表 2.7.3.6-48　初めて目標 Hb 値を超えた被験者の中で目標 Hb 値を超えた後に目標範囲内に 1 回も入らなかった被験者（試験 19349）

	Molidustat (N=82)	Darbepoetin alfa (N=80)
Number of subjects whose Hb level is above target range	30 (100.0%)	36 (100.0%)
Number of subjects whose Hb level is not below upper limit of target range	2 (6.7%)	3 (8.3%)

表 2.7.3.6-49　初めて目標 Hb 値を超えた被験者の中で目標 Hb 値を超えた後に目標範囲内に 1 回も入らなかった被験者（試験 19350）

	Molidustat (N=82)	Darbepoetin alfa (N=82)
Number of subjects whose Hb level is above target range	48 (100.0%)	23 (100.0%)
Number of subjects whose Hb level is not below upper limit of target range	5 (10.4%)	1 (4.3%)

表 2.7.3.6-50　初めて目標 Hb 値を超えた被験者の中で目標 Hb 値を超えた後に目標範囲内に 1 回も入らなかった被験者（試験 19351）

	Molidustat (N=25)
Number of subjects whose Hb level is above target range	8 (100.0%)
Number of subjects whose Hb level is not below upper limit of target range	1 (12.5%)

表 2.7.3.6-51　初めて目標 Hb 値を超えた被験者の中で目標 Hb 値を超えた後に目標範囲内に 1 回も入らなかった被験者（試験 19352）

	Molidustat (N=153)	Darbepoetin alfa (N=76)
Number of subjects whose Hb level is above target range	99 (100.0%)	47 (100.0%)
Number of subjects whose Hb level is not below upper limit of target range	5 (5.1%)	2 (4.3%)

表 2.7.3.6-52　初めて目標 Hb 値を超えた被験者の中で目標 Hb 値を超えた後に目標範囲内に 1 回も入らなかった被験者（試験 19353）

	Pre-treatment with ESAs in Molidustat group (N=49)	Untreated with ESAs in Molidustat group (N=2)	Total (N=51)
Number of subjects whose Hb level is above target range	25 (100.0%)	1 (100.0%)	26 (100.0%)
Number of subjects whose Hb level is not below upper limit of target range	1 (4.0%)	0	1 (3.8%)

表 2.7.3.6-53 EOT に目標 Hb 値を下回った被験者でのモリデュスタット用量の分布（試験 19349）

Actual treatment: Molidustat

Visit	n	0 mg	12.5 mg	25 mg	50 mg	75 mg	100 mg	150 mg	200 mg
Week 0	7	0	0	7 (100.0%)	0	0	0	0	0
Week 2	7	0	0	7 (100.0%)	0	0	0	0	0
Week 4	7	0	0	2 (28.6%)	5 (71.4%)	0	0	0	0
Week 8	7	1 (14.3%)	0	2 (28.6%)	1 (14.3%)	3 (42.9%)	0	0	0
Week 12	7	0	0	2 (28.6%)	1 (14.3%)	1 (14.3%)	3 (42.9%)	0	0
Week 16	7	0	1 (14.3%)	1 (14.3%)	2 (28.6%)	0	1 (14.3%)	2 (28.6%)	0
Week 20	7	0	2 (28.6%)	0	2 (28.6%)	0	1 (14.3%)	1 (14.3%)	1 (14.3%)
Week 24	7	1 (14.3%)	2 (28.6%)	0	1 (14.3%)	1 (14.3%)	1 (14.3%)	0	1 (14.3%)
Week 28	7	1 (14.3%)	2 (28.6%)	0	0	3 (42.9%)	0	0	1 (14.3%)
Week 30	7	1 (14.3%)	2 (28.6%)	0	0	3 (42.9%)	0	0	1 (14.3%)
Week 32	7	0	2 (28.6%)	0	0	3 (42.9%)	1 (14.3%)	1 (14.3%)	0
Week 34	6	0	2 (33.3%)	0	0	3 (50.0%)	0	1 (16.7%)	0
Week 36	7	0	2 (28.6%)	0	2 (28.6%)	0	2 (28.6%)	1 (14.3%)	0
Week 40	7	0	2 (28.6%)	2 (28.6%)	0	0	1 (14.3%)	1 (14.3%)	1 (14.3%)
Week 44	7	2 (28.6%)	1 (14.3%)	3 (42.9%)	0	0	0	1 (14.3%)	0
Week 48	7	1 (14.3%)	1 (14.3%)	3 (42.9%)	0	1 (14.3%)	0	0	1 (14.3%)

表 2.7.3.6-54 EOT に目標 Hb 値を下回った被験者でのモリデュスタット用量の分布（試験 19350）

Actual treatment: Molidustat

Visit	n	0 mg	12.5 mg	25 mg	50 mg	75 mg	100 mg
Week 0	3	0	0	0	3 (100.0%)	0	0
Week 2	3	0	0	0	3 (100.0%)	0	0
Week 4	3	0	0	0	1 (33.3%)	2 (66.7%)	0
Week 8	3	0	0	0	1 (33.3%)	1 (33.3%)	1 (33.3%)
Week 12	3	0	0	1 (33.3%)	0	2 (66.7%)	0
Week 16	3	1 (33.3%)	0	1 (33.3%)	0	1 (33.3%)	0
Week 20	3	0	0	1 (33.3%)	1 (33.3%)	1 (33.3%)	0
Week 24	3	0	0	1 (33.3%)	1 (33.3%)	1 (33.3%)	0
Week 28	3	0	0	1 (33.3%)	1 (33.3%)	1 (33.3%)	0
Week 30	3	0	0	1 (33.3%)	1 (33.3%)	1 (33.3%)	0
Week 32	3	0	0	1 (33.3%)	1 (33.3%)	1 (33.3%)	0
Week 34	3	0	0	1 (33.3%)	1 (33.3%)	1 (33.3%)	0
Week 36	3	0	0	1 (33.3%)	1 (33.3%)	1 (33.3%)	0
Week 40	3	1 (33.3%)	1 (33.3%)	0	1 (33.3%)	0	0
Week 44	3	0	1 (33.3%)	0	2 (66.7%)	0	0
Week 48	3	0	1 (33.3%)	0	1 (33.3%)	1 (33.3%)	0

表 2.7.3.6-55　EOT に目標 Hb 値を下回った被験者でのモリデュスタット用量の分布（試験 19351）

Actual treatment: Molidustat

Visit	n	75	100	150	200
Week 0	1	1 (100.0%)	0	0	0
Week 1	1	1 (100.0%)	0	0	0
Week 2	1	1 (100.0%)	0	0	0
Week 3	1	1 (100.0%)	0	0	0
Week 4	1	0	1 (100.0%)	0	0
Week 6	1	0	1 (100.0%)	0	0
Week 8	1	0	0	1 (100.0%)	0
Week 12	1	0	0	0	1 (100.0%)
Week 16	1	0	0	0	1 (100.0%)
Week 20	1	0	0	0	1 (100.0%)
Week 21	1	0	0	0	1 (100.0%)
Week 22	1	0	0	0	1 (100.0%)
Week 23	1	0	0	0	1 (100.0%)

表 2.7.3.6-56　EOT に目標 Hb 値を下回った被験者でのモリデュスタット用量の分布（試験 19352）

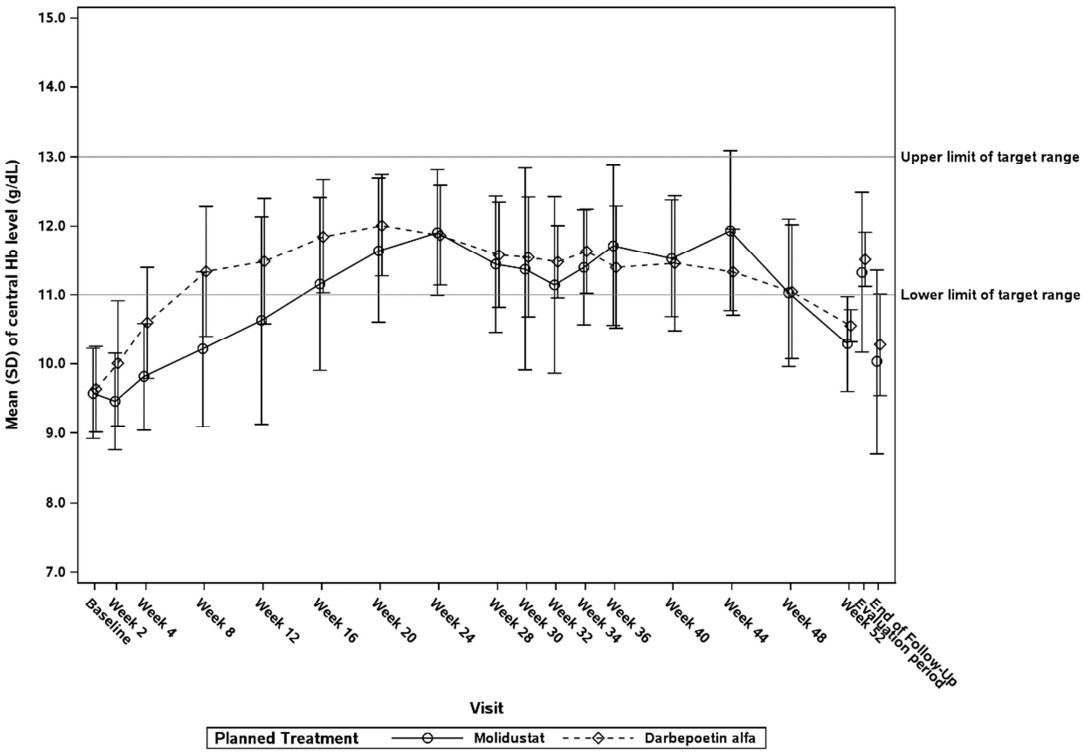
Actual treatment: Molidustat

Visit	n	0 mg	12.5 mg	25 mg	50 mg	75 mg	100 mg	150 mg	200 mg
Week 0	12	0	0	0	0	12 (100.0%)	0	0	0
Week 2	12	0	0	0	0	12 (100.0%)	0	0	0
Week 4	12	0	0	0	1 (8.3%)	6 (50.0%)	5 (41.7%)	0	0
Week 6	12	0	0	0	1 (8.3%)	6 (50.0%)	5 (41.7%)	0	0
Week 8	12	1 (8.3%)	0	0	3 (25.0%)	3 (25.0%)	0	5 (41.7%)	0
Week 10	12	0	0	0	4 (33.3%)	3 (25.0%)	0	5 (41.7%)	0
Week 12	12	1 (8.3%)	0	1 (8.3%)	3 (25.0%)	1 (8.3%)	1 (8.3%)	0	5 (41.7%)
Week 14	12	1 (8.3%)	0	1 (8.3%)	3 (25.0%)	1 (8.3%)	1 (8.3%)	0	5 (41.7%)
Week 16	12	0	0	3 (25.0%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	5 (41.7%)
Week 18	12	0	0	3 (25.0%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	5 (41.7%)
Week 20	12	0	0	3 (25.0%)	1 (8.3%)	0	2 (16.7%)	2 (16.7%)	4 (33.3%)
Week 22	12	1 (8.3%)	0	3 (25.0%)	1 (8.3%)	0	2 (16.7%)	1 (8.3%)	4 (33.3%)
Week 24	12	1 (8.3%)	0	3 (25.0%)	1 (8.3%)	0	2 (16.7%)	0	5 (41.7%)
Week 26	12	1 (8.3%)	0	3 (25.0%)	1 (8.3%)	0	2 (16.7%)	0	5 (41.7%)
Week 28	12	0	1 (8.3%)	2 (16.7%)	1 (8.3%)	0	2 (16.7%)	2 (16.7%)	4 (33.3%)
Week 30	12	0	1 (8.3%)	2 (16.7%)	1 (8.3%)	0	3 (25.0%)	1 (8.3%)	4 (33.3%)
Week 32	12	0	1 (8.3%)	2 (16.7%)	0	2 (16.7%)	1 (8.3%)	2 (16.7%)	4 (33.3%)
Week 33	12	0	1 (8.3%)	2 (16.7%)	0	2 (16.7%)	1 (8.3%)	2 (16.7%)	4 (33.3%)
Week 34	12	0	1 (8.3%)	2 (16.7%)	0	2 (16.7%)	1 (8.3%)	2 (16.7%)	4 (33.3%)
Week 35	12	0	1 (8.3%)	2 (16.7%)	0	2 (16.7%)	1 (8.3%)	2 (16.7%)	4 (33.3%)
Week 36	12	1 (8.3%)	1 (8.3%)	2 (16.7%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	4 (33.3%)
Week 38	12	0	1 (8.3%)	2 (16.7%)	2 (16.7%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	4 (33.3%)
Week 40	12	0	1 (8.3%)	2 (16.7%)	2 (16.7%)	2 (16.7%)	0	1 (8.3%)	4 (33.3%)
Week 42	12	2 (16.7%)	1 (8.3%)	2 (16.7%)	1 (8.3%)	1 (8.3%)	0	1 (8.3%)	4 (33.3%)
Week 44	12	2 (16.7%)	0	3 (25.0%)	1 (8.3%)	1 (8.3%)	0	1 (8.3%)	4 (33.3%)
Week 46	12	1 (8.3%)	0	4 (33.3%)	1 (8.3%)	1 (8.3%)	0	1 (8.3%)	4 (33.3%)
Week 48	12	0	0	1 (8.3%)	5 (41.7%)	1 (8.3%)	0	1 (8.3%)	4 (33.3%)
Week 50	12	0	0	1 (8.3%)	5 (41.7%)	1 (8.3%)	0	1 (8.3%)	4 (33.3%)

表 2.7.3.6-57　EOT に目標 Hb 値を下回った被験者でのモリデュスタット用量の分布（試験 19353）

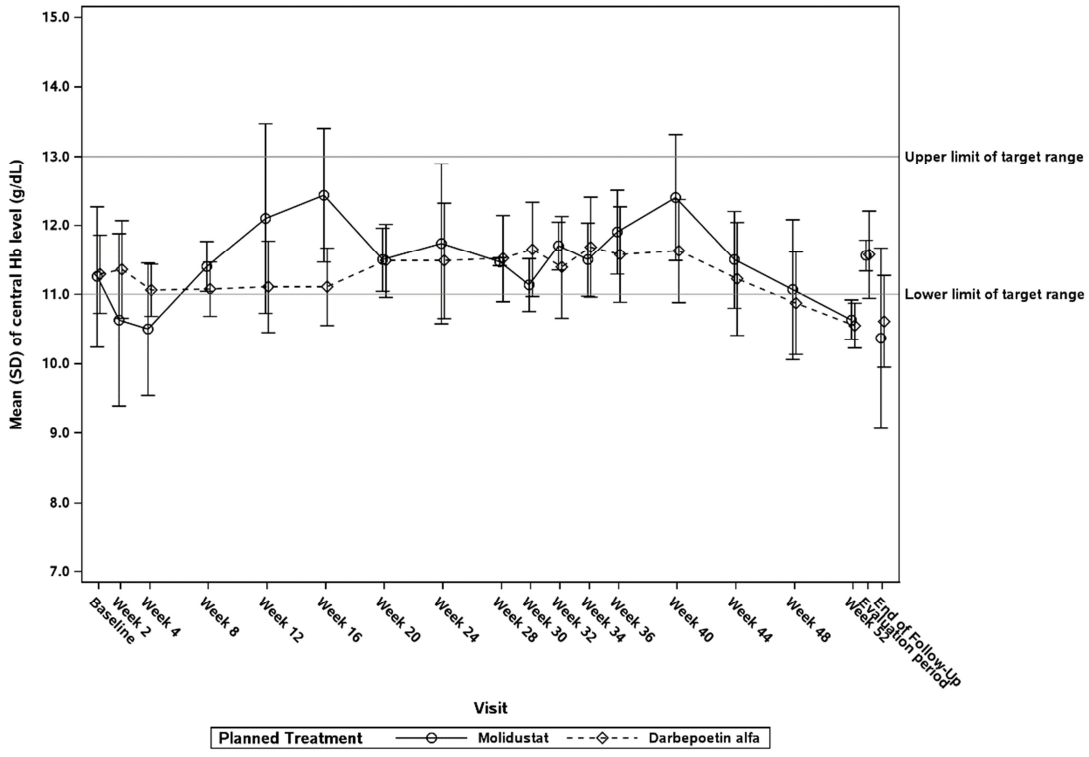
Actual treatment: Pre-treatment with ESAs in Molidustat group

Visit	n	0 mg	5 mg	12.5 mg	25 mg	50 mg	75 mg	100 mg	150 mg	200 mg
Week 0	6	0	0	0	0	0	6 (100.0%)	0	0	0
Week 2	6	0	0	0	0	0	6 (100.0%)	0	0	0
Week 4	6	1 (16.7%)	0	0	0	0	0	5 (83.3%)	0	0
Week 6	6	1 (16.7%)	0	0	0	0	0	5 (83.3%)	0	0
Week 8	6	0	0	0	0	1 (16.7%)	0	0	5 (83.3%)	0
Week 12	6	1 (16.7%)	0	0	0	0	0	0	1 (16.7%)	4 (66.7%)
Week 16	6	1 (16.7%)	0	0	1 (16.7%)	0	0	0	0	4 (66.7%)
Week 20	6	1 (16.7%)	0	1 (16.7%)	0	0	0	1 (16.7%)	0	3 (50.0%)
Week 24	6	0	1 (16.7%)	0	0	0	0	1 (16.7%)	2 (33.3%)	2 (33.3%)
Week 28	6	1 (16.7%)	0	0	0	0	0	1 (16.7%)	0	4 (66.7%)
Week 30	6	2 (33.3%)	0	0	0	0	0	0	0	4 (66.7%)
Week 32	6	1 (16.7%)	0	0	0	0	1 (16.7%)	0	0	4 (66.7%)
Week 34	6	1 (16.7%)	0	0	0	0	1 (16.7%)	0	0	4 (66.7%)



The baseline Hb level is defined as the mean of the last two Hb levels during the screening period and Hb level at Week 0

図 2.7.3.6-18　EOT に目標 Hb 値を下回った被験者での Hb 値の推移（試験 19349）



The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0

図 2.7.3.6-19　EOT に目標 Hb 値を下回った被験者での Hb 値の推移（試験 19350）

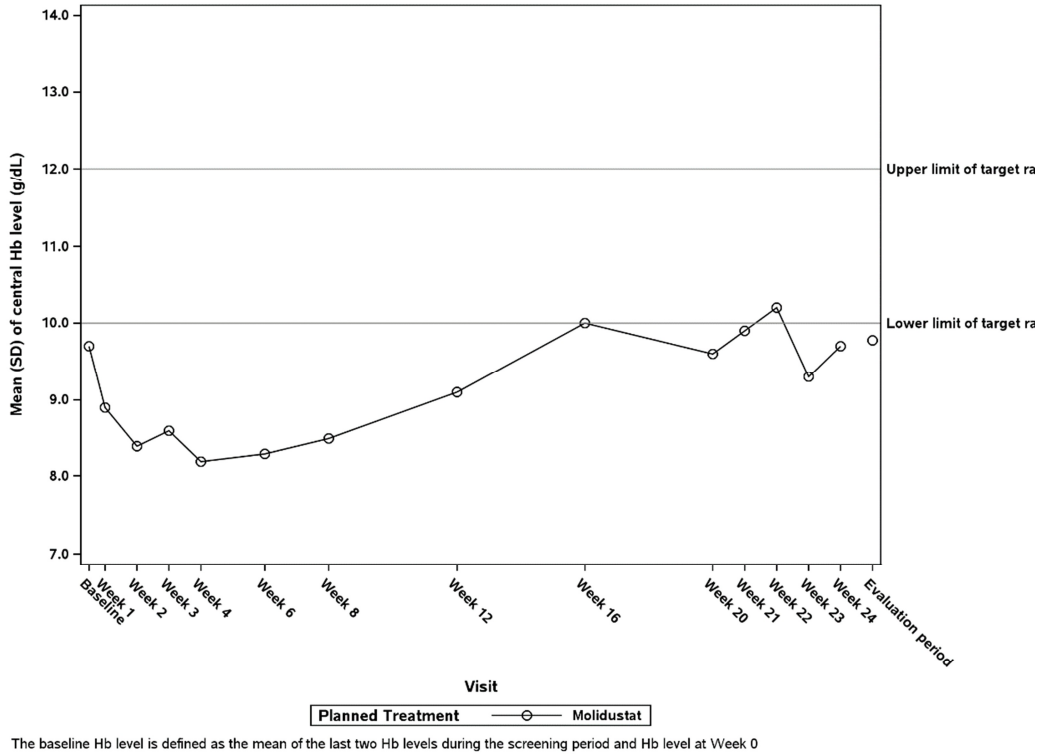


図 2.7.3.6-20　EOT に目標 Hb 値を下回った被験者での Hb 値の推移（試験 19351）

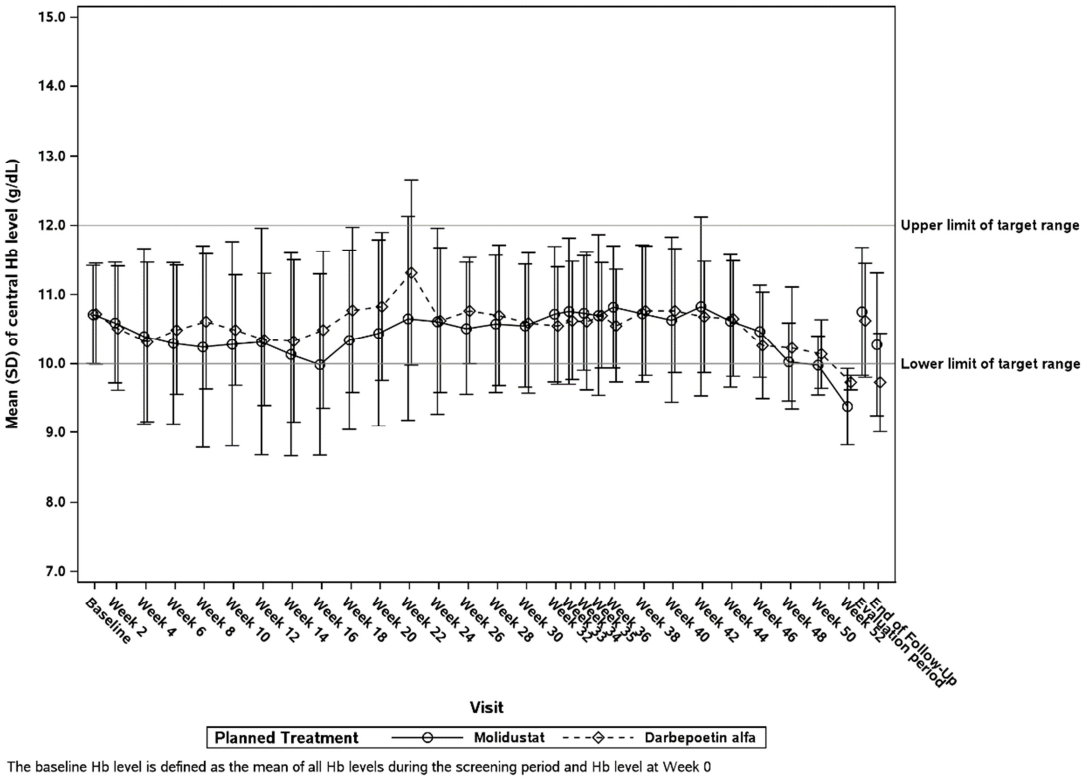


図 2.7.3.6-21　EOT に目標 Hb 値を下回った被験者での Hb 値の推移（試験 19352）

表 2.7.3.6-58　EOT に目標 Hb 値を下回った被験者での各来院時の Hb 値及びベースラインからの変化量（試験 19349）

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=82)	Screening -2	7	9.60	0.75	8.8	9.50	10.9						
	Screening -1	7	9.63	0.63	8.7	9.80	10.5						
	Week 0	7	9.49	0.70	8.7	9.20	10.6						
	Baseline	7	9.57	0.65	8.9	9.47	10.6						
	Week 2	7	9.46	0.70	8.7	9.50	10.5	7	-0.11	0.33	-0.5	-0.20	0.4
	Week 4	7	9.81	0.77	8.7	10.10	10.9	7	0.24	0.51	-0.2	0.30	1.1
	Week 8	7	10.21	1.12	8.6	9.80	11.4	7	0.64	0.75	-0.3	0.50	2.0
	Week 12	7	10.63	1.50	8.6	11.00	12.7	7	1.06	1.25	-0.3	1.03	3.4
	Week 16	7	11.16	1.25	9.3	11.30	12.7	7	1.59	1.08	0.4	1.77	3.4
	Week 20	7	11.64	1.04	9.6	11.90	12.8	7	2.07	0.98	0.7	2.23	3.0
	Week 24	7	11.90	0.91	10.6	12.10	13.1	7	2.33	1.20	1.0	2.27	3.9
	Week 28	7	11.44	0.98	10.4	11.30	13.5	7	1.87	1.44	0.1	1.93	4.6
	Week 30	7	11.37	1.46	8.4	11.40	13.1	7	1.80	1.97	-1.9	2.03	4.2
	Week 32	7	11.14	1.28	8.8	11.30	12.8	7	1.57	1.73	-1.5	2.03	3.9
	Week 34	6	11.40	0.83	10.3	11.60	12.6	6	1.96	0.98	0.8	2.07	3.1
	Week 36	7	11.71	1.16	9.9	11.60	13.2	7	2.14	1.51	-0.4	2.00	4.3
	Week 40	7	11.53	0.85	10.2	11.80	12.6	7	1.96	1.19	-0.1	1.93	3.4
	Week 44	7	11.93	1.16	10.6	11.80	13.8	7	2.36	1.32	1.2	2.17	4.9
	Week 48	7	11.03	1.07	9.5	11.10	12.8	7	1.46	0.64	0.6	1.50	2.5
	Week 52	7	10.29	0.69	8.9	10.40	10.9	7	0.71	0.79	-0.1	0.57	1.6
	End of Follow-Up	7	10.03	1.33	8.6	10.00	12.7	7	0.46	1.05	-0.6	0.53	2.4

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=80)	Screening -2	16	9.67	0.72	8.0	9.65	11.1						
	Screening -1	16	9.58	0.63	8.3	9.60	10.7						
	Week 0	16	9.64	0.69	8.1	9.60	10.5						
	Baseline	16	9.63	0.62	8.4	9.78	10.6						
	Week 2	16	10.01	0.90	8.1	10.20	11.1	16	0.38	0.63	-1.7	0.48	1.0
	Week 4	16	10.59	0.80	8.5	10.80	11.6	16	0.96	0.67	-1.3	1.08	1.5
	Week 8	16	11.34	0.94	9.8	11.40	13.4	16	1.71	0.76	0.0	1.57	3.0
	Week 12	16	11.49	0.91	8.5	11.55	12.4	16	1.86	1.08	-1.4	2.22	3.0
	Week 16	16	11.84	0.82	10.5	11.80	14.2	16	2.21	1.20	0.8	1.75	5.0
	Week 20	16	12.01	0.73	11.2	11.90	13.3	16	2.38	1.25	0.8	2.32	4.7
	Week 24	16	11.86	0.72	11.1	11.70	13.4	16	2.23	1.11	0.5	2.37	4.3
	Week 28	16	11.58	0.76	9.2	11.80	12.3	16	1.95	1.10	-1.2	2.12	3.6
	Week 30	16	11.54	0.87	9.2	11.65	12.8	16	1.91	1.27	-1.2	1.77	3.6
	Week 32	16	11.48	0.52	10.3	11.50	12.3	16	1.85	0.81	-0.1	2.10	3.3
	Week 34	16	11.63	0.61	10.7	11.50	12.5	16	2.00	0.85	0.6	1.95	3.4
	Week 36	16	11.40	0.88	9.7	11.45	12.8	16	1.77	0.94	0.4	1.72	3.5
	Week 40	16	11.46	0.98	9.5	11.35	13.4	16	1.83	1.02	0.6	1.67	3.7
	Week 44	16	11.33	0.62	9.9	11.55	12.4	16	1.70	0.95	-0.7	1.78	3.4
	Week 48	16	11.04	0.97	9.5	10.75	13.6	16	1.41	1.00	-0.4	1.18	3.7
	Week 52	16	10.55	0.24	10.0	10.50	10.9	16	0.92	0.54	-0.1	0.78	1.8
	End of Follow-Up	16	10.28	0.73	8.8	10.30	11.9	16	0.64	0.80	-0.6	0.57	2.7

The baseline Hb level is defined as the mean of the last two Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period

表 2.7.3.6-59　EOT に目標 Hb 値を下回った被験者での各来院時の Hb 値及びベースラインからの変化量（試験 19350）

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=82)	Screening -2	3	11.50	1.08	10.6	11.20	12.7						
	Screening -1	3	11.40	1.13	10.1	12.00	12.1						
	Week 0	3	10.87	1.01	9.7	11.40	11.5						
	Baseline	3	11.26	1.01	10.1	11.53	12.1						
	Week 2	3	10.63	1.24	9.2	11.30	11.4	3	-0.62	0.43	-0.9	-0.80	-0.1
	Week 4	3	10.50	0.95	9.5	10.60	11.4	3	-0.76	0.69	-1.5	-0.63	-0.1
	Week 8	3	11.40	0.36	11.0	11.50	11.7	3	0.14	0.73	-0.6	0.17	0.9
	Week 12	3	12.10	1.37	10.6	12.40	13.3	3	0.84	2.33	-1.5	0.87	3.2
	Week 16	3	12.43	0.97	11.6	12.20	13.5	3	1.18	1.98	-0.5	0.67	3.4
	Week 20	3	11.50	0.46	11.1	11.40	12.0	3	0.24	0.63	-0.1	-0.10	1.0
	Week 24	3	11.73	1.16	10.5	11.90	12.8	3	0.48	0.19	0.4	0.37	0.7
	Week 28	3	11.47	0.06	11.4	11.50	11.5	3	0.21	1.05	-0.7	-0.03	1.4
	Week 30	3	11.13	0.38	10.7	11.30	11.4	3	-0.12	0.64	-0.7	-0.23	0.6
	Week 32	3	11.70	0.35	11.5	11.50	12.1	3	0.44	0.80	0.0	0.00	1.4
	Week 34	3	11.50	0.53	10.9	11.70	11.9	3	0.24	1.32	-0.6	-0.40	1.8
	Week 36	3	11.90	0.61	11.5	11.60	12.6	3	0.64	1.60	-0.5	-0.03	2.5
	Week 40	3	12.40	0.92	11.4	12.60	13.2	3	1.14	1.88	-0.7	1.07	3.1
	Week 44	3	11.50	0.70	10.7	11.80	12.0	3	0.24	0.47	-0.3	0.47	0.6
	Week 48	3	11.07	1.01	9.9	11.60	11.7	3	-0.19	0.34	-0.5	-0.23	0.2
	Week 52	3	10.63	0.29	10.3	10.80	10.8	3	-0.62	0.74	-1.3	-0.73	0.2
	End of Follow-Up	3	10.37	1.30	9.1	10.30	11.7	3	-0.89	0.44	-1.2	-1.03	-0.4

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=82)	Screening -2	12	11.33	0.62	10.0	11.35	12.2						
	Screening -1	12	11.34	0.55	10.5	11.65	11.9						
	Week 0	12	11.20	0.68	10.2	11.00	12.3						
	Baseline	12	11.29	0.57	10.2	11.28	12.1						
	Week 2	12	11.36	0.70	9.9	11.35	12.5	12	0.07	0.39	-0.4	-0.03	0.7
	Week 4	12	11.06	0.38	10.5	11.10	11.5	12	-0.23	0.54	-1.4	-0.13	0.4
	Week 8	12	11.08	0.39	10.5	11.10	11.6	12	-0.21	0.61	-1.4	0.00	0.5
	Week 12	12	11.11	0.66	10.0	11.15	12.3	12	-0.18	0.78	-2.1	0.02	0.6
	Week 16	12	11.11	0.56	10.2	11.05	12.0	12	-0.18	0.67	-1.9	-0.02	0.6
	Week 20	12	11.48	0.53	10.1	11.50	12.1	12	0.19	0.49	-0.6	0.23	1.2
	Week 24	12	11.48	0.83	10.1	11.50	13.5	12	0.19	0.61	-0.6	0.08	1.7
	Week 28	12	11.52	0.62	10.6	11.55	12.9	12	0.23	0.56	-1.2	0.33	1.0
	Week 30	12	11.65	0.68	10.3	11.55	12.9	12	0.36	0.50	-0.8	0.42	1.1
	Week 32	12	11.39	0.74	9.9	11.45	12.7	12	0.10	0.55	-0.7	0.15	1.1
	Week 34	12	11.68	0.72	10.4	11.60	13.4	12	0.39	0.61	-0.6	0.20	1.3
	Week 36	12	11.58	0.69	10.4	11.50	12.7	12	0.29	0.50	-0.7	0.27	1.3
	Week 40	12	11.63	0.75	10.1	11.60	12.7	12	0.34	0.66	-0.5	0.12	1.7
	Week 44	12	11.23	0.81	9.8	11.20	12.6	12	-0.06	0.69	-1.1	-0.08	1.3
	Week 48	12	10.88	0.74	9.2	10.85	11.9	12	-0.41	0.56	-1.2	-0.42	0.6
	Week 52	12	10.55	0.32	9.8	10.55	10.9	12	-0.74	0.49	-1.5	-0.70	0.4
	End of Follow-Up	11	10.61	0.66	9.4	10.50	11.5	11	-0.72	0.65	-1.7	-0.73	0.2

The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period

表 2.7.3.6-60　EOT に目標 Hb 値を下回った被験者での各来院時の Hb 値及びベースラインからの変化量（試験 19351）

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=25)	Week 0	1	9.20	.	9.2	9.20	9.2						
	Baseline	1	9.70	.	9.7	9.70	9.7						
	Week 1	1	8.90	.	8.9	8.90	8.9	1	-0.80	.	-0.8	-0.80	-0.8
	Week 2	1	8.40	.	8.4	8.40	8.4	1	-1.30	.	-1.3	-1.30	-1.3
	Week 3	1	8.60	.	8.6	8.60	8.6	1	-1.10	.	-1.1	-1.10	-1.1
	Week 4	1	8.20	.	8.2	8.20	8.2	1	-1.50	.	-1.5	-1.50	-1.5
	Week 6	1	8.30	.	8.3	8.30	8.3	1	-1.40	.	-1.4	-1.40	-1.4
	Week 8	1	8.50	.	8.5	8.50	8.5	1	-1.20	.	-1.2	-1.20	-1.2
	Week 12	1	9.10	.	9.1	9.10	9.1	1	-0.60	.	-0.6	-0.60	-0.6
	Week 16	1	10.00	.	10.0	10.00	10.0	1	0.30	.	0.3	0.30	0.3
	Week 20	1	9.60	.	9.6	9.60	9.6	1	-0.10	.	-0.1	-0.10	-0.1
	Week 21	1	9.90	.	9.9	9.90	9.9	1	0.20	.	0.2	0.20	0.2
	Week 22	1	10.20	.	10.2	10.20	10.2	1	0.50	.	0.5	0.50	0.5
	Week 23	1	9.30	.	9.3	9.30	9.3	1	-0.40	.	-0.4	-0.40	-0.4
	Week 24	1	9.70	.	9.7	9.70	9.7	1	0.00	.	0.0	0.00	0.0
	End of Follow-Up	1	8.80	.	8.8	8.80	8.8	1	-0.90	.	-0.9	-0.90	-0.9

The baseline Hb level is defined as the mean of the last two Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period

表 2.7.3.6-61　EOT に目標 Hb 値を下回った被験者での各来院時の Hb 値及びベースラインからの変化量（試験 19352）

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=153)	Screening -4	1	11.70	.	11.7	11.70	11.7						
	Screening -3	2	10.70	2.55	8.9	10.70	12.5						
	Screening -2	12	10.73	0.71	9.8	10.55	12.0						
	Screening -1	12	10.69	0.71	10.0	10.30	12.1						
	Week 0	12	10.73	0.77	9.2	10.70	12.0						
	Baseline	12	10.71	0.70	9.5	10.50	11.9						
	Week 2	12	10.59	0.87	9.4	10.50	11.8	12	-0.12	0.61	-1.1	-0.12	0.7
	Week 4	12	10.39	1.27	8.8	10.25	12.4	12	-0.32	0.95	-1.5	-0.27	1.1
	Week 6	12	10.29	1.17	8.9	10.45	11.9	12	-0.42	1.06	-1.5	-0.73	1.4
	Week 8	12	10.24	1.46	8.5	9.95	12.8	12	-0.47	1.29	-1.8	-1.03	2.3
	Week 10	12	10.28	1.48	8.3	9.85	12.4	12	-0.43	1.39	-2.0	-0.53	1.6
	Week 12	12	10.32	1.64	8.2	9.65	13.2	12	-0.40	1.61	-2.6	-0.90	2.7
	Week 14	12	10.13	1.47	8.3	9.85	12.4	12	-0.58	1.49	-2.8	-0.65	1.9
	Week 16	12	9.98	1.31	8.2	9.80	12.1	12	-0.73	1.43	-3.3	-0.55	1.5
	Week 18	12	10.34	1.30	8.6	10.25	12.5	12	-0.37	1.40	-3.0	-0.25	1.9
	Week 20	12	10.44	1.34	7.5	10.70	12.2	12	-0.27	1.35	-2.8	-0.17	1.8
	Week 22	12	10.65	1.48	7.0	10.70	13.5	12	-0.06	1.35	-2.5	-0.25	3.1
	Week 24	12	10.61	1.35	7.7	10.80	13.3	12	-0.10	1.35	-2.1	-0.18	2.9
	Week 26	12	10.51	0.96	9.5	10.10	12.5	12	-0.20	1.22	-2.1	-0.45	2.1
	Week 28	12	10.58	0.99	8.7	10.75	12.0	12	-0.14	1.13	-1.9	-0.08	1.7
	Week 30	12	10.55	0.89	8.7	10.70	11.8	12	-0.16	1.07	-1.9	-0.27	2.3
	Week 32	12	10.72	0.98	9.3	10.90	11.9	12	0.00	1.04	-1.3	-0.12	2.4
	Week 33	12	10.76	1.06	9.4	11.05	12.7	12	0.05	1.02	-1.2	-0.47	2.3
	Week 34	12	10.73	0.83	9.4	11.00	11.9	12	0.02	0.95	-0.9	-0.20	2.4
	Week 35	12	10.70	1.16	8.8	10.75	12.7	12	-0.01	1.31	-1.6	-0.25	3.2
	Week 36	12	10.82	0.88	9.2	11.00	12.4	12	0.10	1.07	-1.0	-0.23	2.9
	Week 38	12	10.73	0.99	9.3	10.80	12.3	12	0.01	1.07	-1.2	-0.27	1.7
	Week 40	12	10.63	1.19	9.3	10.10	12.8	12	-0.08	1.23	-1.3	-0.48	2.4
	Week 42	12	10.83	1.29	9.7	10.25	13.4	12	0.11	1.38	-1.2	-0.48	2.9
	Week 44	12	10.62	0.96	9.7	10.35	12.7	12	-0.10	1.23	-1.4	-0.35	2.3
	Week 46	12	10.47	0.67	9.8	10.30	11.8	12	-0.25	1.04	-1.7	-0.37	1.4
	Week 48	12	10.03	0.56	9.3	9.80	11.0	12	-0.69	1.08	-2.1	-0.65	1.4
	Week 50	12	9.98	0.43	9.4	9.90	10.7	12	-0.74	0.86	-2.2	-0.55	0.3
	Week 52	12	9.38	0.55	8.0	9.50	9.9	12	-1.34	0.63	-2.8	-1.25	-0.6
	End of Follow-Up	12	10.28	1.03	8.7	10.10	11.9	12	-0.44	1.07	-2.1	-0.50	1.5

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=76)	Screening -2	8	10.84	0.73	9.7	10.80	11.8						
	Screening -1	8	10.66	0.78	9.7	10.60	12.1						
	Week 0	8	10.66	0.85	9.5	10.65	11.9						
	Baseline	8	10.72	0.73	9.8	10.62	11.9						
	Week 2	8	10.51	0.90	9.0	10.25	11.8	8	-0.21	0.66	-1.0	-0.32	0.9
	Week 4	8	10.31	1.15	8.9	10.35	11.8	8	-0.41	0.95	-2.0	-0.30	1.4
	Week 6	8	10.49	0.94	9.3	10.60	12.0	8	-0.23	0.92	-1.6	-0.47	1.6
	Week 8	8	10.61	0.98	9.0	10.80	11.9	8	-0.11	0.77	-1.0	-0.33	1.5
	Week 10	8	10.49	0.80	9.2	10.60	11.5	8	-0.23	0.56	-1.0	-0.35	0.7
	Week 12	8	10.35	0.96	9.1	10.45	11.7	8	-0.37	0.80	-1.6	-0.38	0.8
	Week 14	8	10.33	1.17	9.1	10.05	11.9	8	-0.40	0.98	-2.1	-0.33	0.8
	Week 16	8	10.49	1.13	8.7	10.45	12.2	8	-0.23	1.12	-2.6	-0.02	1.0
	Week 18	8	10.78	1.19	8.7	10.75	12.6	8	0.05	1.24	-2.6	0.28	1.4
	Week 20	8	10.83	1.07	8.8	10.95	12.1	8	0.10	1.29	-2.5	0.40	1.8
	Week 22	8	11.31	1.33	9.1	11.60	13.4	8	0.59	1.55	-2.2	0.72	3.0
	Week 24	8	10.63	1.05	8.6	10.90	11.8	8	-0.10	1.30	-2.7	0.13	1.4
	Week 26	8	10.76	0.77	9.7	10.70	12.3	8	0.04	1.17	-1.6	0.05	1.9
	Week 28	8	10.70	1.02	9.3	10.60	12.8	8	-0.02	1.44	-2.0	-0.30	2.4
	Week 30	8	10.59	1.01	9.0	10.40	12.5	8	-0.13	1.39	-1.9	-0.40	2.1
	Week 32	8	10.55	0.85	9.1	10.50	11.9	8	-0.17	1.28	-1.8	-0.27	2.1
	Week 33	8	10.63	0.85	9.2	10.40	12.1	8	-0.10	1.31	-1.7	-0.15	2.3
	Week 34	8	10.61	0.99	9.5	10.25	12.7	8	-0.11	1.45	-1.8	-0.20	2.9
	Week 35	8	10.70	0.76	9.6	10.55	12.1	8	-0.02	1.20	-1.4	0.17	2.3
	Week 36	8	10.55	0.82	9.5	10.40	11.9	8	-0.17	1.24	-1.9	-0.23	2.1
	Week 38	8	10.76	0.94	10.1	10.40	12.6	8	0.04	1.37	-1.8	0.15	2.8
	Week 40	8	10.76	0.90	9.8	10.75	12.2	8	0.04	1.17	-1.4	-0.15	2.4
	Week 42	8	10.68	0.81	10.0	10.25	11.9	8	-0.05	1.12	-1.6	-0.10	2.1
	Week 44	8	10.65	0.83	9.7	10.45	12.0	8	-0.07	0.84	-1.4	0.12	1.1
	Week 46	8	10.26	0.77	9.6	9.95	11.9	8	-0.46	0.97	-1.5	-0.35	1.0
	Week 48	8	10.23	0.88	9.4	10.05	11.8	8	-0.50	1.27	-2.5	-0.23	0.9
	Week 50	8	10.14	0.50	9.5	10.10	10.9	8	-0.58	0.88	-2.1	-0.43	0.5
	Week 52	8	9.73	0.10	9.6	9.70	9.9	8	-1.00	0.80	-2.2	-0.87	-0.1
	End of Follow-Up	8	9.73	0.72	8.2	9.95	10.3	8	-1.00	0.72	-2.1	-0.93	0.2

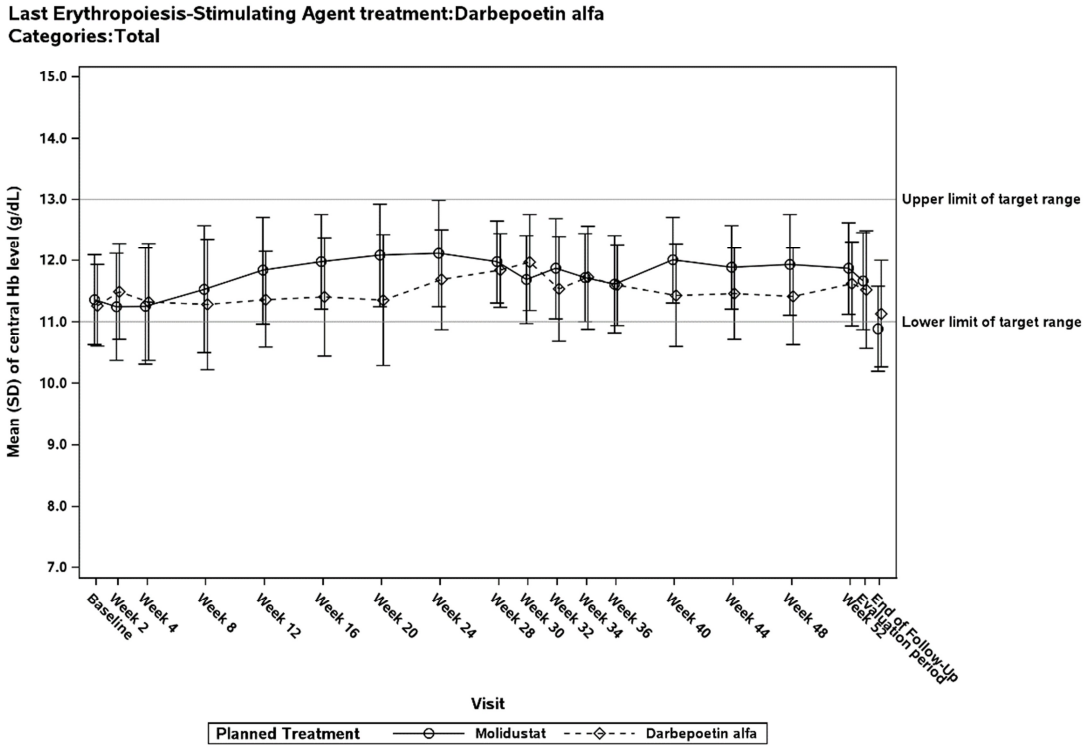
The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period

表 2.7.3.6-62　EOT に目標 Hb 値を下回った被験者での各来院時の Hb 値及びベースラインからの変化量（試験 19353）

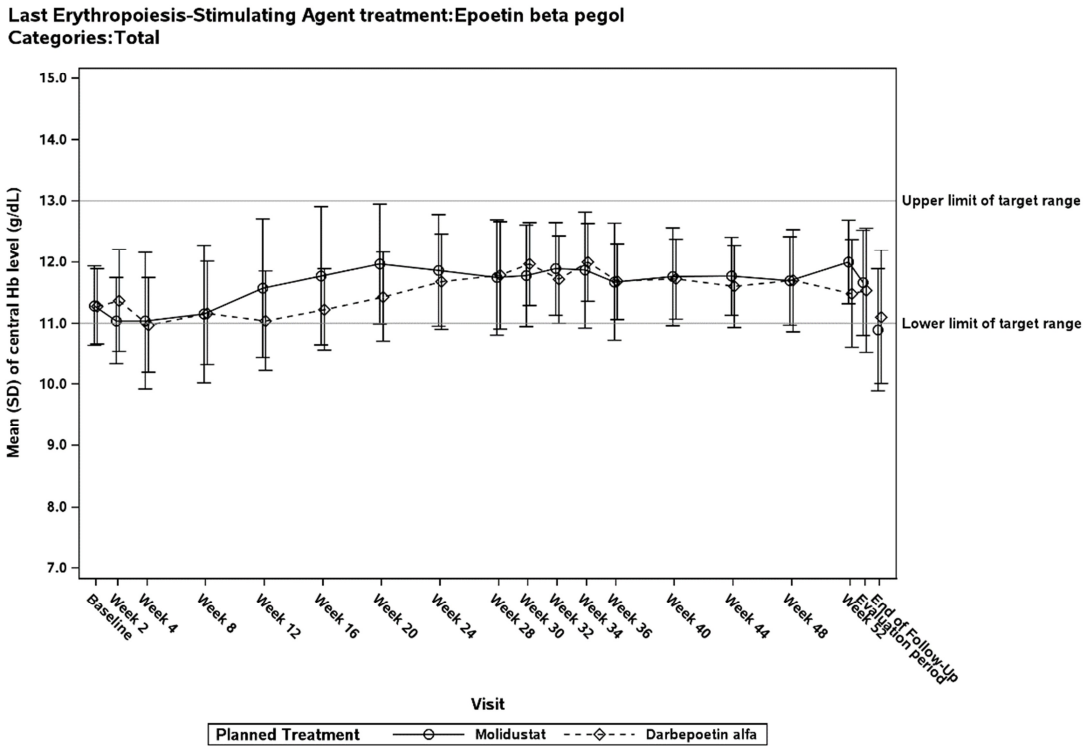
		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Pre-treatment with ESAs in Molidustat group (N=49)	Week 0	6	10.65	0.90	9.5	10.55	11.9						
	Baseline	6	10.87	0.80	10.1	10.57	12.1						
	Week 2	6	10.55	1.09	9.4	10.30	12.6	6	-0.32	0.55	-1.0	-0.30	0.5
	Week 4	6	10.37	1.56	9.0	10.00	13.4	6	-0.51	1.03	-1.4	-0.92	1.3
	Week 6	6	10.48	1.21	9.7	10.05	12.9	6	-0.39	0.83	-1.6	-0.60	0.8
	Week 8	6	10.80	0.99	10.0	10.45	12.7	6	-0.07	0.74	-1.5	0.15	0.6
	Week 12	6	11.02	1.46	9.0	10.75	13.2	6	0.14	1.15	-1.2	0.20	1.6
	Week 16	6	11.52	1.33	9.6	11.75	13.1	6	0.64	1.59	-2.1	0.80	2.6
	Week 20	6	11.78	1.08	10.8	11.45	13.3	6	0.91	1.13	-0.9	0.95	2.6
	Week 24	6	12.02	0.51	11.3	12.05	12.6	6	1.14	0.92	-0.1	1.15	2.4
	Week 28	6	11.52	0.88	10.8	11.15	12.9	6	0.64	0.85	-0.7	0.75	1.8
	Week 30	6	11.42	0.83	10.3	11.45	12.7	6	0.54	1.21	-0.9	0.50	2.2
	Week 32	6	11.12	0.79	10.2	11.15	12.4	6	0.24	1.01	-0.7	-0.10	1.9
	Week 34	6	10.65	0.74	9.9	10.40	11.7	6	-0.22	0.89	-1.1	-0.52	1.5
	Week 36	6	10.42	0.39	9.8	10.55	10.8	6	-0.46	0.72	-1.5	-0.45	0.6
	End of Follow-Up	6	10.33	0.88	9.1	10.30	11.7	6	-0.54	0.65	-1.5	-0.52	0.2
Untreated with ESAs in Molidustat group (N=2)	Week 0	1	10.10	.	10.1	10.10	10.1						
	Baseline	1	10.40	.	10.4	10.40	10.4						
	Week 2	1	11.40	.	11.4	11.40	11.4	1	1.00	.	1.0	1.00	1.0
	Week 4	1	11.80	.	11.8	11.80	11.8	1	1.40	.	1.4	1.40	1.4
	Week 6	1	13.60	.	13.6	13.60	13.6	1	3.20	.	3.2	3.20	3.2
	Week 8	1	12.80	.	12.8	12.80	12.8	1	2.40	.	2.4	2.40	2.4
	Week 12	1	11.60	.	11.6	11.60	11.6	1	1.20	.	1.2	1.20	1.2
	Week 16	1	11.60	.	11.6	11.60	11.6	1	1.20	.	1.2	1.20	1.2
	Week 20	1	12.20	.	12.2	12.20	12.2	1	1.80	.	1.8	1.80	1.8
	Week 24	1	11.70	.	11.7	11.70	11.7	1	1.30	.	1.3	1.30	1.3
	Week 28	1	11.10	.	11.1	11.10	11.1	1	0.70	.	0.7	0.70	0.7
	Week 30	1	11.30	.	11.3	11.30	11.3	1	0.90	.	0.9	0.90	0.9
	Week 32	1	11.10	.	11.1	11.10	11.1	1	0.70	.	0.7	0.70	0.7
	Week 34	1	11.50	.	11.5	11.50	11.5	1	1.10	.	1.1	1.10	1.1
	Week 36	1	10.60	.	10.6	10.60	10.6	1	0.20	.	0.2	0.20	0.2
	End of Follow-Up	1	10.30	.	10.3	10.30	10.3	1	-0.10	.	-0.1	-0.10	-0.1

Planned Treatment	Visit	Value at visit						Change from Baseline					
		n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Total (N=51)	Week 0	7	10.57	0.85	9.5	10.10	11.9						
	Baseline	7	10.80	0.75	10.1	10.47	12.1						
	Week 2	7	10.67	1.05	9.4	10.40	12.6	7	-0.13	0.71	-1.0	-0.13	1.0
	Week 4	7	10.57	1.52	9.0	10.20	13.4	7	-0.23	1.19	-1.4	-0.87	1.4
	Week 6	7	10.93	1.61	9.7	10.10	13.6	7	0.12	1.56	-1.6	-0.53	3.2
	Week 8	7	11.09	1.18	10.0	10.50	12.8	7	0.28	1.15	-1.5	0.27	2.4
	Week 12	7	11.10	1.35	9.0	10.90	13.2	7	0.30	1.12	-1.2	0.23	1.6
	Week 16	7	11.53	1.22	9.6	11.60	13.1	7	0.72	1.47	-2.1	1.17	2.6
	Week 20	7	11.84	1.00	10.8	11.70	13.3	7	1.04	1.08	-0.9	1.07	2.6
	Week 24	7	11.97	0.48	11.3	11.90	12.6	7	1.17	0.84	-0.1	1.30	2.4
	Week 28	7	11.46	0.82	10.8	11.10	12.9	7	0.65	0.78	-0.7	0.70	1.8
	Week 30	7	11.40	0.76	10.3	11.40	12.7	7	0.60	1.12	-0.9	0.90	2.2
	Week 32	7	11.11	0.72	10.2	11.10	12.4	7	0.31	0.94	-0.7	0.27	1.9
	Week 34	7	10.77	0.75	9.9	10.60	11.7	7	-0.03	0.96	-1.1	-0.47	1.5
	Week 36	7	10.44	0.36	9.8	10.60	10.8	7	-0.36	0.70	-1.5	-0.33	0.6
	End of Follow-Up	7	10.33	0.81	9.1	10.30	11.7	7	-0.48	0.61	-1.5	-0.37	0.2

The baseline Hb level is defined as the mean of the last two Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period



The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0



The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0

図 2.7.3.6-22　前治療として使用した ESA の種類別（DA 又は PEGOL）の各来院時の平均 Hb 値（g/dL、平均値±SD）の推移（試験 19350、FAS）

表 2.7.3.6-63　前治療として使用した ESA の種類別（DA 又は PEGOL）の各来院時の平均 Hb 値（g/dL、平均値±SD）の推移（試験 19350、FAS）

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Total

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=35)	Screening -3	1	11.30	.	11.3	11.30	11.3						
	Screening -2	35	11.28	0.77	10.1	11.30	12.9						
	Screening -1	35	11.43	0.77	10.0	11.50	13.1						
	Week 0	35	11.36	0.84	9.7	11.40	12.9						
	Baseline	35	11.36	0.73	10.0	11.33	12.9						
	Week 2	35	11.24	0.87	9.2	11.20	13.2	35	-0.11	0.64	-1.5	-0.13	1.5
	Week 4	35	11.25	0.95	9.4	11.50	12.8	35	-0.10	0.78	-1.7	-0.03	1.5
	Week 8	35	11.53	1.04	9.1	11.60	13.5	35	0.17	1.16	-2.4	0.43	2.6
	Week 12	34	11.84	0.87	9.4	11.85	13.3	34	0.50	1.11	-1.7	0.35	3.2
	Week 16	34	11.98	0.78	10.4	11.85	13.5	34	0.64	1.11	-1.0	0.70	3.4
	Week 20	34	12.08	0.84	10.0	12.00	13.9	34	0.74	1.03	-1.6	0.90	2.5
	Week 24	34	12.11	0.87	10.4	12.05	13.7	34	0.77	0.95	-0.9	0.75	3.0
	Week 28	32	11.98	0.67	10.0	11.90	13.4	32	0.64	0.90	-1.8	0.75	2.5
	Week 30	30	11.69	0.72	9.9	11.75	13.1	30	0.36	1.01	-2.0	0.23	2.5
	Week 32	29	11.87	0.82	9.7	12.00	13.4	29	0.53	1.20	-2.2	0.47	2.3
	Week 34	30	11.72	0.72	9.5	11.90	13.1	30	0.39	1.07	-2.4	0.33	2.6
	Week 36	30	11.61	0.80	9.5	11.85	12.7	30	0.29	1.10	-2.0	0.18	2.5
	Week 40	30	12.01	0.70	10.8	11.85	13.7	30	0.68	1.15	-1.4	0.50	3.1
	Week 44	30	11.89	0.68	10.6	11.90	13.0	30	0.56	1.06	-1.6	0.35	2.7
	Week 48	29	11.93	0.82	9.9	11.90	14.0	29	0.59	0.87	-0.9	0.43	2.4
	Week 52	27	11.87	0.75	10.3	11.90	13.2	27	0.50	0.91	-0.8	0.23	2.9
	Evaluation period	35	11.66	0.79	9.6	11.80	13.6	35	0.31	1.13	-2.4	0.08	2.5
	End of Follow-Up	32	10.89	0.69	9.1	10.80	12.3	32	-0.47	0.87	-2.0	-0.50	1.8

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Total

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=45)	Screening -4	1	11.00	.	11.0	11.00	11.0						
	Screening -3	3	11.03	0.50	10.5	11.10	11.5						
	Screening -2	45	11.22	0.76	9.9	11.20	12.7						
	Screening -1	45	11.32	0.71	9.8	11.30	12.9						
	Week 0	45	11.24	0.78	9.3	11.20	12.7						
	Baseline	45	11.26	0.67	9.8	11.17	12.6						
	Week 2	45	11.49	0.79	9.4	11.40	12.8	45	0.23	0.46	-0.4	0.17	1.6
	Week 4	45	11.32	0.96	8.8	11.10	13.7	45	0.06	0.78	-1.3	0.00	2.6
	Week 8	45	11.28	1.07	7.4	11.30	14.9	45	0.02	1.04	-2.4	0.07	3.9
	Week 12	44	11.36	0.78	9.1	11.30	13.1	44	0.07	0.86	-2.2	0.07	2.3
	Week 16	42	11.40	0.97	8.3	11.50	13.0	42	0.10	1.00	-2.7	0.17	2.2
	Week 20	41	11.35	1.07	7.5	11.50	13.2	41	0.03	1.07	-3.5	0.20	1.7
	Week 24	38	11.69	0.81	10.0	11.70	13.9	38	0.34	0.89	-1.0	0.12	3.4
	Week 28	39	11.84	0.60	10.6	11.80	13.0	39	0.48	0.74	-1.3	0.43	2.1
	Week 30	39	11.97	0.78	10.1	12.00	14.0	39	0.61	0.96	-1.7	0.50	2.8
	Week 32	39	11.53	0.86	8.9	11.60	13.2	39	0.18	1.03	-2.9	0.07	2.2
	Week 34	39	11.72	0.84	8.5	11.80	12.9	39	0.37	1.03	-3.3	0.47	2.2
	Week 36	38	11.60	0.66	10.3	11.50	12.9	38	0.25	0.79	-1.4	0.20	1.8
	Week 40	38	11.43	0.84	9.0	11.40	13.0	38	0.08	1.07	-3.3	0.17	2.5
	Week 44	37	11.46	0.75	9.6	11.40	13.1	37	0.11	0.93	-3.0	0.10	1.9
	Week 48	37	11.41	0.79	9.2	11.40	12.9	37	0.07	0.95	-1.9	-0.07	1.9
	Week 52	34	11.62	0.68	10.5	11.50	13.2	34	0.27	0.82	-1.0	0.22	1.9
	Evaluation period	45	11.52	0.97	7.4	11.63	13.0	45	0.26	0.97	-2.6	0.21	1.9
	End of Follow-Up	44	11.13	0.87	9.3	11.15	13.1	44	-0.14	1.11	-2.7	-0.20	2.0

The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period

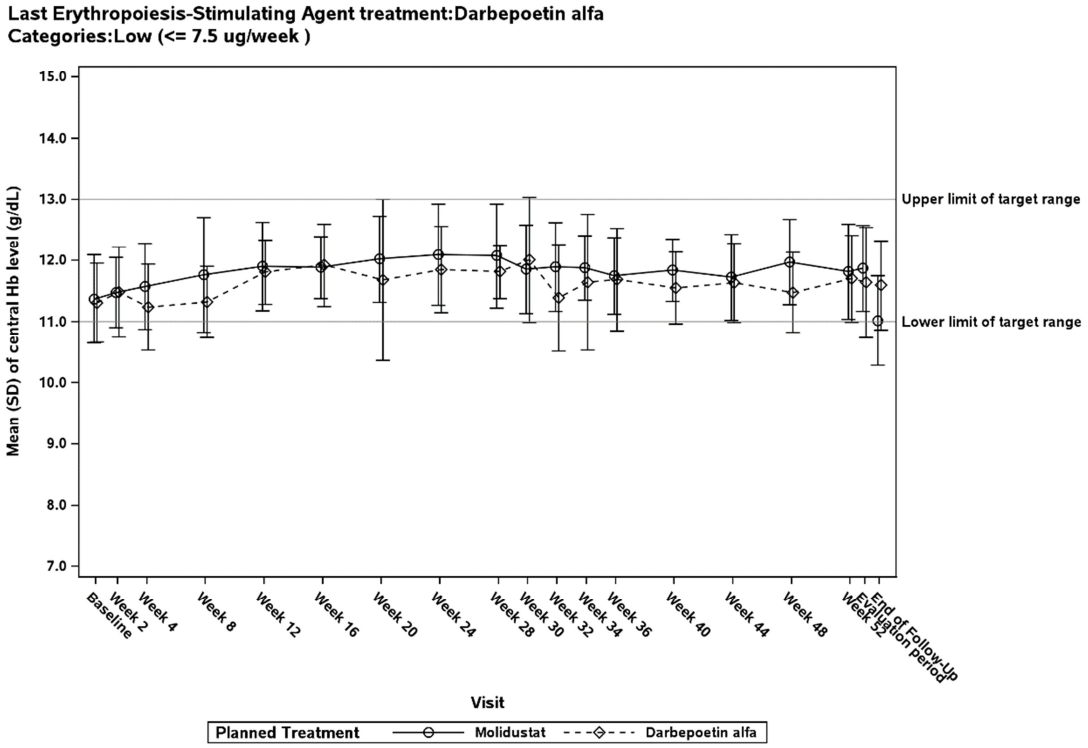
Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Total

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=47)	Screening -4	1	11.50	.	11.5	11.50	11.5						
	Screening -3	5	11.02	0.57	10.6	10.70	11.9						
	Screening -2	47	11.22	0.73	9.8	11.20	12.9						
	Screening -1	47	11.37	0.78	9.7	11.20	13.0						
	Week 0	47	11.27	0.75	9.9	11.30	13.4						
	Baseline	47	11.28	0.65	10.0	11.20	12.5						
	Week 2	47	11.04	0.71	9.3	11.10	13.0	47	-0.25	0.55	-1.2	-0.30	1.2
	Week 4	46	11.04	1.12	9.0	11.05	14.3	46	-0.23	0.92	-1.5	-0.45	1.9
	Week 8	46	11.15	1.13	9.1	11.40	13.5	46	-0.12	1.11	-2.0	-0.20	2.9
	Week 12	45	11.57	1.14	9.2	11.70	14.0	45	0.29	1.17	-1.9	0.27	2.9
	Week 16	45	11.77	1.13	7.6	11.80	13.3	45	0.49	1.21	-3.5	0.67	3.2
	Week 20	42	11.97	0.98	9.3	12.00	13.9	42	0.65	1.10	-1.8	0.73	3.3
	Week 24	40	11.87	0.91	9.2	11.90	13.2	40	0.53	1.06	-2.6	0.53	2.3
	Week 28	40	11.75	0.94	8.9	11.90	13.4	40	0.41	1.08	-2.2	0.52	2.3
	Week 30	39	11.78	0.83	9.5	11.90	13.7	39	0.44	0.99	-1.9	0.53	1.8
	Week 32	37	11.89	0.76	9.8	12.00	13.1	37	0.50	0.96	-1.6	0.47	2.4
	Week 34	36	11.87	0.94	9.4	11.90	14.0	36	0.50	1.04	-2.1	0.60	2.8
	Week 36	36	11.68	0.96	9.1	11.60	13.7	36	0.30	1.11	-2.1	0.25	2.3
	Week 40	34	11.76	0.80	9.0	11.85	13.0	34	0.42	1.00	-2.2	0.53	2.3
	Week 44	32	11.77	0.64	10.3	11.60	13.2	32	0.39	0.69	-0.8	0.33	2.0
	Week 48	31	11.69	0.73	10.1	11.70	13.1	31	0.34	0.97	-1.5	0.27	2.2
	Week 52	30	12.00	0.68	10.8	11.95	13.7	30	0.65	1.07	-1.3	0.42	3.5
	Evaluation period	47	11.67	0.86	8.9	11.78	13.3	47	0.38	0.96	-2.2	0.27	2.1
	End of Follow-Up	43	10.89	1.00	8.6	11.00	13.2	43	-0.41	1.06	-2.1	-0.53	2.2

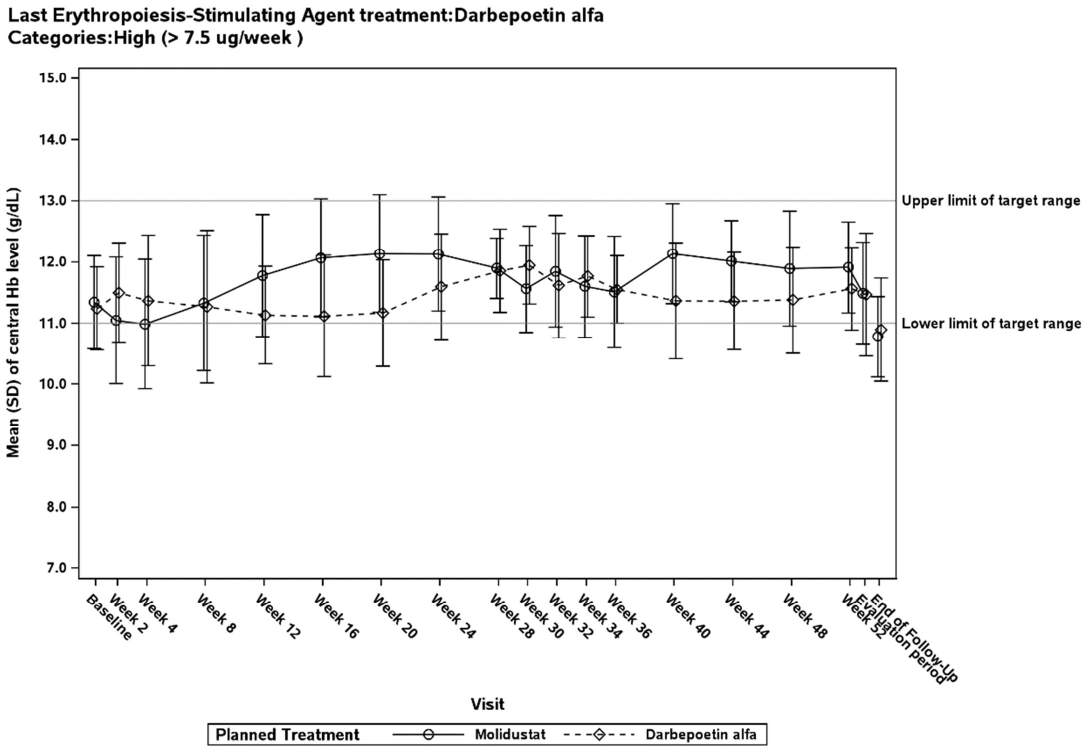
Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Total

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=37)	Screening -4	2	10.30	0.71	9.8	10.30	10.8						
	Screening -3	4	10.38	0.42	9.8	10.45	10.8						
	Screening -2	37	11.32	0.62	10.1	11.30	12.7						
	Screening -1	37	11.26	0.66	9.9	11.30	12.8						
	Week 0	37	11.29	0.74	9.8	11.30	12.9						
	Baseline	37	11.27	0.62	10.1	11.30	12.7						
	Week 2	37	11.37	0.84	9.2	11.30	13.1	37	0.09	0.51	-1.0	0.00	1.0
	Week 4	37	10.97	0.78	9.0	10.90	12.7	37	-0.31	0.61	-1.5	-0.20	1.2
	Week 8	36	11.16	0.85	9.6	11.10	12.9	36	-0.12	0.71	-1.5	-0.08	1.2
	Week 12	34	11.04	0.81	9.5	11.05	12.6	34	-0.24	0.87	-2.1	-0.03	1.4
	Week 16	35	11.22	0.67	10.2	11.10	12.8	35	-0.07	0.85	-1.9	0.00	1.9
	Week 20	35	11.43	0.74	9.1	11.50	13.1	35	0.14	0.97	-1.9	0.20	2.2
	Week 24	34	11.68	0.78	9.8	11.70	14.0	34	0.36	0.99	-1.5	0.42	3.9
	Week 28	32	11.78	0.88	9.4	11.80	13.2	32	0.45	1.01	-1.9	0.47	2.0
	Week 30	30	11.97	0.68	10.7	11.95	13.4	30	0.60	0.90	-1.1	0.77	2.5
	Week 32	30	11.72	0.72	10.4	11.70	13.1	30	0.35	0.98	-1.4	0.48	2.7
	Week 34	29	12.00	0.64	11.0	11.80	13.4	29	0.63	0.91	-1.2	0.67	2.5
	Week 36	29	11.68	0.62	10.1	11.60	13.0	29	0.31	0.82	-1.4	0.30	2.1
	Week 40	28	11.73	0.65	10.0	11.70	12.9	28	0.36	0.83	-1.6	0.20	2.2
	Week 44	28	11.60	0.67	10.2	11.70	12.6	28	0.24	0.91	-1.9	0.18	1.8
	Week 48	28	11.70	0.83	10.3	11.90	13.3	28	0.34	1.04	-1.6	0.35	2.8
	Week 52	28	11.48	0.89	9.8	11.30	13.3	28	0.12	1.11	-1.5	0.05	2.9
	Evaluation period	37	11.53	1.02	7.2	11.63	12.9	37	0.26	1.05	-2.9	0.53	1.9
	End of Follow-Up	35	11.10	1.09	8.0	11.00	13.5	35	-0.19	1.33	-3.0	-0.37	3.0

The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period



The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0



The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0

図 2.7.3.6-23　前治療として使用した DA の用量別（低用量又は高用量）の各来院時の平均 Hb 値（g/dL、平均値±SD）の推移（試験 19350、FAS）

表 2.7.3.6-64　前治療として使用した DA の用量別（低用量又は高用量）の各来院時の平均 Hb 値（g/dL、平均値±SD）の推移（試験 19350、FAS）

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Low (<= 7.5 ug/week)

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=16)	Screening -2	16	11.16	0.76	10.2	11.05	12.9						
	Screening -1	16	11.48	0.73	10.1	11.50	13.1						
	Week 0	16	11.46	0.84	9.9	11.45	12.8						
	Baseline	16	11.37	0.72	10.2	11.28	12.7						
	Week 2	16	11.48	0.57	10.5	11.30	12.5	16	0.11	0.38	-0.6	0.13	0.8
	Week 4	16	11.58	0.70	10.5	11.65	12.7	16	0.21	0.58	-1.0	0.27	1.5
	Week 8	16	11.76	0.94	10.1	11.85	13.0	16	0.39	0.90	-1.8	0.47	1.9
	Week 12	16	11.90	0.73	10.8	11.75	13.3	16	0.53	0.92	-1.0	0.27	2.7
	Week 16	16	11.88	0.51	11.0	11.70	12.7	16	0.51	0.69	-1.0	0.70	1.6
	Week 20	16	12.02	0.71	10.0	12.05	12.9	16	0.65	1.04	-1.6	0.87	2.3
	Week 24	16	12.09	0.83	10.9	11.95	13.6	16	0.73	1.09	-0.9	0.58	3.0
	Week 28	14	12.07	0.85	10.0	11.95	13.4	14	0.70	1.13	-1.8	0.83	2.5
	Week 30	13	11.85	0.72	10.5	11.70	13.1	13	0.53	1.01	-1.3	0.23	2.5
	Week 32	13	11.89	0.72	10.5	11.90	12.9	13	0.57	1.21	-0.8	0.07	2.3
	Week 34	13	11.88	0.53	10.7	12.00	12.5	13	0.55	0.95	-0.9	0.40	1.9
	Week 36	13	11.75	0.63	10.8	11.80	12.7	13	0.42	1.00	-0.7	0.17	1.9
	Week 40	13	11.84	0.51	11.1	11.70	13.0	13	0.51	1.05	-1.4	0.47	2.2
	Week 44	13	11.72	0.70	10.6	11.70	13.0	13	0.40	1.14	-1.6	0.37	2.1
	Week 48	13	11.97	0.70	10.5	11.90	13.1	13	0.64	0.76	-0.4	0.67	2.4
	Week 52	13	11.82	0.78	11.0	11.50	13.2	13	0.49	0.81	-0.6	0.47	2.6
	Evaluation period	16	11.87	0.70	10.9	11.86	13.6	16	0.50	1.08	-0.7	-0.02	2.5
	End of Follow-Up	15	11.01	0.73	9.5	11.00	12.3	15	-0.32	0.85	-1.7	-0.07	1.2

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Low (<= 7.5 ug/week)

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=15)	Screening -2	15	11.30	0.84	10.1	11.20	12.7						
	Screening -1	15	11.25	0.69	9.9	11.10	12.4						
	Week 0	15	11.36	0.67	10.1	11.50	12.6						
	Baseline	15	11.30	0.65	10.4	11.40	12.6						
	Week 2	15	11.48	0.74	10.1	11.30	12.6	15	0.18	0.40	-0.4	0.03	0.9
	Week 4	15	11.23	0.70	9.9	11.10	12.5	15	-0.07	0.37	-0.9	0.07	0.4
	Week 8	15	11.32	0.58	10.0	11.30	12.4	15	0.02	0.48	-0.8	0.13	0.8
	Week 12	15	11.81	0.52	10.9	12.00	12.5	15	0.50	0.56	-0.6	0.53	1.4
	Week 16	15	11.92	0.67	10.7	11.90	13.0	15	0.62	0.50	-0.5	0.67	1.3
	Week 20	15	11.68	1.32	7.5	12.00	13.2	15	0.38	1.23	-3.5	0.47	1.7
	Week 24	14	11.85	0.71	10.5	11.95	13.1	14	0.48	0.75	-0.5	0.28	1.9
	Week 28	14	11.81	0.44	10.9	11.85	12.5	14	0.44	0.64	-0.5	0.43	1.8
	Week 30	14	12.01	1.02	10.1	12.10	14.0	14	0.64	1.18	-1.7	0.55	2.8
	Week 32	14	11.39	0.87	8.9	11.65	12.2	14	0.01	1.10	-2.9	0.10	1.8
	Week 34	14	11.64	1.11	8.5	11.95	12.9	14	0.27	1.30	-3.3	0.57	2.2
	Week 36	13	11.68	0.84	10.3	11.80	12.9	13	0.35	0.82	-1.4	0.27	1.5
	Week 40	13	11.55	0.59	10.8	11.40	13.0	13	0.21	0.72	-0.9	0.20	1.8
	Week 44	13	11.63	0.65	10.6	11.60	13.1	13	0.29	0.71	-0.9	0.27	1.9
	Week 48	13	11.48	0.65	10.5	11.60	12.9	13	0.14	0.73	-0.9	-0.07	1.7
	Week 52	13	11.70	0.71	10.8	11.50	13.2	13	0.36	0.71	-0.9	0.30	1.9
	Evaluation period	15	11.64	0.90	9.2	11.70	13.0	15	0.34	1.10	-2.6	0.45	1.8
	End of Follow-Up	15	11.59	0.73	10.1	11.80	13.1	15	0.29	1.03	-1.4	0.50	1.9

The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period

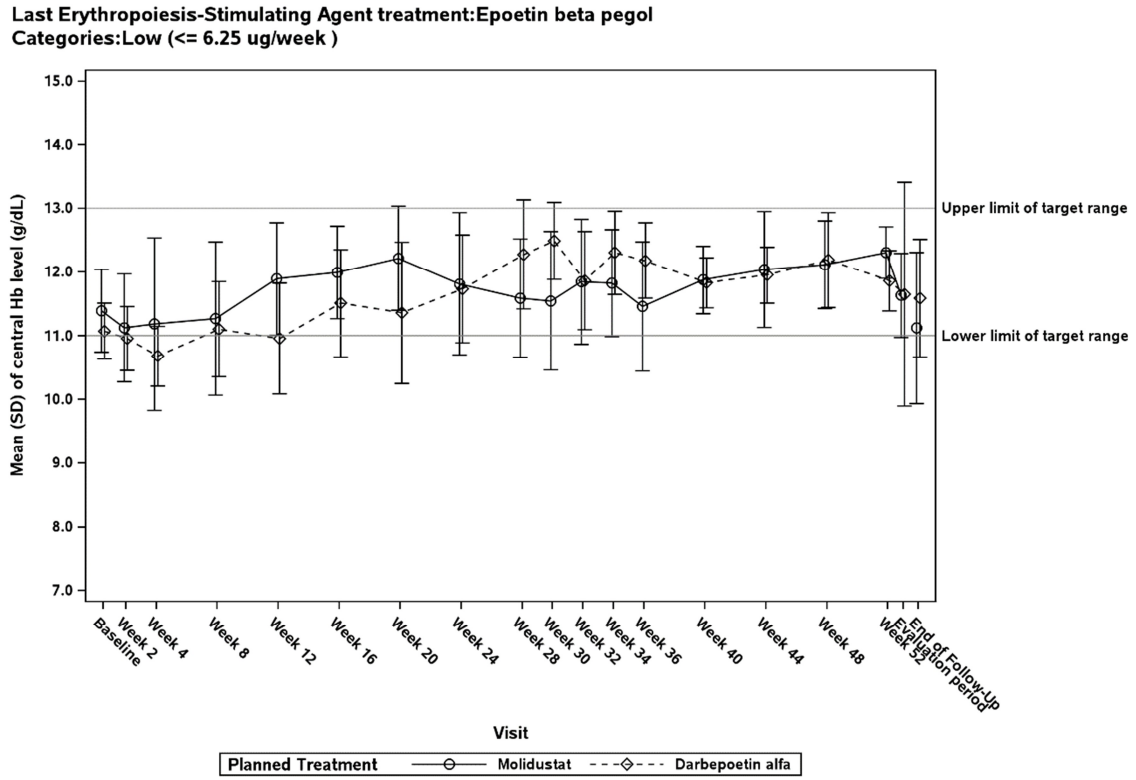
Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: High (> 7.5 ug/week)

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=19)	Screening -3	1	11.30	.	11.3	11.30	11.3						
	Screening -2	19	11.37	0.79	10.1	11.40	12.7						
	Screening -1	19	11.39	0.82	10.0	11.50	13.1						
	Week 0	19	11.28	0.84	9.7	11.40	12.9						
	Baseline	19	11.35	0.76	10.0	11.38	12.9						
	Week 2	19	11.05	1.03	9.2	10.90	13.2	19	-0.30	0.76	-1.5	-0.47	1.5
	Week 4	19	10.98	1.06	9.4	10.80	12.8	19	-0.36	0.84	-1.7	-0.47	1.5
	Week 8	19	11.33	1.11	9.1	11.30	13.5	19	-0.01	1.34	-2.4	0.23	2.6
	Week 12	18	11.78	1.00	9.4	11.95	13.3	18	0.47	1.28	-1.7	0.55	3.2
	Week 16	18	12.07	0.96	10.4	12.05	13.5	18	0.76	1.39	-1.0	0.68	3.4
	Week 20	18	12.14	0.96	10.8	11.95	13.9	18	0.83	1.05	-1.0	0.90	2.5
	Week 24	18	12.13	0.93	10.4	12.10	13.7	18	0.82	0.83	-0.7	0.95	2.3
	Week 28	18	11.90	0.50	11.2	11.85	12.8	18	0.59	0.70	-0.6	0.68	1.9
	Week 30	17	11.56	0.72	9.9	11.80	12.5	17	0.24	1.02	-2.0	0.17	1.8
	Week 32	16	11.85	0.91	9.7	12.15	13.4	16	0.50	1.23	-2.2	0.50	2.2
	Week 34	17	11.60	0.83	9.5	11.70	13.1	17	0.27	1.17	-2.4	0.33	2.6
	Week 36	17	11.51	0.91	9.5	11.90	12.6	17	0.19	1.19	-2.0	0.23	2.5
	Week 40	17	12.14	0.81	10.8	11.90	13.7	17	0.81	1.24	-1.0	0.53	3.1
	Week 44	17	12.01	0.66	10.7	12.20	13.0	17	0.69	1.01	-0.9	0.33	2.7
	Week 48	16	11.89	0.94	9.9	11.90	14.0	16	0.55	0.98	-0.9	0.40	2.0
	Week 52	14	11.91	0.74	10.3	12.10	13.2	14	0.50	1.02	-0.8	0.20	2.9
	Evaluation period	19	11.49	0.84	9.6	11.73	12.8	19	0.14	1.18	-2.4	0.23	2.2
	End of Follow-Up	17	10.78	0.66	9.1	10.80	12.1	17	-0.61	0.89	-2.0	-0.67	1.8

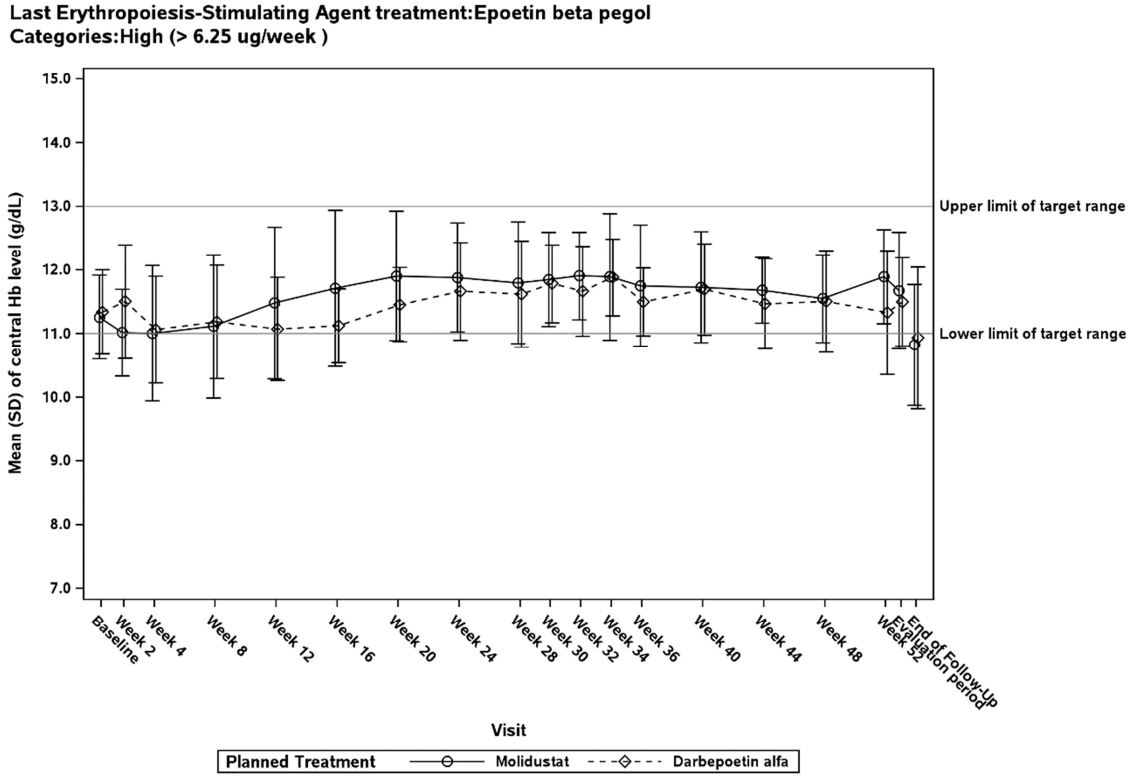
Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: High (> 7.5 ug/week)

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=30)	Screening -4	1	11.00	.	11.0	11.00	11.0						
	Screening -3	3	11.03	0.50	10.5	11.10	11.5						
	Screening -2	30	11.17	0.73	9.9	11.15	12.6						
	Screening -1	30	11.36	0.73	9.8	11.35	12.9						
	Week 0	30	11.17	0.84	9.3	11.00	12.7						
	Baseline	30	11.24	0.68	9.8	11.12	12.6						
	Week 2	30	11.50	0.82	9.4	11.40	12.8	30	0.26	0.49	-0.4	0.18	1.6
	Week 4	30	11.37	1.07	8.8	11.25	13.7	30	0.13	0.92	-1.3	-0.05	2.6
	Week 8	30	11.27	1.25	7.4	11.15	14.9	30	0.03	1.24	-2.4	-0.01	3.9
	Week 12	29	11.13	0.80	9.1	11.20	13.1	29	-0.16	0.91	-2.2	-0.20	2.3
	Week 16	27	11.12	0.99	8.3	11.30	13.0	27	-0.19	1.09	-2.7	-0.17	2.2
	Week 20	26	11.17	0.87	9.2	11.35	12.5	26	-0.17	0.94	-2.0	-0.17	1.6
	Week 24	24	11.59	0.87	10.0	11.55	13.9	24	0.26	0.97	-1.0	-0.02	3.4
	Week 28	25	11.86	0.68	10.6	11.80	13.0	25	0.51	0.81	-1.3	0.43	2.1
	Week 30	25	11.95	0.64	10.3	12.00	12.9	25	0.60	0.83	-0.7	0.43	2.3
	Week 32	25	11.62	0.86	9.9	11.50	13.2	25	0.27	1.01	-1.1	0.07	2.2
	Week 34	25	11.77	0.67	10.3	11.70	12.9	25	0.42	0.86	-1.3	0.43	1.9
	Week 36	25	11.55	0.55	10.4	11.40	12.6	25	0.20	0.79	-1.1	0.17	1.8
	Week 40	25	11.37	0.95	9.0	11.40	13.0	25	0.02	1.22	-3.3	0.13	2.5
	Week 44	24	11.36	0.80	9.6	11.10	12.8	24	0.01	1.02	-3.0	-0.03	1.9
	Week 48	24	11.38	0.87	9.2	11.40	12.8	24	0.03	1.06	-1.9	-0.08	1.9
	Week 52	21	11.57	0.68	10.5	11.50	12.6	21	0.21	0.90	-1.0	-0.07	1.8
	Evaluation period	30	11.46	1.01	7.4	11.58	12.7	30	0.22	0.92	-2.4	0.20	1.9
	End of Follow-Up	29	10.89	0.85	9.3	11.00	13.0	29	-0.36	1.09	-2.7	-0.30	2.0

The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period



The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0



The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0

図 2.7.3.6-24　前治療として使用した PEGOL の用量別（低用量又は高用量）の各来院時の平均 Hb 値（g/dL、平均値±SD）の推移（試験 19350、FAS）

表 2.7.3.6-65　前治療として使用した PEGOL の用量別（低用量又は高用量）の各来院時の平均 Hb 値（g/dL、平均値±SD）の推移（試験 19350、FAS）

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Low (<= 6.25 ug/week)

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=10)	Screening -4	1	11.50	.	11.5	11.50	11.5						
	Screening -3	2	11.30	0.85	10.7	11.30	11.9						
	Screening -2	10	11.40	0.81	10.1	11.45	12.9						
	Screening -1	10	11.53	0.93	10.3	11.25	13.0						
	Week 0	10	11.21	0.58	10.4	11.15	12.3						
	Baseline	10	11.39	0.65	10.3	11.28	12.4						
	Week 2	10	11.12	0.85	10.0	10.95	13.0	10	-0.27	0.56	-1.0	-0.26	0.6
	Week 4	10	11.18	1.35	9.4	11.20	14.2	10	-0.21	0.93	-1.4	-0.38	1.8
	Week 8	10	11.27	1.20	9.9	10.85	13.5	10	-0.12	1.13	-1.7	-0.35	2.3
	Week 12	10	11.89	0.88	10.2	12.35	12.7	10	0.50	0.93	-0.6	0.47	2.0
	Week 16	10	11.99	0.72	11.0	11.90	13.3	10	0.60	0.94	-0.9	0.83	1.6
	Week 20	9	12.21	0.81	11.2	12.20	13.8	9	0.70	0.94	-0.6	1.00	2.0
	Week 24	9	11.81	1.12	9.2	11.90	12.9	9	0.30	1.36	-2.6	0.30	1.9
	Week 28	9	11.59	0.93	10.1	11.80	12.9	9	0.08	1.15	-1.7	-0.13	1.9
	Week 30	9	11.54	1.09	9.5	12.00	12.7	9	0.04	1.19	-1.9	0.27	1.7
	Week 32	9	11.84	0.98	9.8	12.10	13.0	9	0.34	1.09	-1.6	0.47	1.8
	Week 34	9	11.82	0.84	10.2	12.10	12.8	9	0.31	0.91	-1.2	0.27	1.6
	Week 36	9	11.46	1.01	9.8	11.30	13.7	9	-0.05	0.93	-1.4	-0.17	1.9
	Week 40	8	11.88	0.53	10.8	11.95	12.6	8	0.38	0.48	-0.2	0.33	0.9
	Week 44	8	12.04	0.90	10.3	12.15	13.2	8	0.55	0.90	-0.7	0.34	2.0
	Week 48	8	12.11	0.68	11.3	12.00	13.1	8	0.62	0.90	-0.9	0.77	1.9
	Week 52	8	12.30	0.40	11.9	12.25	12.9	8	0.81	0.72	0.1	0.62	1.9
	Evaluation period	10	11.63	0.66	10.2	11.84	12.5	10	0.24	0.76	-1.2	0.18	1.2
	End of Follow-Up	10	11.12	1.19	9.0	11.15	13.2	10	-0.27	1.16	-1.8	-0.63	2.1

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Low (<= 6.25 ug/week)

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=9)	Screening -4	1	10.80	.	10.8	10.80	10.8						
	Screening -3	1	10.40	.	10.4	10.40	10.4						
	Screening -2	9	11.22	0.57	10.1	11.30	12.0						
	Screening -1	9	11.17	0.41	10.5	11.30	11.6						
	Week 0	9	10.86	0.55	9.8	10.90	11.5						
	Baseline	9	11.07	0.44	10.1	11.27	11.4						
	Week 2	9	10.96	0.51	10.2	11.10	11.5	9	-0.12	0.31	-0.8	-0.10	0.3
	Week 4	9	10.68	0.47	9.9	10.80	11.4	9	-0.39	0.48	-1.5	-0.20	0.0
	Week 8	9	11.10	0.74	10.3	11.00	12.1	9	0.03	0.81	-1.1	0.16	1.2
	Week 12	9	10.96	0.87	9.5	11.00	12.0	9	-0.12	0.98	-1.9	0.16	0.9
	Week 16	9	11.51	0.84	10.5	11.20	12.8	9	0.44	0.96	-0.8	0.46	1.9
	Week 20	9	11.36	1.11	9.1	11.60	12.7	9	0.28	0.96	-1.0	0.30	1.8
	Week 24	9	11.73	0.84	9.9	11.80	12.9	9	0.66	0.64	-0.2	0.70	1.5
	Week 28	8	12.28	0.85	11.1	12.65	13.0	8	1.09	0.70	0.1	1.50	1.7
	Week 30	8	12.49	0.60	11.8	12.30	13.4	8	1.30	0.64	0.6	1.13	2.5
	Week 32	8	11.86	0.77	10.8	11.80	13.1	8	0.67	0.73	-0.6	0.60	1.7
	Week 34	8	12.30	0.65	11.1	12.60	12.9	8	1.11	0.64	0.2	1.27	2.0
	Week 36	8	12.18	0.59	11.5	12.10	13.0	8	0.99	0.69	0.2	0.93	2.1
	Week 40	7	11.83	0.39	11.4	11.90	12.5	7	0.67	0.40	0.1	0.66	1.1
	Week 44	8	11.95	0.44	11.3	11.85	12.5	8	0.76	0.60	0.0	0.75	1.5
	Week 48	8	12.19	0.74	10.8	12.25	13.3	8	1.00	0.62	0.1	1.05	1.9
	Week 52	8	11.86	0.47	11.1	12.00	12.4	8	0.67	0.54	-0.3	0.77	1.5
	Evaluation period	9	11.65	1.75	7.2	11.93	12.9	9	0.58	1.43	-2.9	0.69	1.9
	End of Follow-Up	9	11.59	0.92	10.1	11.70	12.6	9	0.52	1.17	-1.2	0.66	2.5

The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: High (> 6.25 ug/week)

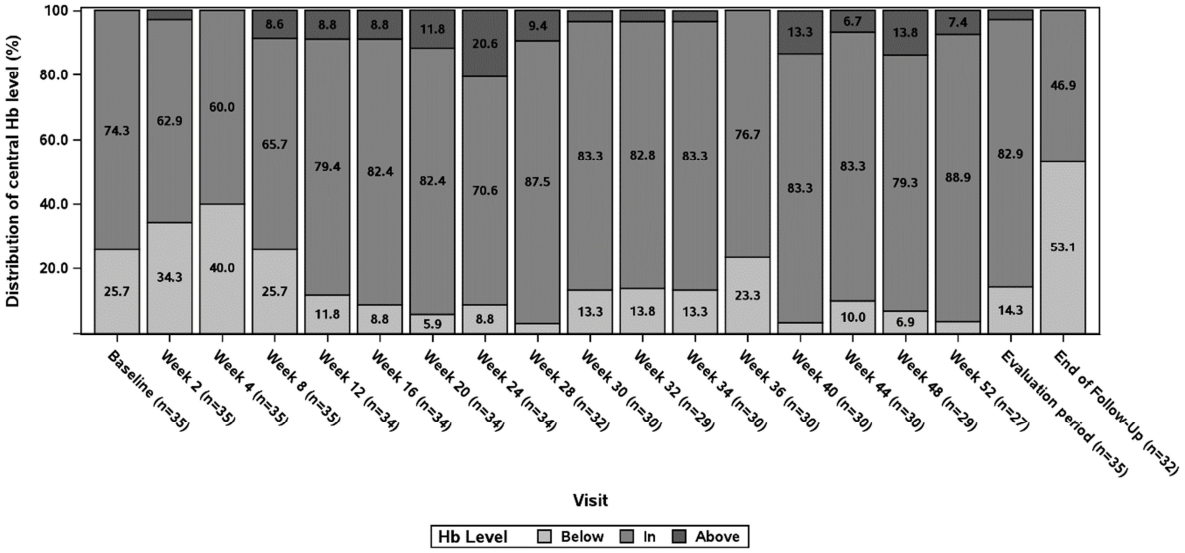
		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=37)	Screening -3	3	10.83	0.40	10.6	10.60	11.3						
	Screening -2	37	11.18	0.71	9.8	11.20	12.7						
	Screening -1	37	11.32	0.75	9.7	11.20	12.7						
	Week 0	37	11.29	0.79	9.9	11.30	13.4						
	Baseline	37	11.25	0.66	10.0	11.20	12.5						
	Week 2	37	11.01	0.68	9.3	11.10	12.3	37	-0.24	0.55	-1.2	-0.30	1.2
	Week 4	36	11.00	1.06	9.0	11.00	14.3	36	-0.24	0.93	-1.5	-0.48	1.9
	Week 8	36	11.12	1.13	9.1	11.50	12.9	36	-0.13	1.13	-2.0	-0.13	2.9
	Week 12	35	11.48	1.19	9.2	11.60	14.0	35	0.23	1.24	-1.9	0.05	2.9
	Week 16	35	11.71	1.23	7.6	11.80	13.3	35	0.46	1.29	-3.5	0.63	3.2
	Week 20	33	11.90	1.02	9.3	12.00	13.9	33	0.63	1.15	-1.8	0.70	3.3
	Week 24	31	11.88	0.86	9.4	11.90	13.2	31	0.59	0.97	-1.9	0.67	2.3
	Week 28	31	11.80	0.95	8.9	11.90	13.4	31	0.51	1.06	-2.2	0.73	2.3
	Week 30	30	11.85	0.74	10.1	11.90	13.7	30	0.56	0.91	-1.8	0.78	1.8
	Week 32	28	11.90	0.69	10.2	11.95	13.1	28	0.55	0.93	-1.3	0.53	2.4
	Week 34	27	11.89	0.99	9.4	11.80	14.0	27	0.56	1.08	-2.1	0.67	2.8
	Week 36	27	11.75	0.96	9.1	11.70	13.5	27	0.42	1.15	-2.1	0.43	2.3
	Week 40	26	11.73	0.87	9.0	11.75	13.0	26	0.43	1.12	-2.2	0.60	2.3
	Week 44	24	11.68	0.52	10.9	11.60	13.0	24	0.34	0.62	-0.8	0.33	1.6
	Week 48	23	11.55	0.69	10.1	11.60	12.8	23	0.25	0.99	-1.5	0.17	2.2
	Week 52	22	11.89	0.74	10.8	11.85	13.7	22	0.60	1.18	-1.3	0.32	3.5
	Evaluation period	37	11.68	0.92	8.9	11.70	13.3	37	0.42	1.01	-2.2	0.36	2.1
	End of Follow-Up	33	10.82	0.95	8.6	10.70	12.4	33	-0.46	1.04	-2.1	-0.53	2.2

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: High (> 6.25 ug/week)

		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=28)	Screening -4	1	9.80	.	9.8	9.80	9.8						
	Screening -3	3	10.37	0.51	9.8	10.50	10.8						
	Screening -2	28	11.35	0.64	10.2	11.30	12.7						
	Screening -1	28	11.30	0.73	9.9	11.25	12.8						
	Week 0	28	11.43	0.74	10.2	11.50	12.9						
	Baseline	28	11.34	0.66	10.1	11.30	12.7						
	Week 2	28	11.50	0.89	9.2	11.55	13.1	28	0.16	0.54	-1.0	0.00	1.0
	Week 4	28	11.06	0.84	9.0	11.10	12.7	28	-0.28	0.65	-1.4	-0.25	1.2
	Week 8	27	11.19	0.89	9.6	11.20	12.9	27	-0.17	0.69	-1.5	-0.10	1.2
	Week 12	25	11.07	0.81	9.5	11.20	12.6	25	-0.29	0.85	-2.1	-0.07	1.4
	Week 16	26	11.12	0.58	10.2	11.05	12.3	26	-0.25	0.74	-1.9	-0.15	0.9
	Week 20	26	11.45	0.58	10.2	11.50	13.1	26	0.09	0.99	-1.9	0.13	2.2
	Week 24	25	11.66	0.77	9.8	11.70	14.0	25	0.25	1.08	-1.5	0.30	3.9
	Week 28	24	11.62	0.84	9.4	11.70	13.2	24	0.24	1.01	-1.9	0.28	2.0
	Week 30	22	11.78	0.61	10.7	11.65	12.9	22	0.35	0.85	-1.1	0.43	1.9
	Week 32	22	11.66	0.71	10.4	11.65	13.1	22	0.23	1.05	-1.4	0.25	2.7
	Week 34	21	11.88	0.61	11.0	11.70	13.4	21	0.44	0.94	-1.2	0.43	2.5
	Week 36	21	11.50	0.53	10.1	11.40	12.5	21	0.06	0.72	-1.4	0.23	1.1
	Week 40	21	11.69	0.72	10.0	11.70	12.9	21	0.25	0.92	-1.6	0.17	2.2
	Week 44	20	11.47	0.71	10.2	11.45	12.6	20	0.03	0.94	-1.9	-0.05	1.8
	Week 48	20	11.51	0.80	10.3	11.40	12.9	20	0.07	1.07	-1.6	-0.05	2.8
	Week 52	20	11.33	0.98	9.8	11.10	13.3	20	-0.11	1.21	-1.5	-0.32	2.9
	Evaluation period	28	11.50	0.69	9.4	11.54	12.9	28	0.16	0.90	-1.9	0.24	1.9
	End of Follow-Up	26	10.93	1.11	8.0	10.85	13.5	26	-0.43	1.31	-3.0	-0.73	3.0

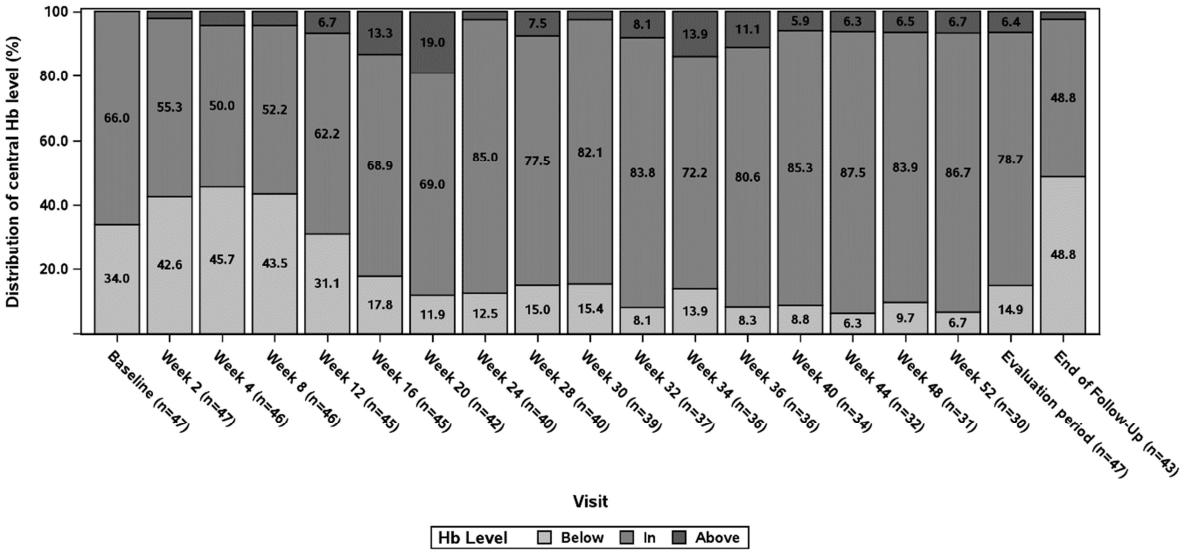
The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
Screening - X: the Xth last Hb level of scheduled visit during screening period

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Total
Planned Treatment: Molidustat

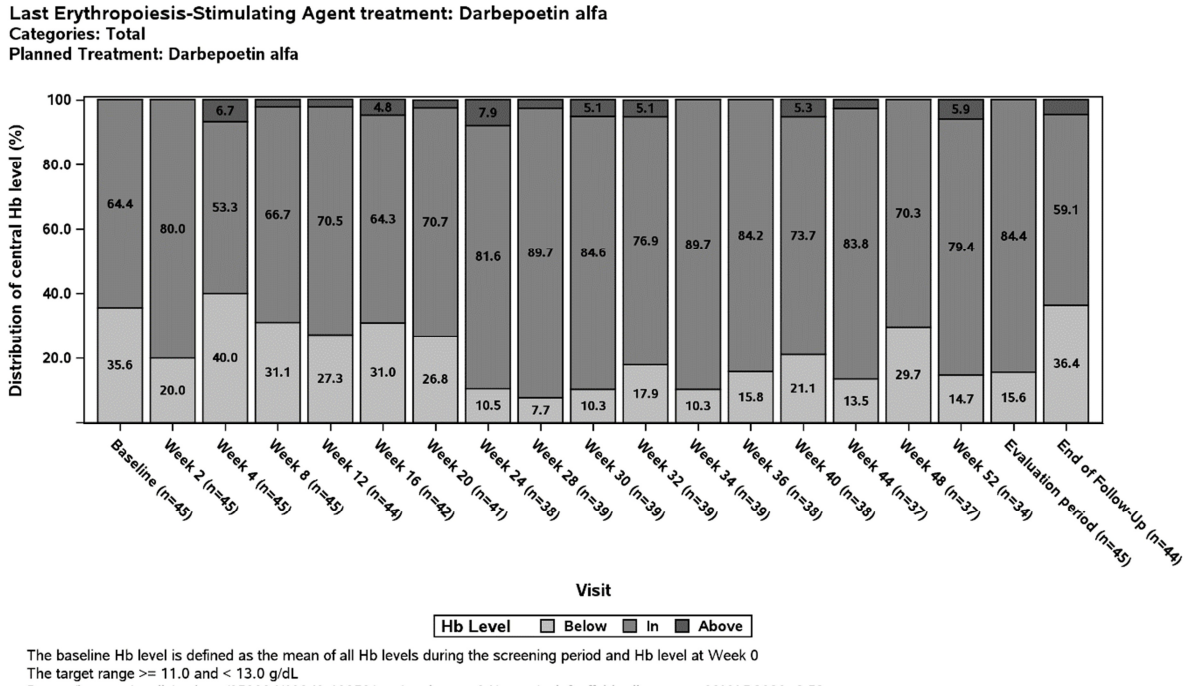


The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
The target range >= 11.0 and < 13.0 g/dL

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Total
Planned Treatment: Molidustat



The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
The target range >= 11.0 and < 13.0 g/dL



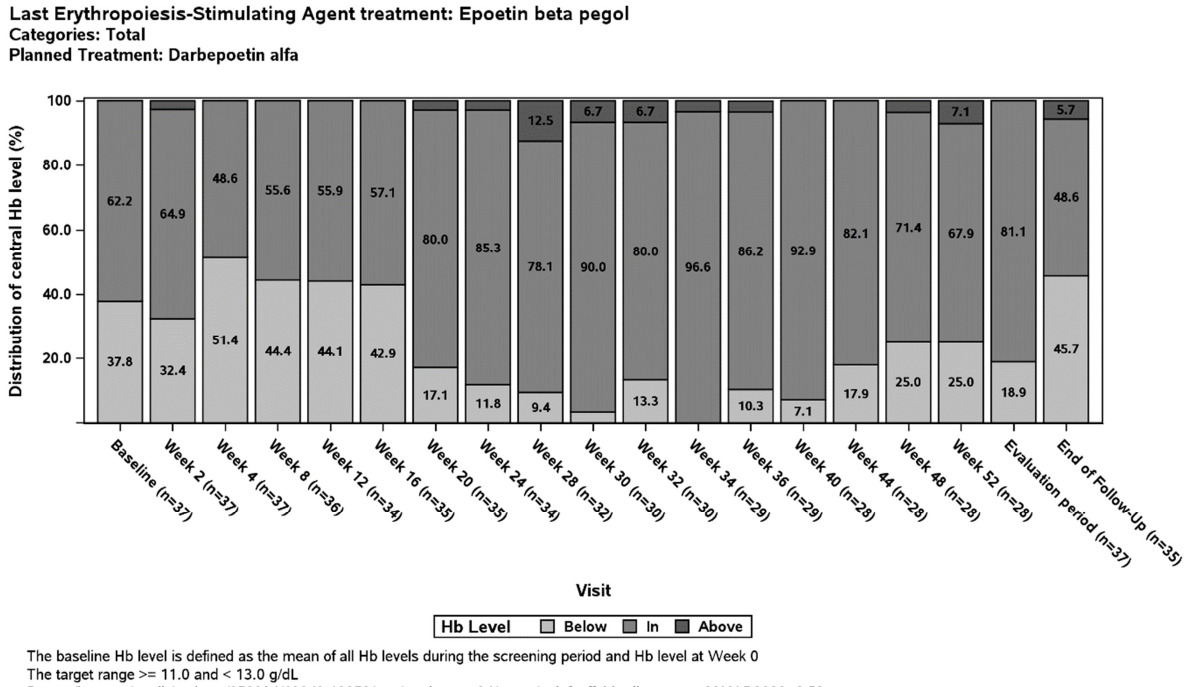


図 2.7.3.6-25 前治療として使用した ESA の種類別（DA 又は PEGOL）の各来院時の Hb 値が目標 Hb 値内、上限以上又は下限未満に該当する被験者の割合（試験 19350、FAS）

表 2.7.3.6-66 前治療として使用した ESA の種類別（DA 又は PEGOL）の各来院時の Hb 値が目標 Hb 値内、上限以上又は下限未満に該当する被験者の割合（試験 19350、FAS）

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Total

Visit	Hb Level	Molidustat (N=35)	Darbepoetin alfa (N=45)
Baseline	n	35	45
	Below	9 (25.7%)	16 (35.6%)
	In	26 (74.3%)	29 (64.4%)
	Above	0 (0.0%)	0 (0.0%)
Week 2	n	35	45
	Below	12 (34.3%)	9 (20.0%)
	In	22 (62.9%)	36 (80.0%)
	Above	1 (2.9%)	0 (0.0%)
Week 4	n	35	45
	Below	14 (40.0%)	18 (40.0%)
	In	21 (60.0%)	24 (53.3%)
	Above	0 (0.0%)	3 (6.7%)
Week 8	n	35	45
	Below	9 (25.7%)	14 (31.1%)
	In	23 (65.7%)	30 (66.7%)
	Above	3 (8.6%)	1 (2.2%)
Week 12	n	34	44
	Below	4 (11.8%)	12 (27.3%)
	In	27 (79.4%)	31 (70.5%)
	Above	3 (8.8%)	1 (2.3%)
Week 16	n	34	42
	Below	3 (8.8%)	13 (31.0%)
	In	28 (82.4%)	27 (64.3%)
	Above	3 (8.8%)	2 (4.8%)
Week 20	n	34	41
	Below	2 (5.9%)	11 (26.8%)
	In	28 (82.4%)	29 (70.7%)
	Above	4 (11.8%)	1 (2.4%)
Week 24	n	34	38
	Below	3 (8.8%)	4 (10.5%)
	In	24 (70.6%)	31 (81.6%)
	Above	7 (20.6%)	3 (7.9%)
Week 28	n	32	39
	Below	1 (3.1%)	3 (7.7%)
	In	28 (87.5%)	35 (89.7%)
	Above	3 (9.4%)	1 (2.6%)
Week 30	n	30	39
	Below	4 (13.3%)	4 (10.3%)
	In	25 (83.3%)	33 (84.6%)
	Above	1 (3.3%)	2 (5.1%)
Week 32	n	29	39
	Below	4 (13.8%)	7 (17.9%)
	In	24 (82.8%)	30 (76.9%)
	Above	1 (3.4%)	2 (5.1%)
Week 34	n	30	39
	Below	4 (13.3%)	4 (10.3%)
	In	25 (83.3%)	35 (89.7%)
	Above	1 (3.3%)	0 (0.0%)
Week 36	n	30	38
	Below	7 (23.3%)	6 (15.8%)
	In	23 (76.7%)	32 (84.2%)
	Above	0 (0.0%)	0 (0.0%)

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Total

Visit	Hb Level	Molidustat (N=35)	Darbepoetin alfa (N=45)
Week 40	n	30	38
	Below	1 (3.3%)	8 (21.1%)
	In	25 (83.3%)	28 (73.7%)
	Above	4 (13.3%)	2 (5.3%)
Week 44	n	30	37
	Below	3 (10.0%)	5 (13.5%)
	In	25 (83.3%)	31 (83.8%)
	Above	2 (6.7%)	1 (2.7%)
Week 48	n	29	37
	Below	2 (6.9%)	11 (29.7%)
	In	23 (79.3%)	26 (70.3%)
	Above	4 (13.8%)	0 (0.0%)
Week 52	n	27	34
	Below	1 (3.7%)	5 (14.7%)
	In	24 (88.9%)	27 (79.4%)
	Above	2 (7.4%)	2 (5.9%)
Evaluation period	n	35	45
	Below	5 (14.3%)	7 (15.6%)
	In	29 (82.9%)	38 (84.4%)
	Above	1 (2.9%)	0 (0.0%)
End of Follow-Up	n	32	44
	Below	17 (53.1%)	16 (36.4%)
	In	15 (46.9%)	26 (59.1%)
	Above	0 (0.0%)	2 (4.5%)

The target range >= 11.0 and < 13.0 g/dL
n: The number of subjects who had a valid Hb level
The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Total

Visit	Hb Level	Molidustat (N=47)	Darbepoetin alfa (N=37)
Baseline	n	47	37
	Below	16 (34.0%)	14 (37.8%)
	In	31 (66.0%)	23 (62.2%)
	Above	0 (0.0%)	0 (0.0%)
Week 2	n	47	37
	Below	20 (42.6%)	12 (32.4%)
	In	26 (55.3%)	24 (64.9%)
	Above	1 (2.1%)	1 (2.7%)
Week 4	n	46	37
	Below	21 (45.7%)	19 (51.4%)
	In	23 (50.0%)	18 (48.6%)
	Above	2 (4.3%)	0 (0.0%)
Week 8	n	46	36
	Below	20 (43.5%)	16 (44.4%)
	In	24 (52.2%)	20 (55.6%)
	Above	2 (4.3%)	0 (0.0%)
Week 12	n	45	34
	Below	14 (31.1%)	15 (44.1%)
	In	28 (62.2%)	19 (55.9%)
	Above	3 (6.7%)	0 (0.0%)
Week 16	n	45	35
	Below	8 (17.8%)	15 (42.9%)
	In	31 (68.9%)	20 (57.1%)
	Above	6 (13.3%)	0 (0.0%)
Week 20	n	42	35
	Below	5 (11.9%)	6 (17.1%)
	In	29 (69.0%)	28 (80.0%)
	Above	8 (19.0%)	1 (2.9%)
Week 24	n	40	34
	Below	5 (12.5%)	4 (11.8%)
	In	34 (85.0%)	29 (85.3%)
	Above	1 (2.5%)	1 (2.9%)
Week 28	n	40	32
	Below	6 (15.0%)	3 (9.4%)
	In	31 (77.5%)	25 (78.1%)
	Above	3 (7.5%)	4 (12.5%)
Week 30	n	39	30
	Below	6 (15.4%)	1 (3.3%)
	In	32 (82.1%)	27 (90.0%)
	Above	1 (2.6%)	2 (6.7%)
Week 32	n	37	30
	Below	3 (8.1%)	4 (13.3%)
	In	31 (83.8%)	24 (80.0%)
	Above	3 (8.1%)	2 (6.7%)
Week 34	n	36	29
	Below	5 (13.9%)	0 (0.0%)
	In	26 (72.2%)	28 (96.6%)
	Above	5 (13.9%)	1 (3.4%)
Week 36	n	36	29
	Below	3 (8.3%)	3 (10.3%)
	In	29 (80.6%)	25 (86.2%)
	Above	4 (11.1%)	1 (3.4%)
Week 40	n	34	28
	Below	3 (8.8%)	2 (7.1%)
	In	29 (85.3%)	26 (92.9%)
	Above	2 (5.9%)	0 (0.0%)

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Total

Visit	Hb Level	Molidustat (N=47)	Darbepoetin alfa (N=37)
Week 44	n	32	28
	Below	2 (6.3%)	5 (17.9%)
	In	28 (87.5%)	23 (82.1%)
	Above	2 (6.3%)	0 (0.0%)
Week 48	n	31	28
	Below	3 (9.7%)	7 (25.0%)
	In	26 (83.9%)	20 (71.4%)
	Above	2 (6.5%)	1 (3.6%)
Week 52	n	30	28
	Below	2 (6.7%)	7 (25.0%)
	In	26 (86.7%)	19 (67.9%)
	Above	2 (6.7%)	2 (7.1%)
Evaluation period	n	47	37
	Below	7 (14.9%)	7 (18.9%)
	In	37 (78.7%)	30 (81.1%)
	Above	3 (6.4%)	0 (0.0%)
End of Follow-Up	n	43	35
	Below	21 (48.8%)	16 (45.7%)
	In	21 (48.8%)	17 (48.6%)
	Above	1 (2.3%)	2 (5.7%)

The target range >= 11.0 and < 13.0 g/dL
n: The number of subjects who had a valid Hb level
The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0