表 2.7.4.4-2-1　バイタルサイン　収縮期血圧（02CLL III 試験）（続き）

Astellas Pharma GmbH, Germany / Sequence 0000

ribosepharm GmbH　　Bendamustine Hydrochloride versus Chlorambucil　　- Page 1923
Report　　in patients with B-CLL requiring therapy　　24/04/2007
Final Analysis

Table 20.4
Vital signs
Diastolic blood pressure [mmHg] - Summary statistics by visit and treatment

Safety Population

Visit / Summary statistics	BEN (A) (N = 154) Actual	BEN (A) (N = 154) Change	CLB (B) (N = 144) Actual	CLB (B) (N = 144) Change	Difference 1 B - A
Cycle 6					
n	95	90	75	74	
Mean (SD)	79.1 (8.8)	-0.5 (10.8)	78.6 (8.7)	-0.5 (9.6)	-0.60 (8.22)
95% CL	[77.3; 80.9]	[-2.7; 1.8]	[76.6; 80.6]	[-2.7; 1.7]	[-3.15; 1.95]
Min-Max	60.0 - 101.0	-30.0 - 25.0	53.0 - 106.0	-20.0 - 25.0	F = 0.2159
Median	80.0	0.0	80.0	0.0	P = 0.6428
Q1-Q3	70.0 - 85.0	-10.0 - 10.0	74.0 - 85.0	-10.0 - 5.0	
Follow-up 1					
n	71	68	43	42	
Mean (SD)	79.1 (7.8)	0.3 (10.8)	78.9 (6.9)	1.6 (8.3)	0.07 (7.34)
95% CL	[77.2; 80.9]	[-2.3; 2.9]	[76.8; 81.1]	[-1.0; 4.2]	[-2.79; 2.94]
Min-Max	60.0 - 105.0	-20.0 - 35.0	64.0 - 100.0	-15.0 - 25.0	F = 0.0025
Median	80.0	0.0	80.0	0.0	P = 0.9603
Q1-Q3	75.0 - 80.0	-5.0 - 6.5	75.0 - 80.0	-5.0 - 10.0	
Follow-up 2					
n	54	53	22	22	
Mean (SD)	80.4 (9.3)	1.8 (10.9)	75.9 (8.0)	-1.7 (10.6)	-4.23 (8.74)
95% CL	[77.9; 83.0]	[-1.2; 4.8]	[72.4; 79.4]	[-6.4; 3.0]	[-8.66; 0.20]
Min-Max	56.0 - 110.0	-23.0 - 27.0	60.0 - 90.0	-20.0 - 25.0	F = 3.6279
Median	80.0	0.0	75.0	0.0	P = 0.0608
Q1-Q3	75.0 - 85.0	-5.0 - 10.0	70.0 - 80.0	-10.0 - 5.0	
Follow-up 3					
n	40	38	11	11	
Mean (SD)	79.8 (10.3)	1.6 (11.4)	79.5 (9.1)	5.0 (11.0)	1.05 (9.92)
95% CL	[76.5; 83.1]	[-2.2; 5.3]	[73.5; 85.6]	[-2.4; 12.4]	[-5.90; 8.00]
Min-Max	60.0 - 110.0	-20.0 - 30.0	60.0 - 90.0	-20.0 - 20.0	F = 0.0926
Median	80.0	0.0	80.0	5.0	P = 0.7622
Q1-Q3	72.0 - 85.0	-10.0 - 10.0	75.0 - 90.0	0.0 - 15.0	
Follow-up 4					
n	34	31	5	5	
Mean (SD)	80.9 (10.2)	1.4 (11.1)	83.6 (14.3)	6.2 (17.5)	3.30 (10.56)
95% CL	[77.4; 84.5]	[-2.7; 5.5]	[65.8; 101.4]	[-15.6; 28.0]	[-7.09; 13.69]
Min-Max	60.0 - 109.0	-20.0 - 29.0	70.0 - 108.0	-10.0 - 36.0	F = 0.4186
Median	80.0	0.0	80.0	0.0	P = 0.5221
Q1-Q3	78.0 - 85.0	-10.0 - 10.0	80.0 - 80.0	0.0 - 5.0	

Baseline=Cycle 1/Day 1 if data at screening examination not available
For change from baseline only patients with pairewise available visits are considered
Differences between groups and 95% confidence limits are adjusted for baseline values
(Least square means from analysis of variance)
Data after follow-up 4 are not displayed

d.s.h. statistical services gmbh

Ribomustin Test 1 MS/ 5.3.5.1.1 CLL Mundipharma 02CLLIII-ID900 /p10854

引用:CSR Appendix14 Table20.4

表 2.7.4.4-2-2　バイタルサイン　収縮期血圧（02CLL III FU）

Visit	BEN (A) (N = 161)			CLB (B) (N = 151)			Difference [1] B – A [95% CI]
	N	Actual	Change	N	Actual	Change	
Baseline	152	134.8 (16.0)		139	135.7 (18.2)		
Cycle 2	129	131.8 (17.7)	-3.0 (14.9)	128	133.0 (16.0)	-2.9 (15.8)	0.54 (13.67) [-2.92; 3.99]
Cycle 3	118	132.1 (16.3)	-3.1 (15.4)	121	130.6 (17.4)	-6.2 (16.9)	-2.56 (13.92) [-6.21; 1.09]
Cycle 4	114	133.1 (16.7)	-1.9 (17.5)	107	132.2 (17.3)	-4.1 (16.4)	-1.75 (14.30) [-5.63; 2.14]
Cycle 5	109	134.1 (14.8)	-1.6 (16.3)	94	132.2 (14.7)	-3.4 (17.2)	-1.87 (12.96) [-5.57; 1.83]
Cycle 6	101	135.3 (15.0)	-0.8 (15.1)	82	132.6 (14.9)	-2.9 (15.8)	-2.21 (12.15) [-5.85; 1.43]

引用: 02CLL III FU　　Table 75

表 2.7.4.2.2-3-1　バイタルサイン 脈拍数（02CLLⅢ試験）

Astellas Pharma GmbH, Germany / Sequence 0000

ribosepharm GmbH　　Bendamustine Hydrochloride versus Chlorambucil　　- Page 1924
Report　　in patients with B-CLL requiring therapy　　24/04/2007
Final Analysis

Table 20.5
Vital signs
Pulse [/min] - Summary statistics by visit and treatment

Safety Population

Visit / Summary statistics	BEN (A) (N = 154) Actual	BEN (A) (N = 154) Change	CLB (B) (N = 144) Actual	CLB (B) (N = 144) Change	Difference [1] B - A
Baseline					
n	142		130		
Mean (SD)	77.5 (10.5)		78.3 (8.9)		
95% CL	[75.8; 79.3]		[76.8; 79.8]		
Min-Max	52.0 - 104.0		52.0 - 108.0		
Median	76.0		80.0		
Q1-Q3	70.0 - 84.0		72.0 - 84.0		
Cycle 2					
n	122	114	120	112	
Mean (SD)	75.3 (8.8)	-1.8 (9.4)	78.7 (8.6)	0.2 (9.3)	2.91 (7.40)
95% CL	[73.8; 76.9]	[-3.5; -0.0]	[77.1; 80.2]	[-1.5; 1.9]	[0.96; 4.85]
Min-Max	48.0 - 104.0	-28.0 - 28.0	60.0 - 112.0	-36.0 - 39.0	F = 8.6658
Median	76.0	0.0	79.5	0.0	P = 0.0036
Q1-Q3	70.0 - 80.0	-7.0 - 4.0	72.0 - 83.0	-4.0 - 4.0	
Cycle 3					
n	113	106	114	106	
Mean (SD)	76.9 (9.3)	-0.1 (11.0)	77.2 (8.6)	-0.5 (8.8)	0.06 (8.14)
95% CL	[75.1; 78.6]	[-2.2; 2.0]	[75.6; 78.8]	[-2.2; 1.2]	[-2.15; 2.27]
Min-Max	60.0 - 104.0	-32.0 - 28.0	60.0 - 100.0	-32.0 - 28.0	F = 0.0030
Median	76.0	0.0	76.0	0.0	P = 0.9564
Q1-Q3	70.0 - 84.0	-8.0 - 7.0	70.0 - 82.0	-6.0 - 5.0	
Cycle 4					
n	111	104	99	95	
Mean (SD)	75.9 (8.1)	-0.9 (12.0)	76.8 (8.5)	-0.4 (8.7)	0.85 (7.96)
95% CL	[74.4; 77.5]	[-3.2; 1.4]	[75.1; 78.5]	[-2.2; 1.4]	[-1.37; 3.08]
Min-Max	55.0 - 100.0	-32.0 - 32.0	44.0 - 110.0	-28.0 - 32.0	F = 0.5722
Median	76.0	0.0	76.0	0.0	P = 0.4503
Q1-Q3	70.0 - 80.0	-8.0 - 8.0	72.0 - 80.0	-6.0 - 4.0	
Cycle 5					
n	103	95	83	79	
Mean (SD)	75.1 (8.7)	-2.3 (11.5)	77.3 (8.2)	-0.5 (8.5)	2.30 (7.56)
95% CL	[73.4; 76.8]	[-4.6; 0.0]	[75.5; 79.0]	[-2.4; 1.4]	[0.03; 4.58]
Min-Max	52.0 - 100.0	-28.0 - 32.0	55.0 - 96.0	-34.0 - 16.0	F = 3.9950
Median	76.0	-2.0	78.0	0.0	P = 0.0472
Q1-Q3	70.0 - 80.0	-10.0 - 6.0	70.0 - 83.0	-4.0 - 4.0	

Baseline=Cycle 1/Day 1 if data at screening examination not available
For change from baseline only patients with pairwise available visits are considered
Differences between groups and 95% confidence limits are adjusted for baseline values
(Least square means from analysis of variance)
Data after follow-up 4 are not displayed

d.s.h. statistical services gmbh

Ribomustin Test 1 MS/ 5.3.5.1.1 CLL Mundipharma 02CLLIII-ID900 /p10855

引用:CSR Appendix14 Table20.5