PRES

PRES PRES

MRI

PRES

PRES

•

•

/

11

<25000/ μ L

40%

16

≥ 3

5%

4%

•

•

		669		245	37%		≥ 65
125	38%	120	36%			≥ 65	
						5.5	4.3
8.0	4.9		≥ 65			40%	n=46
CR+PR		18%	n=21			≤ 50	51~64 ≥ 65
3	4	64%	78%	75%			

2

/

202

M34100-025

6 17

1.3mg/m²

2

2

10

21

1

8

17

*

	202
	59 34 84
	60% 40%
	81% 10% 8%
≤70	20%
<100g/L	44%
<75×10 ⁹ /L	21%
% IgG / IgA /	60% 24% 14%
β ₂ - mg/L	3.5
ml/min	73.9
	35%
13	15%
	4.0
VAD	99%
VBMCP	92%
VAD	81%
	83%

	98%
	92%
	66%
	64%
	44%
*	

18

Bladé

5% M- 100%
 IF⁻ 18 SWOG SWOG
 M ≥75% M- ≥90% 188 9
 5
 98% 1.3mg/m² 28%
 33% 63%
 2 6
 38 30~127
 16 1~18
 18

N=188		N	%	95	CI
Bladé	CR+PR	52	27.7%	21	35
	CR ¹	5	2.7%	1	6
	PR ²	47	25%	19	32
	SWOG ³	33	17.6%	12	24
Kaplan-Meier 95%CI		365		224 NE	
¹		5% M-	100%	IF ⁻	
²	6	M	≥50%	M-	≥90%
³	SWOG 6	M	≥75%	M-	≥90%

50%

13

	54				M34100-24		1.0
mg/m ²	1.3 mg/m ²		2	2	1		
	CR+PR		30%	8/27	38%	10/26	

				1:1		III	[M34101-039
(APEX)]						TTP	

669

1 3

2 2

<50000/μL

627

1 1

6

6

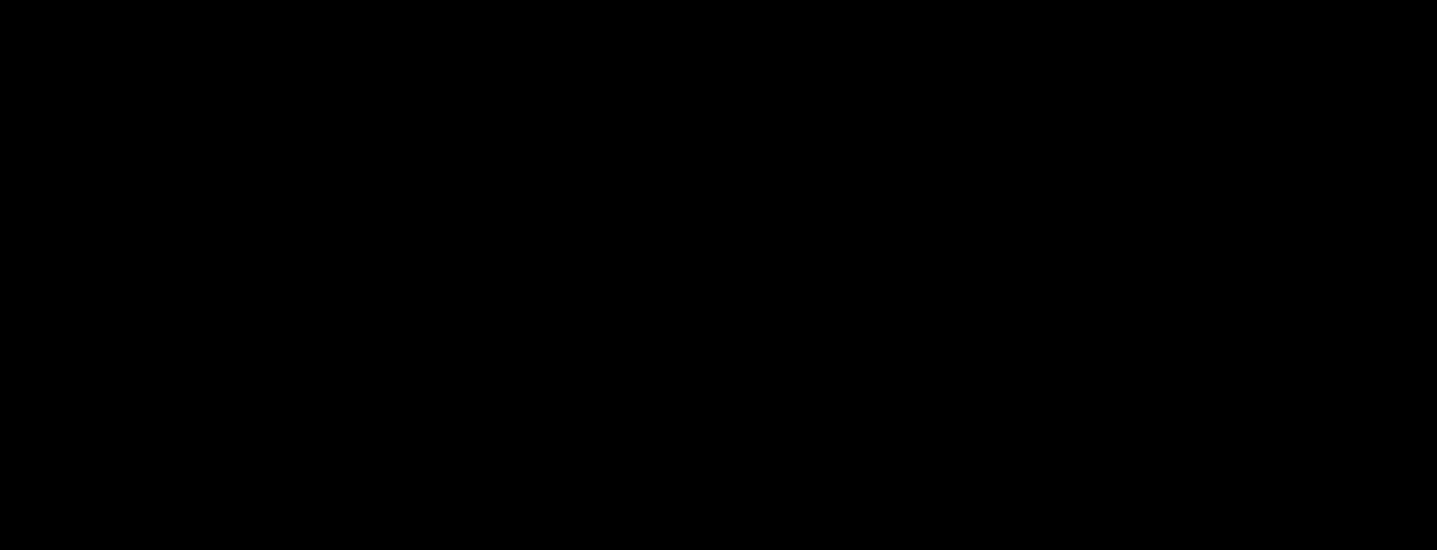
β₂-

≤2.5mg/L

>2.5mg/L

19

19 III



n=534 8.3

8 3 34% 1

11 13% 1

22 1 44 4 5 40%

1 9 6% 1

III 20

EBMT CR 5%

M 100% IF⁻ PR 6

M ≥50% M- ≥90%

nCR M- 100%

M- IF⁺

20 III

	n=333		n=336		n=132		n=119		n=200		n=217	
n (%)	147(44)		196(58)		55(42)		64(54)		92(46)		132(61)	
^a (95% CI)	6.2 (4.9, 6.9)		3.5 (2.9, 4.2)		7.0 (6.2, 8.8)		5.6 (3.4, 6.3)		4.9 (4.2, 6.3)		2.9 (2.8, 3.5)	
^b (95% CI)	0.55 (0.44, 0.69)				0.55 (0.38, 0.81)				0.54 (0.41, 0.72)			
^p ^c	< 0.0001				0.0019				<0.0001			
() n (%)	51(15)		84(25)		12(9)		24(20)		39(20)		60(28)	
^b	0.57				0.39				0.65			

(95% CI)	(0.40, 0.81)		(0.19, 0.81)		(0.43, 0.97)	
p ^{c,d}	<0.05		<0.05		<0.05	
^e n = 627	n=315	n=312	n=128	n=110	n=187	n=202
CR ^f n (%)	20(6)	2(<1)	8(6)	2(2)	12(6)	0(0)
PR ^f n(%)	101(32)	54(17)	49(38)	27(25)	52(28)	27(13)
nCR ^{f,g} n(%)	21(7)	3(<1)	8(6)	2(2)	13(7)	1(<1)
CR + PR ^f n (%)	121 (38)	56 (18)	57(45)	29(26)	64(34)	27(13)
p ^h	<0.0001		0.0035		<0.0001	
n						
CR ^f	9.9	NE ⁱ	9.9	NE	6.3	NA ^j
nCR ^f	11.5	9.2	NE	NE	11.5	9.2
CR + PR ^f	8.0	5.6	8.1	6.2	7.8	4.1
^a Kaplan-Meier						
^b	COX				1	
^c p	log-rank					
^d	p					
^e						
^f	EBMT	nCR	EBMT	CR	IF	EBMT nCR
	PR					
^g	2	IF				
^h	(CR + PR) p		Cochran-Mantel-Haenszel			
ⁱ						
^j						

682 (1:1) III
 [MMY-3002 (VISTA)] MP 1.3mg/m² MP
 TTP 9

54

21

21 VISTA

	MP N=344	MP N=338
	71.0 (57, 90)	71.0 (48, 91)
/	51% / 49%	49% / 51%
/ / /	88% / 10% / 1% / 1%	87% / 11% / 2% / 0%
≤70	35%	33%
<100 g/L	37%	36%
<75 × 10 ⁹ /L	<1%	1%
% IgG/IgA/	64% / 24% / 8%	62% / 26% / 8%
β ₂ - (mg/L)	4.2	4.3
(g/L)	33.0	33.0
≤30ml/min [n (%)]	20 (6%)	16 (5%)

16.3

MP

MP

60.1

MP

HR=0.695 p=0.00043

MP

43.1

MP

56.4

22

22 VISTA

	MP n=344	MP n=338
n (%)	101 (29)	152 (45)
^a (95% CI)	20.7 (17.6, 24.7)	15.0 (14.1, 17.9)

^b (95% CI)	0.54 (0.42, 0.70)	
^p ^c	0.000002	
n (%)	135 (39)	190 (56)
^a (95% CI)	18.3 (16.6, 21.7)	14.0 (11.1, 15.0)
^b (95% CI)	0.61 (0.49, 0.76)	
^p ^c	0.00001	
^h () n (%)	176 (51.2)	211 (62.4)
^a (95% CI)	56.4 (52.8, 60.9)	43.1 (35.3, 48.3)
^b (95% CI)	0.695 (0.567, 0.852)	
^p ^c	0.00043	
^e n = 668	n=337	n=331
CR ^f n (%)	102 (30)	12 (4)
PR ^f n (%)	136 (40)	103 (31)
nCR n (%)	5 (1)	0
CR + PR ^f n (%)	238 (71)	115 (35)
^p ^d	<10 ⁻¹⁰	
M ^g n=667	n=336	n=331
>=90% n (%)	151 (45)	34 (10)
CR PR		

	1.4	4.2
a		
CR ^f	24.0	12.8
CR + PR ^f	19.9	13.1
n (%)	224 (65.1)	260 (76.9)
a (95% CI)	27.0 (24.7, 31.1)	19.2 (17.0, 21.0)
b (95% CI)	0.557 (0.462, 0.671)	
p ^c	< 0.000001	
<p>16.3</p> <p>60.1</p> <p>^a Kaplan-Meier</p> <p>^b β_2-1 MP COX</p> <p>^c p β_2- log-rank</p> <p>^d (CR + PR) p Cochran-Mantel-Haenszel</p> <p>^e</p> <p>^f EBMT</p> <p>^g</p> <p>^h 60.1</p> <p>NE:</p>		

MP

21

MP

41

23

20

23 VISTA

	MP n=21	MP n=20
n (%)	14 67	9 45
(95%CI)	11.1 (8.4, 15.7)	14.8 7.2, NE
(95%CI)	0.468 0.183 1.199	
p	0.10676	
n (%)	19 90	12 60
(95%CI)	9.7 7.3, 12.6	9.6 6.2, NE
(95%CI)	0.604 0.279 1.309	
p	0.1975	
n (%)	9 43	4 20
(95%CI)	0.385 0.117 1.259	
p	0.10135	
CR n (%)	0 0	8 40
PR n (%)	5 24	5 25
CR + PR n (%)	5 24	13 65
	6.1 1.4 27.2	

P	0.01112
NE	16.3

II

[M34103-053 (PINNACLE)]

155

65 42~89 81% 92%

75% 77% IV 91%

37%

1.3mg/m² 2 2 1

4 8 11 10 4

1~17 8 24

International Workshop Response Criteria, IWRC CT

13 1 Kaplan

Meier 69% 1- Kaplan Meier 94% CR

CRu 1- Kaplan Meier 100%

24

II

76%			IV	R-CHOP	VcR-CAP			6
	17%	14%		2		R-CHOP	83%	VcR-
CAP	84%			≥6				
				IRC				
	TTP				TNT		TFI	
ORR			CR/CR _u		OS			
						IWRC		6
	PFS	TTP	TNT	TFI			VcR-CAP	
				40	VcR-CAP		PFS	24.7
	R-CHOP			14.4		59%	[HR]=0.63	p
<0.001	VcR-CAP					42.1	R-CHOP	18
					R-CHOP	21.4		40
	OS	R-CHOP	56.3		VcR-CAP		VcR-CAP	
HR=0.80	p=0.173					VcR-CAP		R-CHOP
	VcR-CAP	4			53.9%	64.4%	25	
40	OS							
			82		OS	VcR-CAP		OS
	R-CHOP	55.7			OS	HR=0.66	p=0.001	90.7

^c 95% CI	30.7 (25.1; 37.3)	16.1 (14.0; 18.4)	p ^e < 0.001	
^a				
n %	114 (46.9)	148 (60.7)	HR ^d (95% CI)=0.58 (0.45;0.74)	
^c 95% CI	30.5 (22.9; 40.9)	16.1(13.7;18.1)	p ^e < 0.001	
^a				
n %	94 (38.7)	145 (59.4)	HR ^d (95% CI)=0.50 (0.38;0.65)	
^c 95% CI	44.5 (38.8; NE)	24.8 (22.1; 27.5)	p ^e < 0.001	
^a				
n	240	242		
n %	93 (38.8)	145 (59.9)	HR ^d (95% CI)=0.50 (0.38; 0.65)	
^c 95% CI	40.6 (33.6; NE)	20.5 (17.8; 22.8)	p ^e < 0.001	
82				
n ITT	243	244		
n %	103 (42.4)	138 (56.6)	HR ^d (95% CI)=0.66 (0.51; 0.85)	
^c 95% CI	90.7 (71.4; NE)	55.7 (47.2; 68.9)	p ^e =0.001	
^a				
n	229	228		
^h n % <i>CR+CRu</i>	122 (53.3)	95(41.7)	OR ^f (95% CI)=1.688 (1.148; 2.481)	
			p ^g =0.007	
ⁱ n % <i>CR+CRu+PR</i>	211 (92.1)	204 (89.5)	OR ^f (95% CI)=1.428 (0.749; 2.722)	
			p ^g =0.275	
^a				
<i>CR+CRu</i> ^j				
n =	122	95		
^c 95% CI	42.1 (30.7; 49.1)	18.0 (14.0; 23.4)		
^a				
<i>CR+CRu+PR</i> ^k				
n	211	204		

0.05mg/kg 0.6mg/m²

1.3mg/m²

11 1.0mg/m² 1.3mg/m² 1

57 112ng/mL

67 106ng/mL 1.0mg/m² 89 120ng/mL 1.3mg/m²

40~193

1.0mg/m² 1.3mg/m² 102 112L/h

1.0mg/m² 1.3mg/m² 15~32 L/h

III PK/PD 1.3mg/m²

n = 14 n = 17

AUC_{last} 20.4ng/mL 223ng/mL

AUC_{last} 0.99 90% 80.18% ~ 122.80%

1.0mg/m² 1.3mg/m²

489~1884L/m²

100~1000ng/mL 83%

cDNA P450

P450 3A4 2C19 1A2

2D6 2C9 2 26S 8

10 30

36

JX20160089

1.0mg H20171070

1.0mg J20180010

Janssen-Cilag International N.V.

Turnhoutseweg 30, B-2340 Beerse, Belgium

BSP Pharmaceuticals S.p.A.

Via Appia Km 65, 561, 04013 Latina, Italy

19

710304

400 888 9988

(029) 82576616

<http://www.xian-janssen.com.cn>

25°C

8

8

8

53 / 54

30°C

5%

0.9%

	1mg	3.5mg
0.9%	1.0ml	3.5ml
(mg/ml)	1.0mg/ml	1.0mg/ml