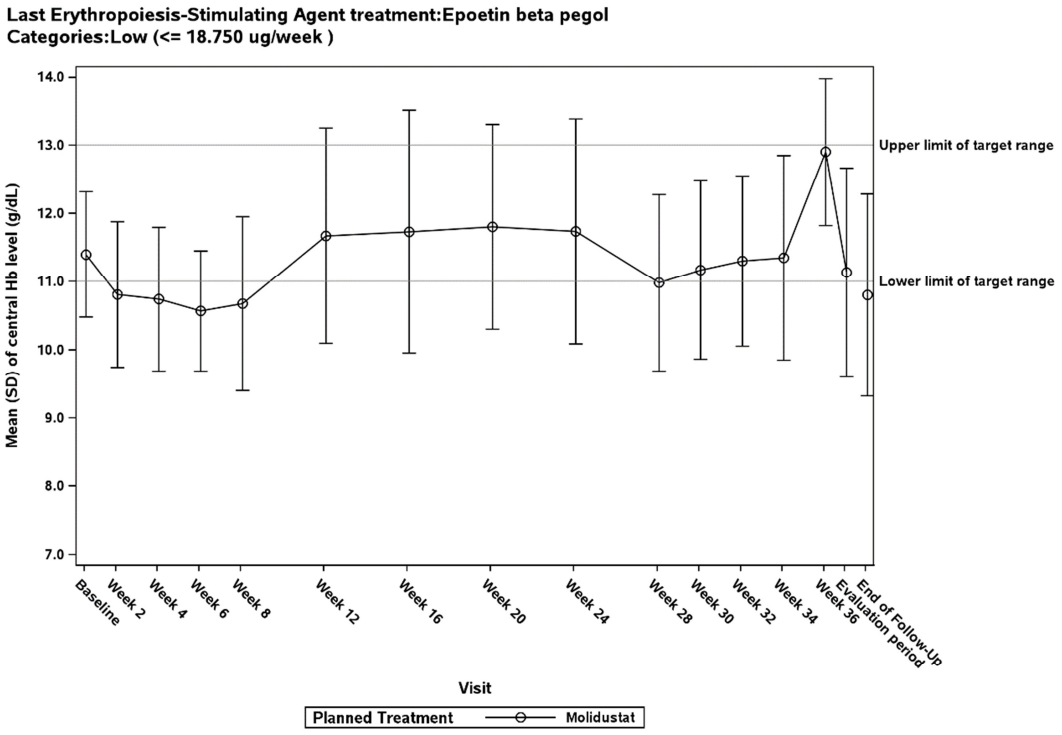
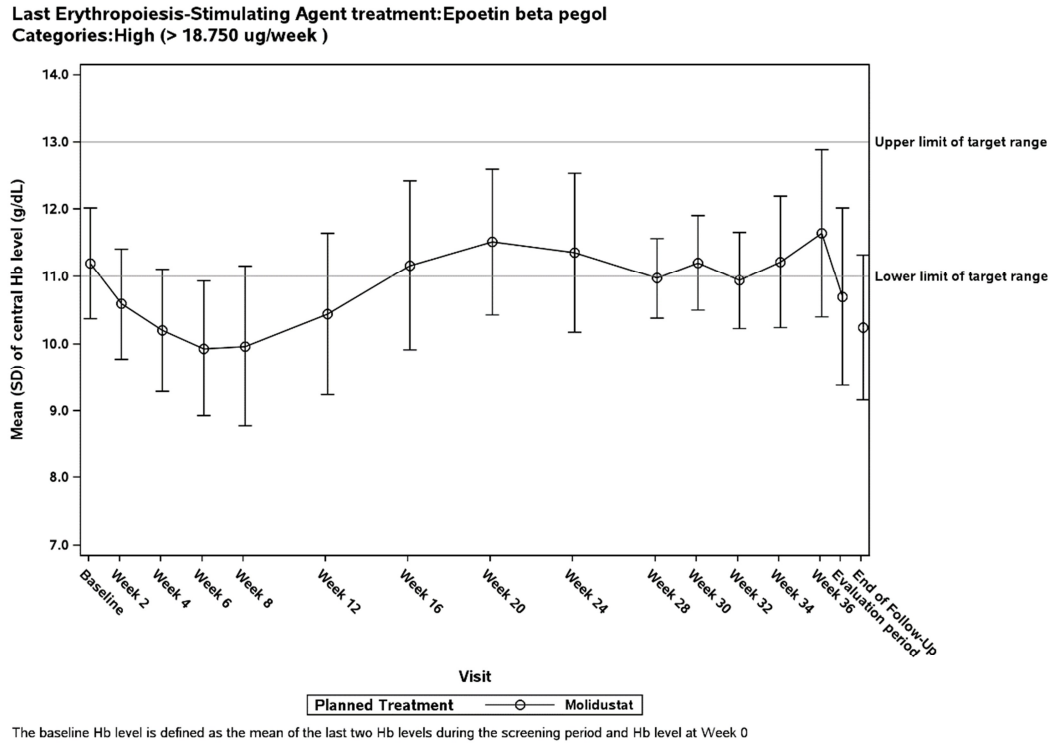


The baseline Hb level is defined as the mean of the last two Hb levels during the screening period and Hb level at Week 0



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 2.7.3.6-42　前治療として使用した PEGOL の投与量別（中央値以下又は中央値超別）の各来院時の平均 Hb 値（g/dL、平均値±SD）の推移（試験 19353、FAS）

表 2.7.3.6-83 前治療として使用した PEGOL の投与量別（中央値以下又は中央値超別）の各来院時の平均 Hb 値（g/dL、平均値±SD）の推移（試験 19353、FAS）

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Low (<= 18.750 ug/week)

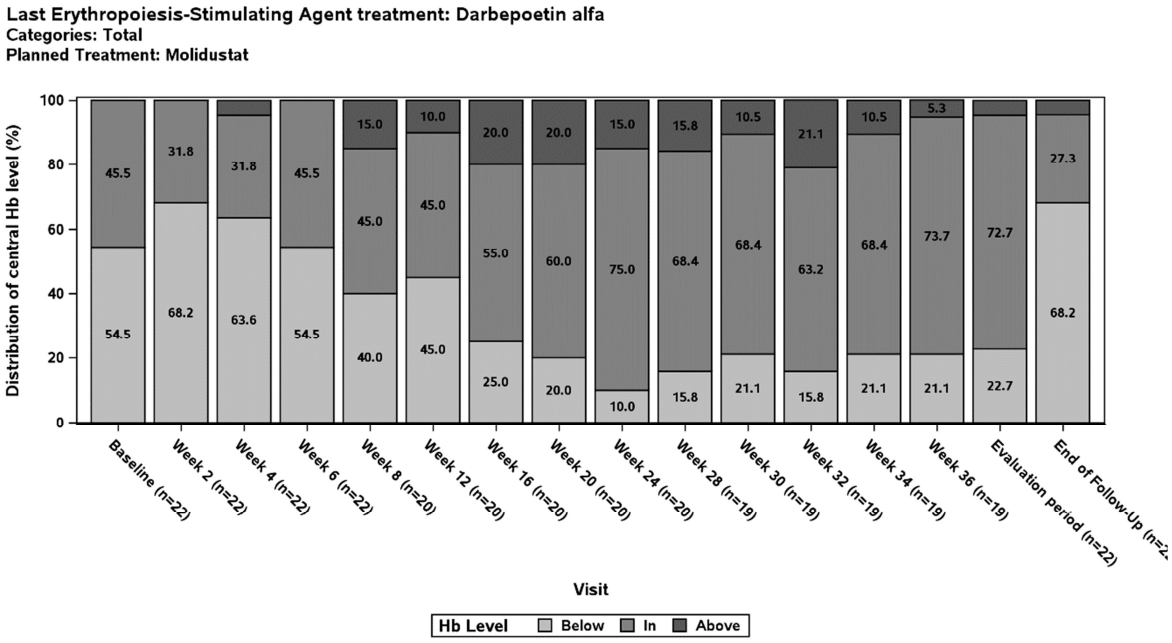
		Value at visit						Change from Baseline					
Planned Treatment	Visit	n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Molidustat (N=14)	Screening -2	14	11.63	0.97	10.0	11.70	13.1						
	Screening -1	14	11.41	1.04	9.7	11.50	13.1						
	Week 0	14	11.15	0.91	9.3	11.20	12.4						
	Baseline	14	11.40	0.92	9.8	11.45	12.6						
	Week 2	14	10.81	1.07	8.5	11.05	12.4	14	-0.59	0.70	-1.6	-0.80	1.0
	Week 4	14	10.74	1.05	8.8	11.00	12.1	14	-0.65	1.04	-2.0	-0.80	1.3
	Week 6	13	10.57	0.88	8.8	10.90	11.7	13	-0.76	0.78	-2.1	-0.53	0.3
	Week 8	12	10.68	1.27	8.1	10.85	12.8	12	-0.73	1.14	-2.2	-0.50	1.4
	Week 12	10	11.67	1.58	8.6	11.85	15.0	10	0.15	1.84	-2.9	-0.23	3.6
	Week 16	10	11.73	1.78	8.2	12.50	13.7	10	0.21	1.76	-3.3	0.50	2.4
	Week 20	9	11.80	1.50	8.3	12.20	13.5	9	0.27	1.34	-3.2	0.50	1.4
	Week 24	9	11.73	1.64	8.2	11.90	14.1	9	0.20	2.10	-3.3	-0.07	3.2
	Week 28	9	10.98	1.29	8.6	11.00	12.7	9	-0.56	1.67	-3.0	0.13	1.0
	Week 30	9	11.17	1.30	8.3	11.50	12.5	9	-0.37	1.70	-3.2	0.03	2.6
	Week 32	9	11.30	1.25	8.6	11.20	12.6	9	-0.23	1.66	-2.9	0.43	1.9
	Week 34	9	11.34	1.50	8.0	11.90	12.6	9	-0.19	1.62	-3.5	-0.03	2.1
	Week 36	8	12.90	1.08	11.8	12.40	14.7	8	1.36	1.65	-0.5	0.98	3.8
	Evaluation period	14	11.13	1.53	8.1	11.49	13.0	14	-0.26	1.58	-3.2	-0.23	2.6
	End of Follow-Up	13	10.80	1.48	8.8	10.90	13.9	13	-0.59	1.65	-3.5	-0.93	3.6

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

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: High (> 18.750 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=13)	Screening -2	13	10.98	1.06	9.8	10.80	13.1						
	Screening -1	13	11.40	0.80	10.5	11.30	12.8						
	Week 0	13	11.19	0.92	9.5	11.30	12.4						
	Baseline	13	11.19	0.82	10.1	10.93	12.7						
	Week 2	13	10.59	0.82	9.4	10.40	11.9	13	-0.60	0.66	-1.7	-0.83	0.6
	Week 4	13	10.20	0.91	9.0	10.20	12.0	13	-0.99	0.80	-2.3	-1.07	0.4
	Week 6	13	9.93	1.01	7.9	10.30	11.3	13	-1.26	1.04	-2.9	-1.37	0.4
	Week 8	13	9.96	1.19	7.3	10.00	12.0	13	-1.23	1.35	-3.5	-1.33	0.7
	Week 12	12	10.44	1.20	8.9	10.60	12.5	12	-0.79	1.21	-2.9	-1.23	1.1
	Week 16	11	11.16	1.25	8.3	11.30	13.1	11	0.02	1.28	-2.4	0.17	1.8
	Week 20	9	11.51	1.09	9.4	11.60	13.2	9	0.41	0.81	-1.3	0.47	1.4
	Week 24	9	11.36	1.18	9.8	11.10	13.7	9	0.26	1.47	-1.6	-0.13	2.4
	Week 28	7	10.97	0.59	9.8	11.00	11.5	7	-0.13	0.95	-1.7	-0.03	1.1
	Week 30	7	11.20	0.70	10.0	11.40	12.1	7	0.10	1.28	-2.0	0.43	1.3
	Week 32	7	10.94	0.71	10.0	11.00	12.1	7	-0.16	1.05	-1.7	0.27	0.9
	Week 34	7	11.21	0.97	10.1	11.30	12.4	7	0.11	1.31	-2.1	-0.03	1.5
	Week 36	7	11.64	1.24	9.8	11.50	13.4	7	0.54	1.22	-1.2	0.47	2.1
	Evaluation period	13	10.70	1.31	7.3	11.00	12.4	13	-0.50	1.56	-3.5	-0.41	1.3
	End of Follow-Up	13	10.24	1.08	8.6	10.40	11.7	13	-0.95	0.92	-2.4	-1.03	0.4

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



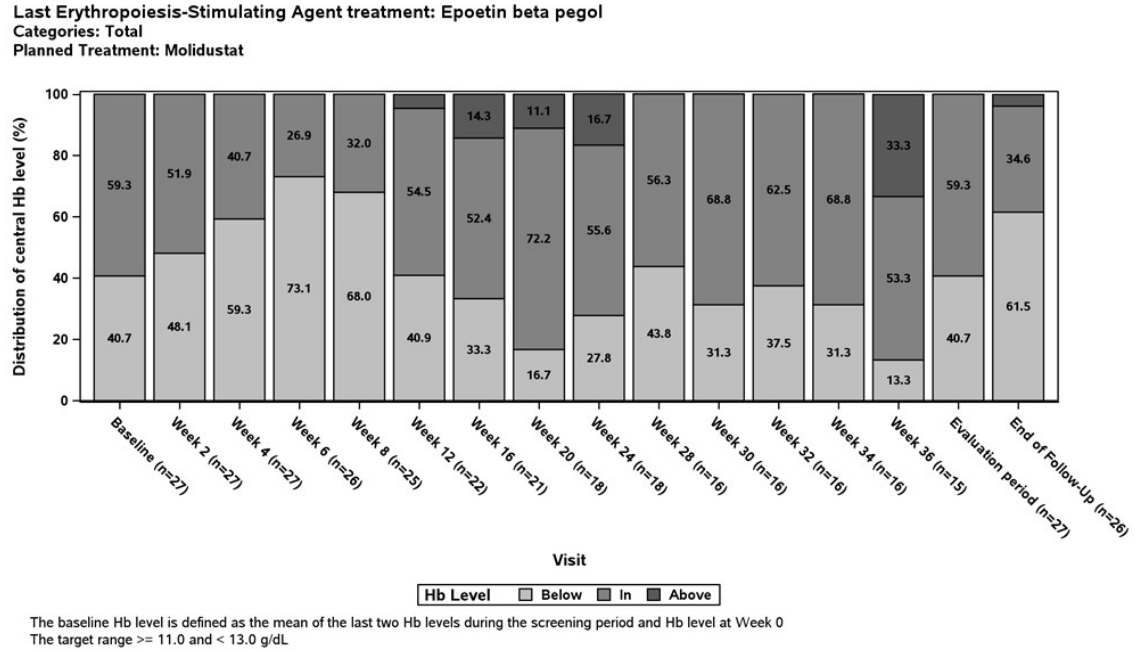


図 2.7.3.6-43 前治療として使用した ESA の種類別（DA 又は PEGOL）の各来院時の Hb 値が目標 Hb 値内、上限以上又は下限未満に該当する被験者の割合（試験 19353、FAS）

表 2.7.3.6-84 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 19353、FAS）

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

Visit	Hb Level	Molidustat (N=22)
Baseline	n	22
	Below	12 (54.5%)
	In	10 (45.5%)
	Above	0 (0.0%)
Week 2	n	22
	Below	15 (68.2%)
	In	7 (31.8%)
	Above	0 (0.0%)
Week 4	n	22
	Below	14 (63.6%)
	In	7 (31.8%)
	Above	1 (4.5%)
Week 6	n	22
	Below	12 (54.5%)
	In	10 (45.5%)
	Above	0 (0.0%)
Week 8	n	20
	Below	8 (40.0%)
	In	9 (45.0%)
	Above	3 (15.0%)
Week 12	n	20
	Below	9 (45.0%)
	In	9 (45.0%)
	Above	2 (10.0%)
Week 16	n	20
	Below	5 (25.0%)
	In	11 (55.0%)
	Above	4 (20.0%)
Week 20	n	20
	Below	4 (20.0%)
	In	12 (60.0%)
	Above	4 (20.0%)
Week 24	n	20
	Below	2 (10.0%)
	In	15 (75.0%)
	Above	3 (15.0%)
Week 28	n	19
	Below	3 (15.8%)
	In	13 (68.4%)
	Above	3 (15.8%)
Week 30	n	19
	Below	4 (21.1%)
	In	13 (68.4%)
	Above	2 (10.5%)
Week 32	n	19
	Below	3 (15.8%)
	In	12 (63.2%)
	Above	4 (21.1%)
Week 34	n	19
	Below	4 (21.1%)
	In	13 (68.4%)
	Above	2 (10.5%)

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

Visit	Hb Level	Molidustat (N=22)
Week 36	n	19
	Below	4 (21.1%)
	In	14 (73.7%)
	Above	1 (5.3%)
Evaluation period	n	22
	Below	5 (22.7%)
	In	16 (72.7%)
	Above	1 (4.5%)
End of Follow-Up	n	22
	Below	15 (68.2%)
	In	6 (27.3%)
	Above	1 (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 the last two Hb levels during the screening period and Hb level at Week 0

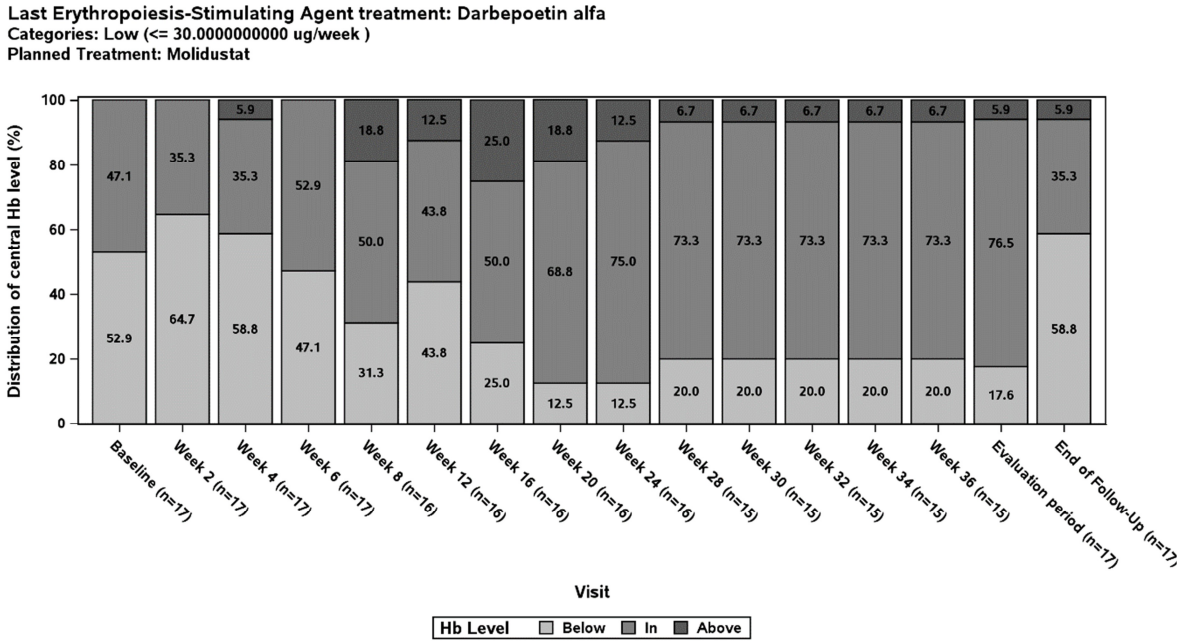
Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Total

Visit	Hb Level	Molidustat (N=27)
Baseline	n	27
	Below	11 (40.7%)
	In	16 (59.3%)
	Above	0 (0.0%)
Week 2	n	27
	Below	13 (48.1%)
	In	14 (51.9%)
	Above	0 (0.0%)
Week 4	n	27
	Below	16 (59.3%)
	In	11 (40.7%)
	Above	0 (0.0%)
Week 6	n	26
	Below	19 (73.1%)
	In	7 (26.9%)
	Above	0 (0.0%)
Week 8	n	25
	Below	17 (68.0%)
	In	8 (32.0%)
	Above	0 (0.0%)
Week 12	n	22
	Below	9 (40.9%)
	In	12 (54.5%)
	Above	1 (4.5%)
Week 16	n	21
	Below	7 (33.3%)
	In	11 (52.4%)
	Above	3 (14.3%)
Week 20	n	18
	Below	3 (16.7%)
	In	13 (72.2%)
	Above	2 (11.1%)
Week 24	n	18
	Below	5 (27.8%)
	In	10 (55.6%)
	Above	3 (16.7%)
Week 28	n	16
	Below	7 (43.8%)
	In	9 (56.3%)
	Above	0 (0.0%)
Week 30	n	16
	Below	5 (31.3%)
	In	11 (68.8%)
	Above	0 (0.0%)
Week 32	n	16
	Below	6 (37.5%)
	In	10 (62.5%)
	Above	0 (0.0%)
Week 34	n	16
	Below	5 (31.3%)
	In	11 (68.8%)
	Above	0 (0.0%)
Week 36	n	15
	Below	2 (13.3%)
	In	8 (53.3%)
	Above	5 (33.3%)

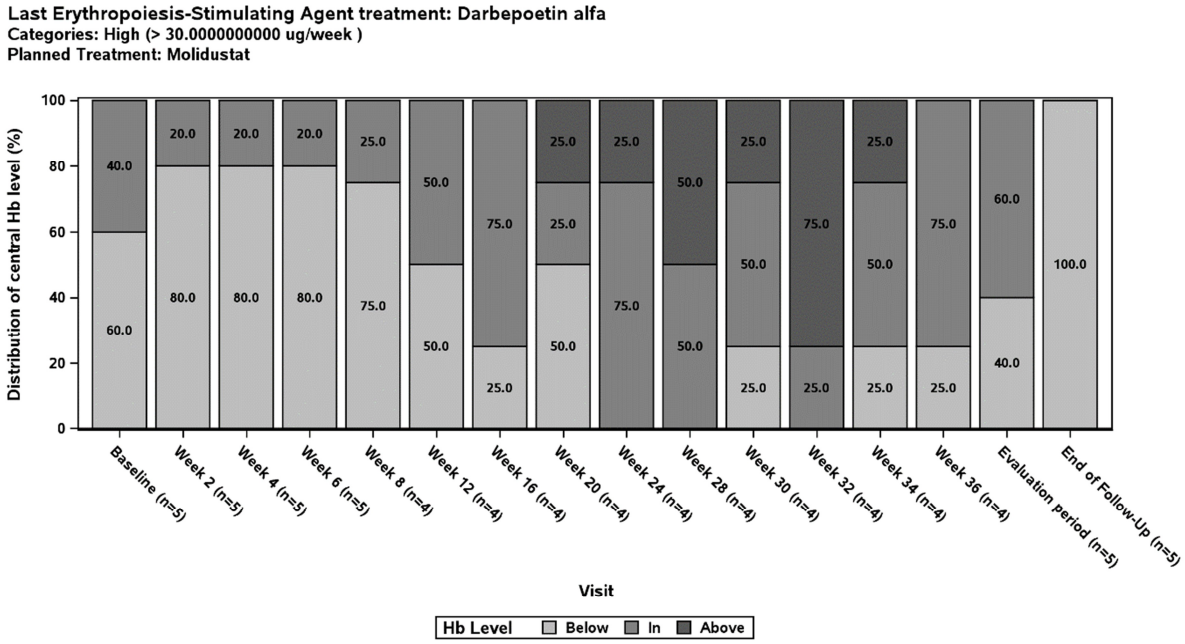
Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Total

Visit	Hb Level	Molidustat (N=27)
Evaluation period	n	27
	Below	11 (40.7%)
	In	16 (59.3%)
	Above	0 (0.0%)
End of Follow-Up	n	26
	Below	16 (61.5%)
	In	9 (34.6%)
	Above	1 (3.8%)

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 the last two Hb levels during the screening period and Hb level at Week 0



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
The target range >= 11.0 and < 13.0 g/dL



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
The target range >= 11.0 and < 13.0 g/dL

図 2.7.3.6-44 前治療として使用した DA の用量別（中央値以下又は中央値超別）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 19353、FAS）

表 2.7.3.6-85 前治療として使用した DA の用量別（中央値以下又は中央値超別）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 19353、FAS）

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Low (<= 30.000 ug/week)

Visit	Hb Level	Molidustat (N=17)
Baseline	n	17
	Below	9 (52.9%)
	In	8 (47.1%)
	Above	0 (0.0%)
Week 2	n	17
	Below	11 (64.7%)
	In	6 (35.3%)
	Above	0 (0.0%)
Week 4	n	17
	Below	10 (58.8%)
	In	6 (35.3%)
	Above	1 (5.9%)
Week 6	n	17
	Below	8 (47.1%)
	In	9 (52.9%)
	Above	0 (0.0%)
Week 8	n	16
	Below	5 (31.3%)
	In	8 (50.0%)
	Above	3 (18.8%)
Week 12	n	16
	Below	7 (43.8%)
	In	7 (43.8%)
	Above	2 (12.5%)
Week 16	n	16
	Below	4 (25.0%)
	In	8 (50.0%)
	Above	4 (25.0%)
Week 20	n	16
	Below	2 (12.5%)
	In	11 (68.8%)
	Above	3 (18.8%)
Week 24	n	16
	Below	2 (12.5%)
	In	12 (75.0%)
	Above	2 (12.5%)
Week 28	n	15
	Below	3 (20.0%)
	In	11 (73.3%)
	Above	1 (6.7%)
Week 30	n	15
	Below	3 (20.0%)
	In	11 (73.3%)
	Above	1 (6.7%)
Week 32	n	15
	Below	3 (20.0%)
	In	11 (73.3%)
	Above	1 (6.7%)
Week 34	n	15
	Below	3 (20.0%)
	In	11 (73.3%)
	Above	1 (6.7%)

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Low (<= 30.000 ug/week)

Visit	Hb Level	Molidustat (N=17)
Week 36	n	15
	Below	3 (20.0%)
	In	11 (73.3%)
	Above	1 (6.7%)
Evaluation period	n	17
	Below	3 (17.6%)
	In	13 (76.5%)
	Above	1 (5.9%)
End of Follow-Up	n	17
	Below	10 (58.8%)
	In	6 (35.3%)
	Above	1 (5.9%)

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 the last two Hb levels during the screening period and Hb level at Week 0

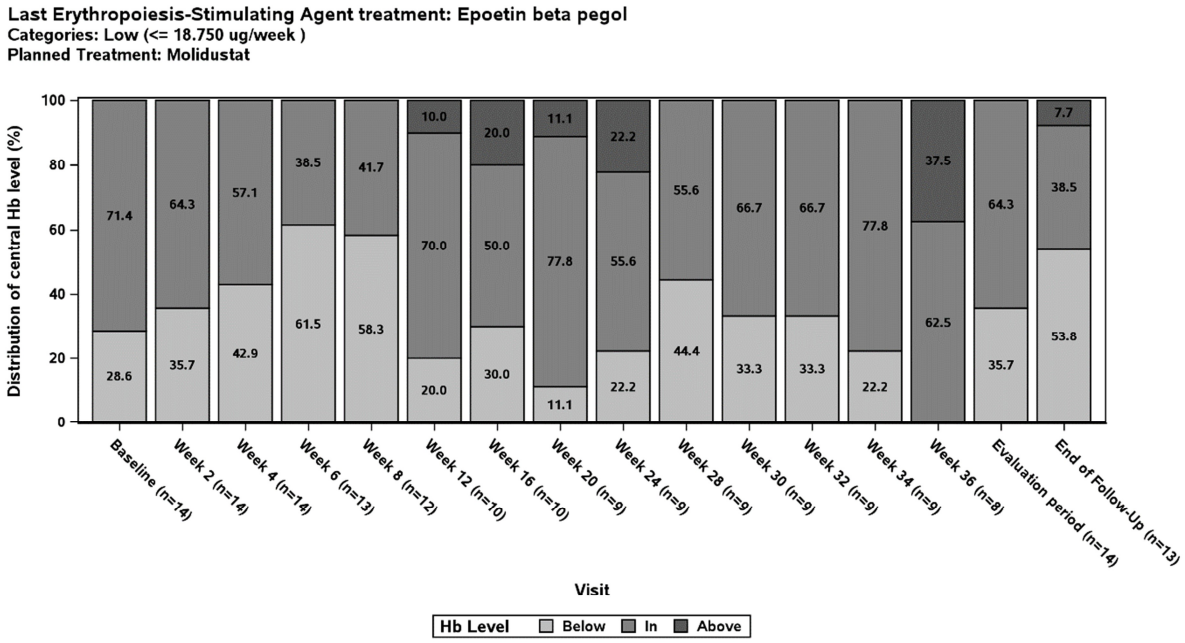
Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: High (> 30.000 ug/week)

Visit	Hb Level	Molidustat (N=5)
Baseline	n	5
	Below	3 (60.0%)
	In	2 (40.0%)
	Above	0 (0.0%)
Week 2	n	5
	Below	4 (80.0%)
	In	1 (20.0%)
	Above	0 (0.0%)
Week 4	n	5
	Below	4 (80.0%)
	In	1 (20.0%)
	Above	0 (0.0%)
Week 6	n	5
	Below	4 (80.0%)
	In	1 (20.0%)
	Above	0 (0.0%)
Week 8	n	4
	Below	3 (75.0%)
	In	1 (25.0%)
	Above	0 (0.0%)
Week 12	n	4
	Below	2 (50.0%)
	In	2 (50.0%)
	Above	0 (0.0%)
Week 16	n	4
	Below	1 (25.0%)
	In	3 (75.0%)
	Above	0 (0.0%)
Week 20	n	4
	Below	2 (50.0%)
	In	1 (25.0%)
	Above	1 (25.0%)
Week 24	n	4
	Below	0 (0.0%)
	In	3 (75.0%)
	Above	1 (25.0%)
Week 28	n	4
	Below	0 (0.0%)
	In	2 (50.0%)
	Above	2 (50.0%)
Week 30	n	4
	Below	1 (25.0%)
	In	2 (50.0%)
	Above	1 (25.0%)
Week 32	n	4
	Below	0 (0.0%)
	In	1 (25.0%)
	Above	3 (75.0%)
Week 34	n	4
	Below	1 (25.0%)
	In	2 (50.0%)
	Above	1 (25.0%)
Week 36	n	4
	Below	1 (25.0%)
	In	3 (75.0%)
	Above	0 (0.0%)

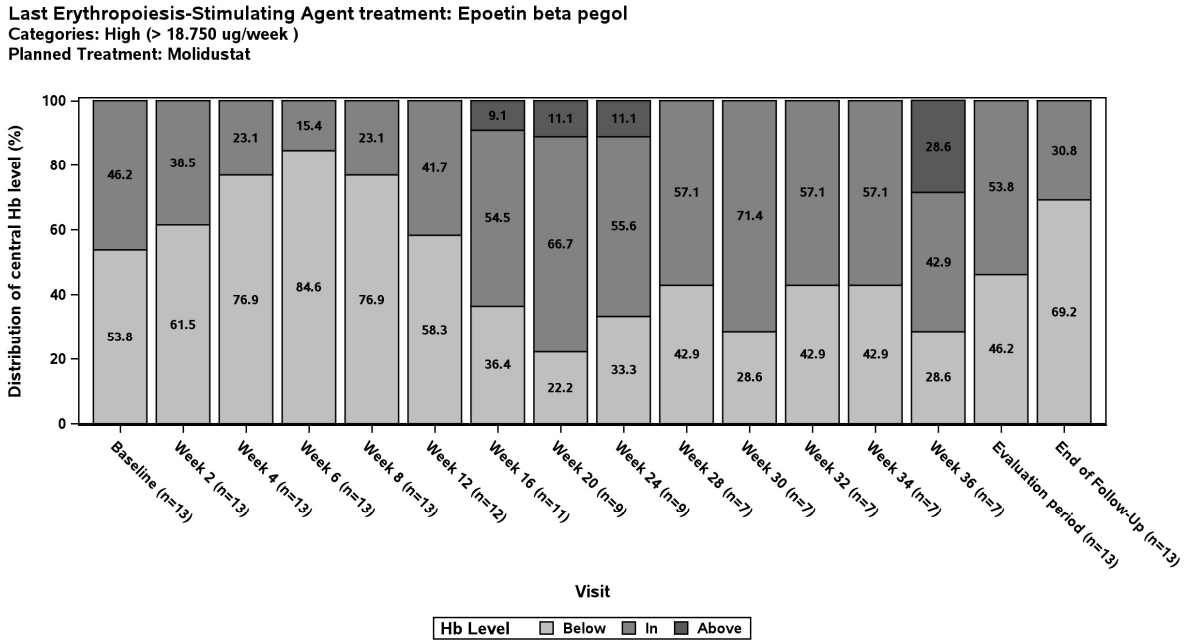
Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: High (> 30.000 ug/week)

Visit	Hb Level	Molidustat (N=5)
Evaluation period	n	5
	Below	2 (40.0%)
	In	3 (60.0%)
	Above	0 (0.0%)
End of Follow-Up	n	5
	Below	5 (100.0%)
	In	0 (0.0%)
	Above	0 (0.0%)

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 the last two Hb levels during the screening period and Hb level at Week 0



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
The target range >= 11.0 and < 13.0 g/dL



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
The target range >= 11.0 and < 13.0 g/dL

図 2.7.3.6-45 前治療として使用した PEGOL の用量別（中央値以下又は中央値超別）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 19353、FAS）

表 2.7.3.6-86 前治療として使用した PEGOL の用量別（中央値以下又は中央値超別）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 19353、FAS）

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Low (<= 18.750 ug/week)

Visit	Hb Level	Molidustat (N=14)
Baseline	n	14
	Below	4 (28.6%)
	In	10 (71.4%)
	Above	0 (0.0%)
Week 2	n	14
	Below	5 (35.7%)
	In	9 (64.3%)
	Above	0 (0.0%)
Week 4	n	14
	Below	6 (42.9%)
	In	8 (57.1%)
	Above	0 (0.0%)
Week 6	n	13
	Below	8 (61.5%)
	In	5 (38.5%)
	Above	0 (0.0%)
Week 8	n	12
	Below	7 (58.3%)
	In	5 (41.7%)
	Above	0 (0.0%)
Week 12	n	10
	Below	2 (20.0%)
	In	7 (70.0%)
	Above	1 (10.0%)
Week 16	n	10
	Below	3 (30.0%)
	In	5 (50.0%)
	Above	2 (20.0%)
Week 20	n	9
	Below	1 (11.1%)
	In	7 (77.8%)
	Above	1 (11.1%)
Week 24	n	9
	Below	2 (22.2%)
	In	5 (55.6%)
	Above	2 (22.2%)
Week 28	n	9
	Below	4 (44.4%)
	In	5 (55.6%)
	Above	0 (0.0%)
Week 30	n	9
	Below	3 (33.3%)
	In	6 (66.7%)
	Above	0 (0.0%)
Week 32	n	9
	Below	3 (33.3%)
	In	6 (66.7%)
	Above	0 (0.0%)
Week 34	n	9
	Below	2 (22.2%)
	In	7 (77.8%)
	Above	0 (0.0%)
Week 36	n	8
	Below	0 (0.0%)
	In	5 (62.5%)
	Above	3 (37.5%)

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Low (<= 18.750 ug/week)

Visit	Hb Level	Molidustat (N=14)
Evaluation period	n	14
	Below	5 (35.7%)
	In	9 (64.3%)
	Above	0 (0.0%)
End of Follow-Up	n	13
	Below	7 (53.8%)
	In	5 (38.5%)
	Above	1 (7.7%)

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 the last two Hb levels during the screening period and Hb level at Week 0

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: High (> 18.750 ug/week)

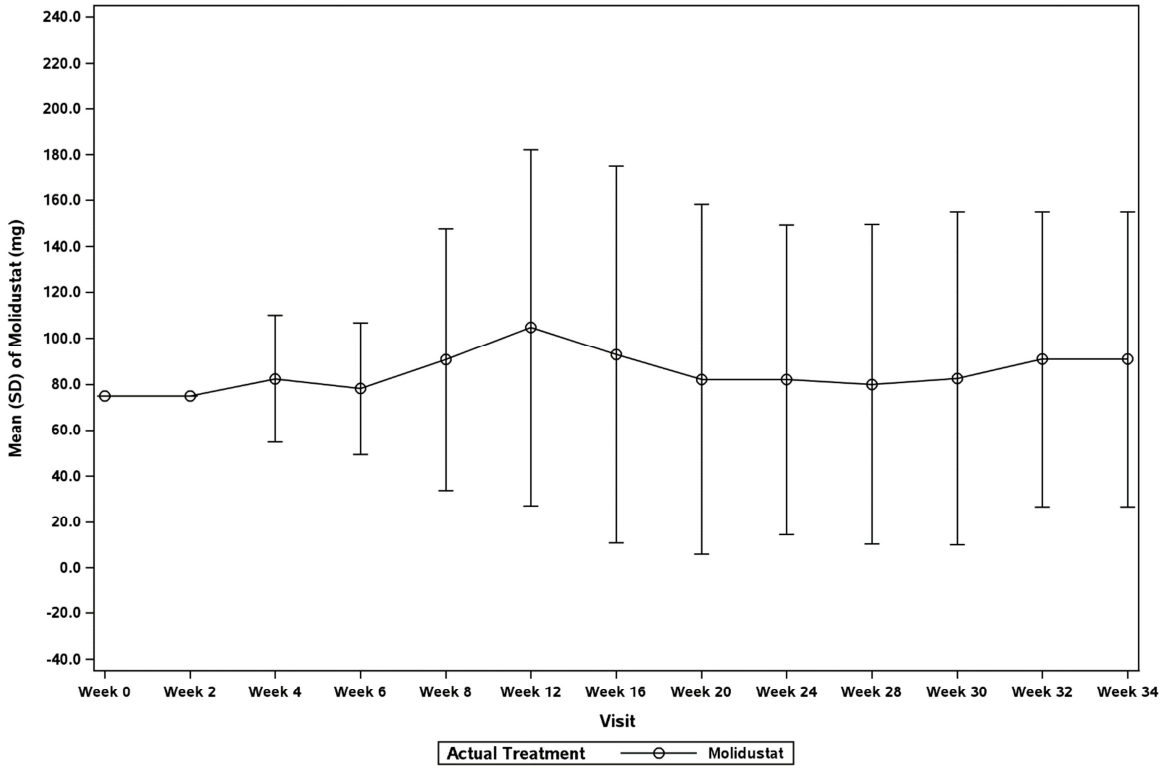
Visit	Hb Level	Molidustat (N=13)
Baseline	n	13
	Below	7 (53.8%)
	In	6 (46.2%)
	Above	0 (0.0%)
Week 2	n	13
	Below	8 (61.5%)
	In	5 (38.5%)
	Above	0 (0.0%)
Week 4	n	13
	Below	10 (76.9%)
	In	3 (23.1%)
	Above	0 (0.0%)
Week 6	n	13
	Below	11 (84.6%)
	In	2 (15.4%)
	Above	0 (0.0%)
Week 8	n	13
	Below	10 (76.9%)
	In	3 (23.1%)
	Above	0 (0.0%)
Week 12	n	12
	Below	7 (58.3%)
	In	5 (41.7%)
	Above	0 (0.0%)
Week 16	n	11
	Below	4 (36.4%)
	In	6 (54.5%)
	Above	1 (9.1%)
Week 20	n	9
	Below	2 (22.2%)
	In	6 (66.7%)
	Above	1 (11.1%)
Week 24	n	9
	Below	3 (33.3%)
	In	5 (55.6%)
	Above	1 (11.1%)
Week 28	n	7
	Below	3 (42.9%)
	In	4 (57.1%)
	Above	0 (0.0%)
Week 30	n	7
	Below	2 (28.6%)
	In	5 (71.4%)
	Above	0 (0.0%)
Week 32	n	7
	Below	3 (42.9%)
	In	4 (57.1%)
	Above	0 (0.0%)
Week 34	n	7
	Below	3 (42.9%)
	In	4 (57.1%)
	Above	0 (0.0%)
Week 36	n	7
	Below	2 (28.6%)
	In	3 (42.9%)
	Above	2 (28.6%)

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: High (> 18.750 ug/week)

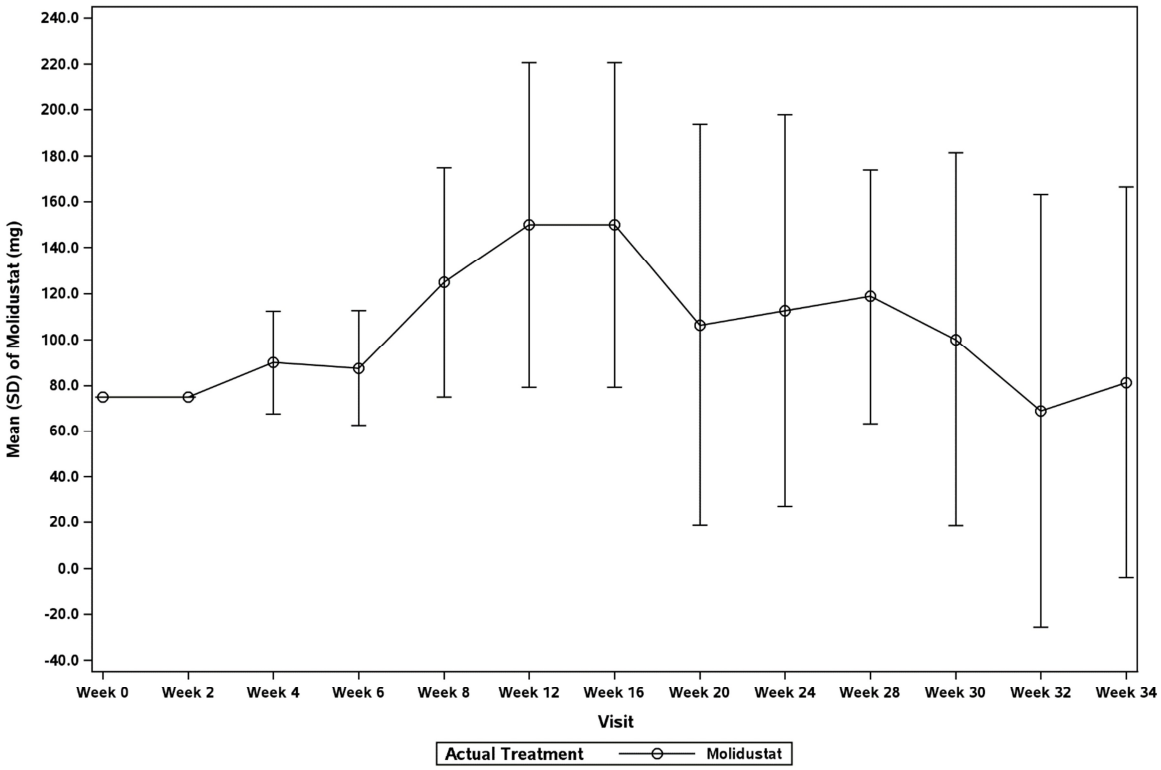
Visit	Hb Level	Molidustat (N=13)
Evaluation period	n	13
	Below	6 (46.2%)
	In	7 (53.8%)
	Above	0 (0.0%)
End of Follow-Up	n	13
	Below	9 (69.2%)
	In	4 (30.8%)
	Above	0 (0.0%)

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 the last two Hb levels during the screening period and Hb level at Week 0

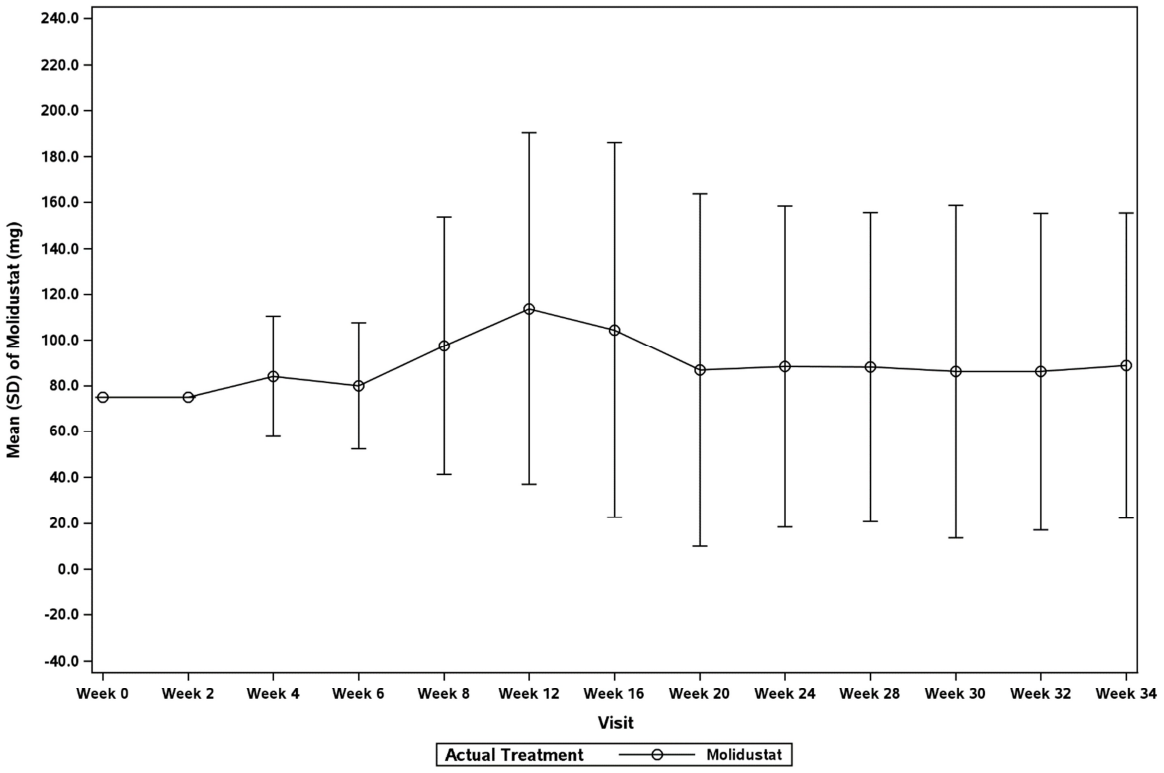
Last Erythropoiesis-Stimulating Agent treatment:Darbepoetin alfa
Categories:Low (<= 30.000 ug/week)



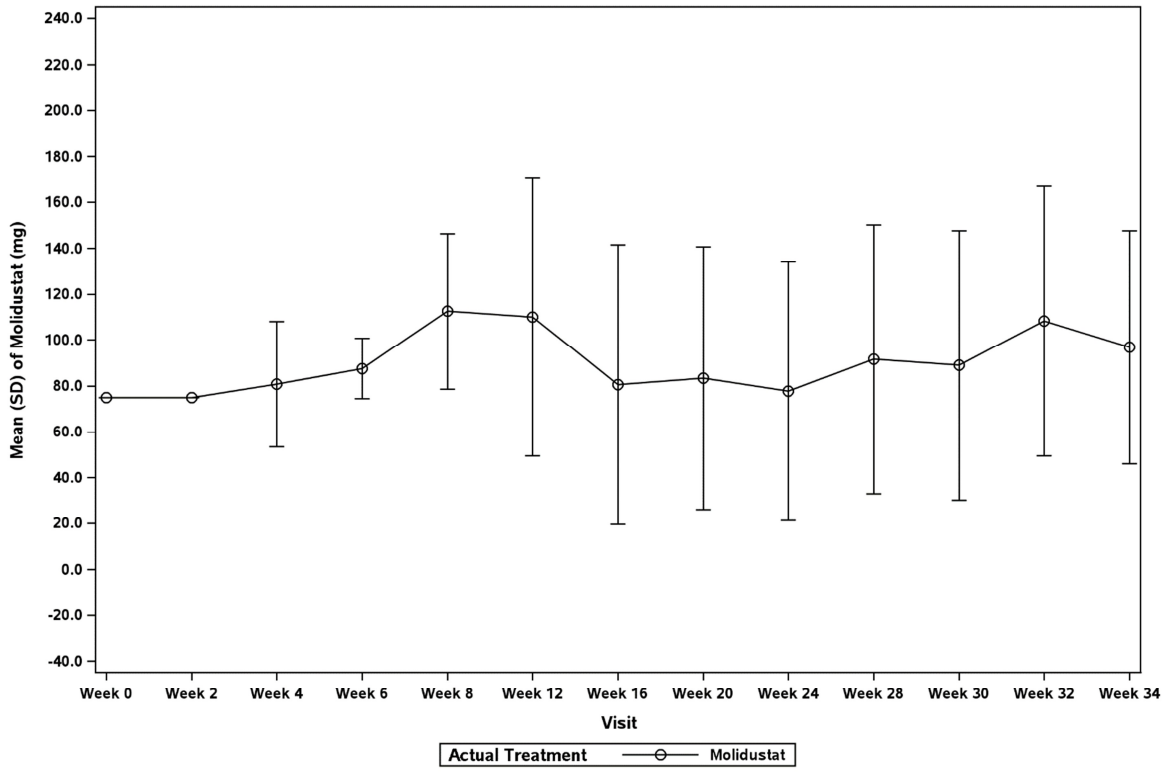
Last Erythropoiesis-Stimulating Agent treatment:Darbepoetin alfa
Categories:High (> 30.000 ug/week)

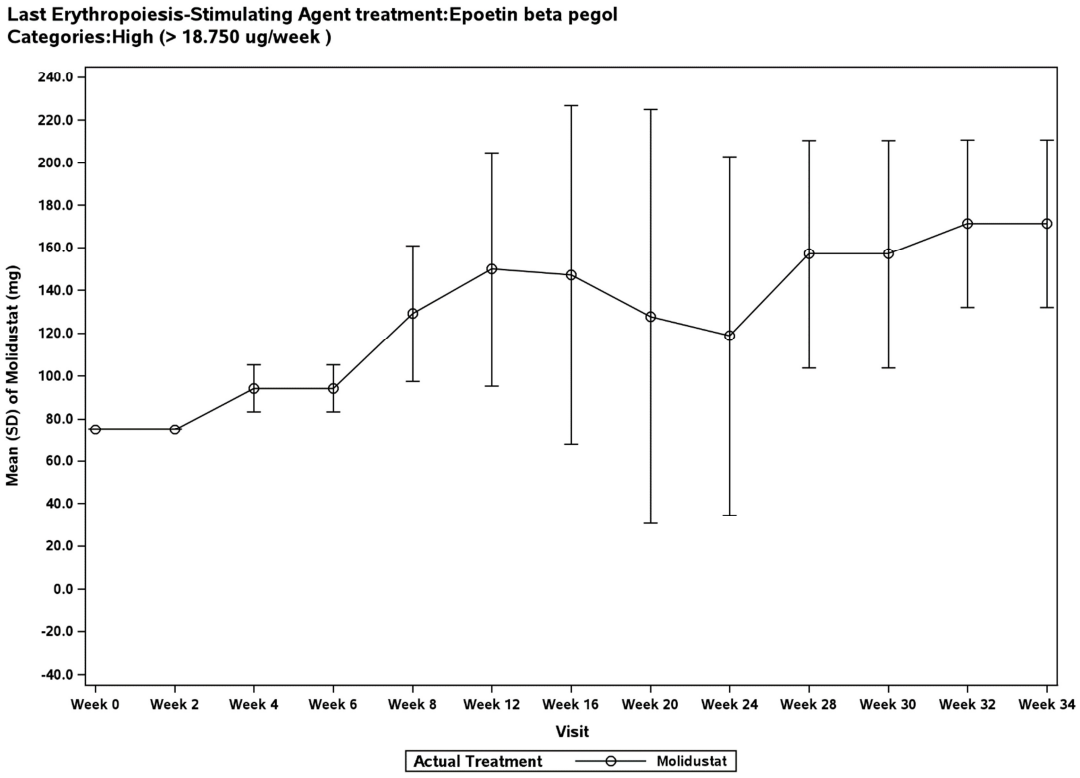


Last Erythropoiesis-Stimulating Agent treatment:Darbepoetin alfa
Categories:Total



Last Erythropoiesis-Stimulating Agent treatment:Epoetin beta pegol
Categories:Low (<= 18.750 ug/week)





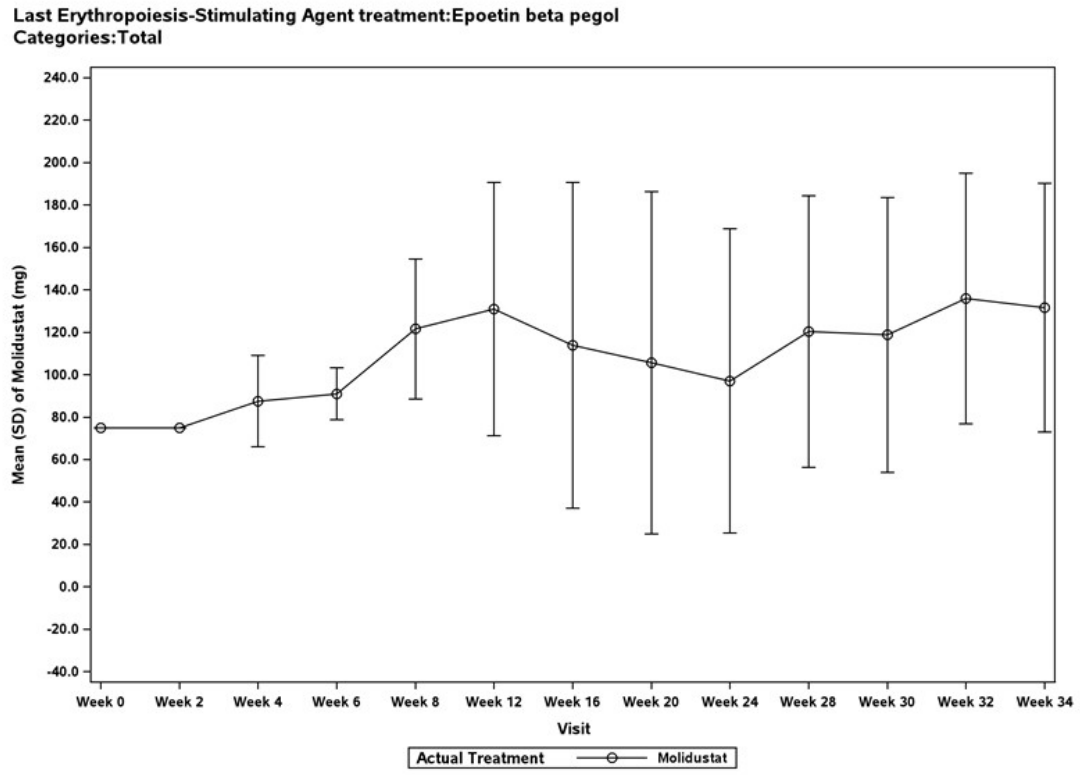


図 2.7.3.6-46　前治療として使用した ESA の種類別のモリデュスタットの各来院での用量（試験 19353、FAS）

表 2.7.3.6-87 前治療として使用した ESA の種類別のモリデュスタットの各来院での用量（試験 19353、FAS）

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Low (<= 30.000 ug/week)

		Value at visit (mg)					
Actual Treatment	Visit	n	Mean	SD	Min	Median	Max
Molidustat (N=17)	Week 0	17	75.00	0.00	75.0	75.00	75.0
	Week 2	17	75.00	0.00	75.0	75.00	75.0
	Week 4	17	82.35	27.62	0.0	100.00	100.0
	Week 6	16	78.13	28.69	0.0	87.50	100.0
	Week 8	16	90.63	56.92	0.0	87.50	150.0
	Week 12	16	104.69	77.58	0.0	100.00	200.0
	Week 16	16	92.97	82.15	0.0	62.50	200.0
	Week 20	16	82.03	76.24	0.0	75.00	200.0
	Week 24	15	82.00	67.37	0.0	100.00	200.0
	Week 28	15	80.00	69.56	0.0	50.00	200.0
	Week 30	15	82.50	72.55	0.0	50.00	200.0
	Week 32	15	90.83	64.17	0.0	75.00	200.0
	Week 34	15	90.83	64.17	0.0	75.00	200.0

Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: High (> 30.000 ug/week)

		Value at visit (mg)					
Actual Treatment	Visit	n	Mean	SD	Min	Median	Max
Molidustat (N=5)	Week 0	5	75.00	0.00	75.0	75.00	75.0
	Week 2	5	75.00	0.00	75.0	75.00	75.0
	Week 4	5	90.00	22.36	50.0	100.00	100.0
	Week 6	4	87.50	25.00	50.0	100.00	100.0
	Week 8	4	125.00	50.00	50.0	150.00	150.0
	Week 12	4	150.00	70.71	50.0	175.00	200.0
	Week 16	4	150.00	70.71	50.0	175.00	200.0
	Week 20	4	106.25	87.50	0.0	112.50	200.0
	Week 24	4	112.50	85.39	0.0	125.00	200.0
	Week 28	4	118.75	55.43	75.0	100.00	200.0
	Week 30	4	100.00	81.65	0.0	100.00	200.0
	Week 32	4	68.75	94.37	0.0	37.50	200.0
	Week 34	4	81.25	85.09	0.0	62.50	200.0

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

		Value at visit (mg)					
Actual Treatment	Visit	n	Mean	SD	Min	Median	Max
Molidustat (N=22)	Week 0	22	75.00	0.00	75.0	75.00	75.0
	Week 2	22	75.00	0.00	75.0	75.00	75.0
	Week 4	22	84.09	26.22	0.0	100.00	100.0
	Week 6	20	80.00	27.63	0.0	100.00	100.0
	Week 8	20	97.50	56.14	0.0	100.00	150.0
	Week 12	20	113.75	76.72	0.0	100.00	200.0
	Week 16	20	104.38	81.64	0.0	112.50	200.0
	Week 20	20	86.88	76.79	0.0	75.00	200.0
	Week 24	19	88.42	70.06	0.0	100.00	200.0
	Week 28	19	88.16	67.38	0.0	100.00	200.0
	Week 30	19	86.18	72.52	0.0	100.00	200.0
	Week 32	19	86.18	69.08	0.0	75.00	200.0
	Week 34	19	88.82	66.52	0.0	75.00	200.0

Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Low (<= 18.750 ug/week)

		Value at visit (mg)					
Actual Treatment	Visit	n	Mean	SD	Min	Median	Max
Molidustat (N=14)	Week 0	14	75.00	0.00	75.0	75.00	75.0
	Week 2	14	75.00	0.00	75.0	75.00	75.0
	Week 4	13	80.77	27.30	0.0	75.00	100.0
	Week 6	12	87.50	13.06	75.0	87.50	100.0
	Week 8	10	112.50	33.85	75.0	100.00	150.0
	Week 12	10	110.00	60.32	0.0	100.00	200.0
	Week 16	9	80.56	60.95	0.0	100.00	200.0
	Week 20	9	83.33	57.28	0.0	100.00	200.0
	Week 24	9	77.78	56.52	0.0	75.00	200.0
	Week 28	9	91.67	58.63	0.0	100.00	200.0
	Week 30	9	88.89	58.78	0.0	75.00	200.0
	Week 32	9	108.33	58.63	50.0	75.00	200.0
	Week 34	8	96.88	50.78	50.0	75.00	200.0

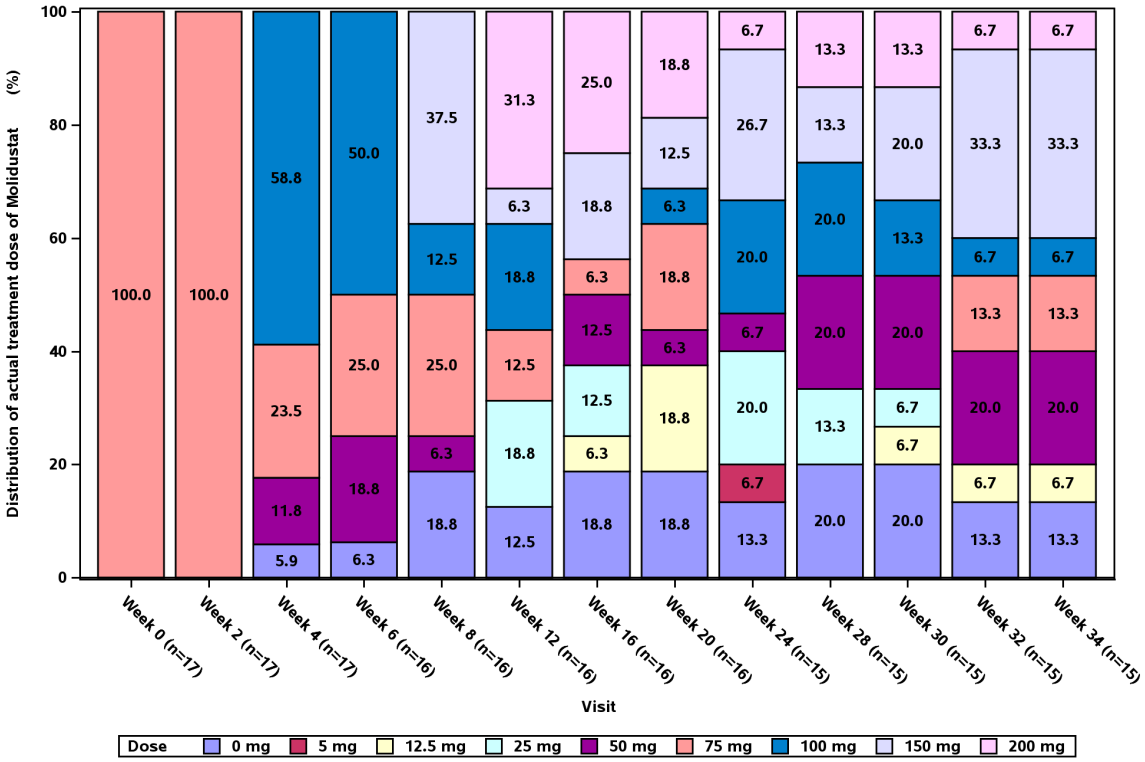
Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: High (> 18.750 ug/week)

		Value at visit (mg)					
Actual Treatment	Visit	n	Mean	SD	Min	Median	Max
Molidustat (N=13)	Week 0	13	75.00	0.00	75.0	75.00	75.0
	Week 2	13	75.00	0.00	75.0	75.00	75.0
	Week 4	13	94.23	10.96	75.0	100.00	100.0
	Week 6	13	94.23	10.96	75.0	100.00	100.0
	Week 8	12	129.17	31.68	75.0	150.00	150.0
	Week 12	11	150.00	54.77	50.0	150.00	200.0
	Week 16	9	147.22	79.49	0.0	200.00	200.0
	Week 20	9	127.78	97.18	0.0	200.00	200.0
	Week 24	8	118.75	84.25	0.0	125.00	200.0
	Week 28	7	157.14	53.45	100.0	200.00	200.0
	Week 30	7	157.14	53.45	100.0	200.00	200.0
	Week 32	7	171.43	39.34	100.0	200.00	200.0
	Week 34	7	171.43	39.34	100.0	200.00	200.0

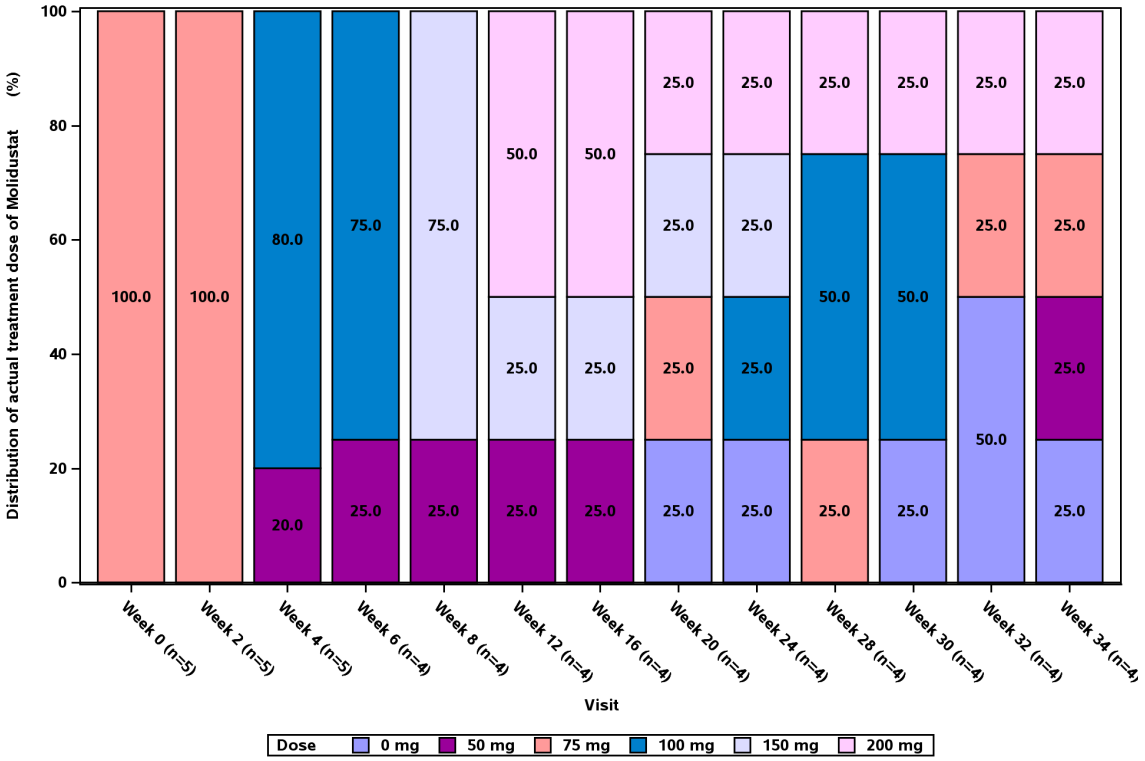
Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Total

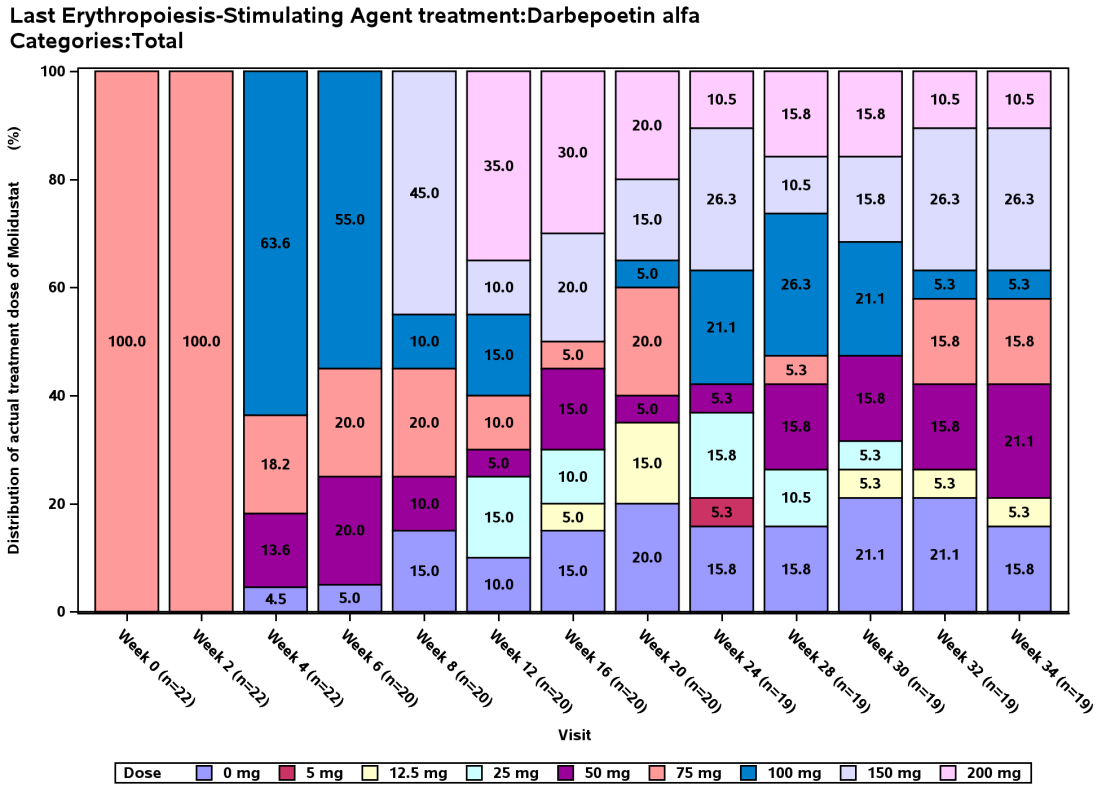
		Value at visit (mg)					
Actual Treatment	Visit	n	Mean	SD	Min	Median	Max
Molidustat (N=27)	Week 0	27	75.00	0.00	75.0	75.00	75.0
	Week 2	27	75.00	0.00	75.0	75.00	75.0
	Week 4	26	87.50	21.51	0.0	100.00	100.0
	Week 6	25	91.00	12.25	75.0	100.00	100.0
	Week 8	22	121.59	33.00	75.0	150.00	150.0
	Week 12	21	130.95	59.64	0.0	100.00	200.0
	Week 16	18	113.89	76.80	0.0	100.00	200.0
	Week 20	18	105.56	80.69	0.0	100.00	200.0
	Week 24	17	97.06	71.74	0.0	100.00	200.0
	Week 28	16	120.31	64.04	0.0	100.00	200.0
	Week 30	16	118.75	64.87	0.0	100.00	200.0
	Week 32	16	135.94	59.14	50.0	150.00	200.0
	Week 34	15	131.67	58.60	50.0	150.00	200.0

Last Erythropoiesis-Stimulating Agent treatment:Darbepoetin alfa
Categories:Low (<= 30.000 ug/week)

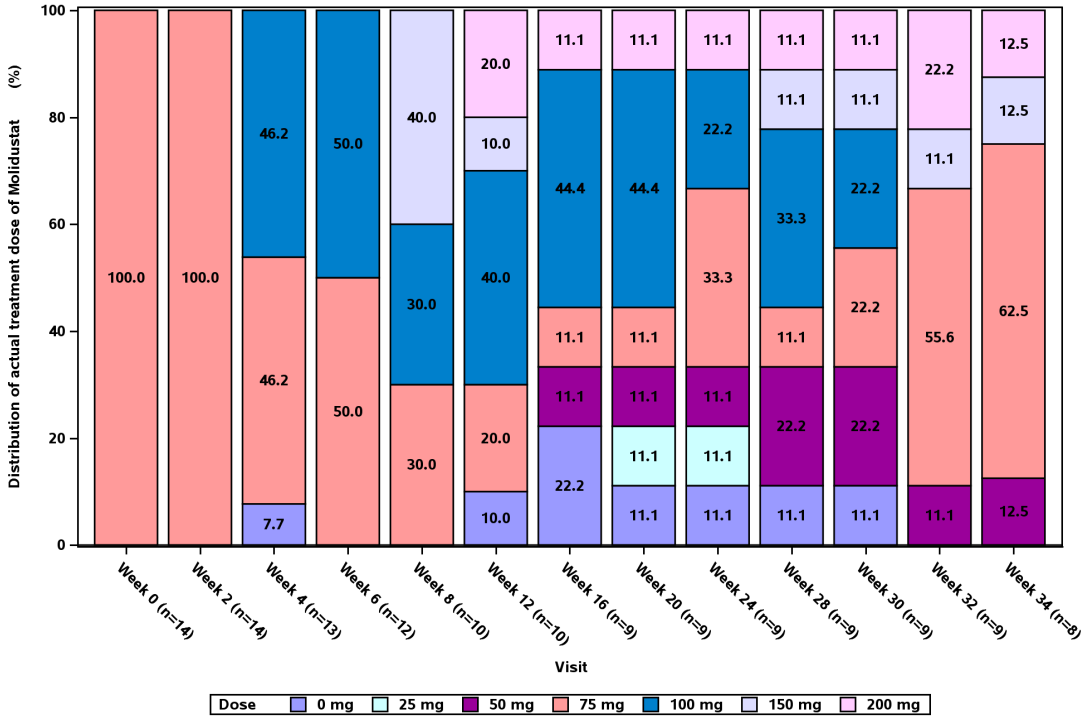


Last Erythropoiesis-Stimulating Agent treatment:Darbepoetin alfa
Categories:High (> 30.000 ug/week)

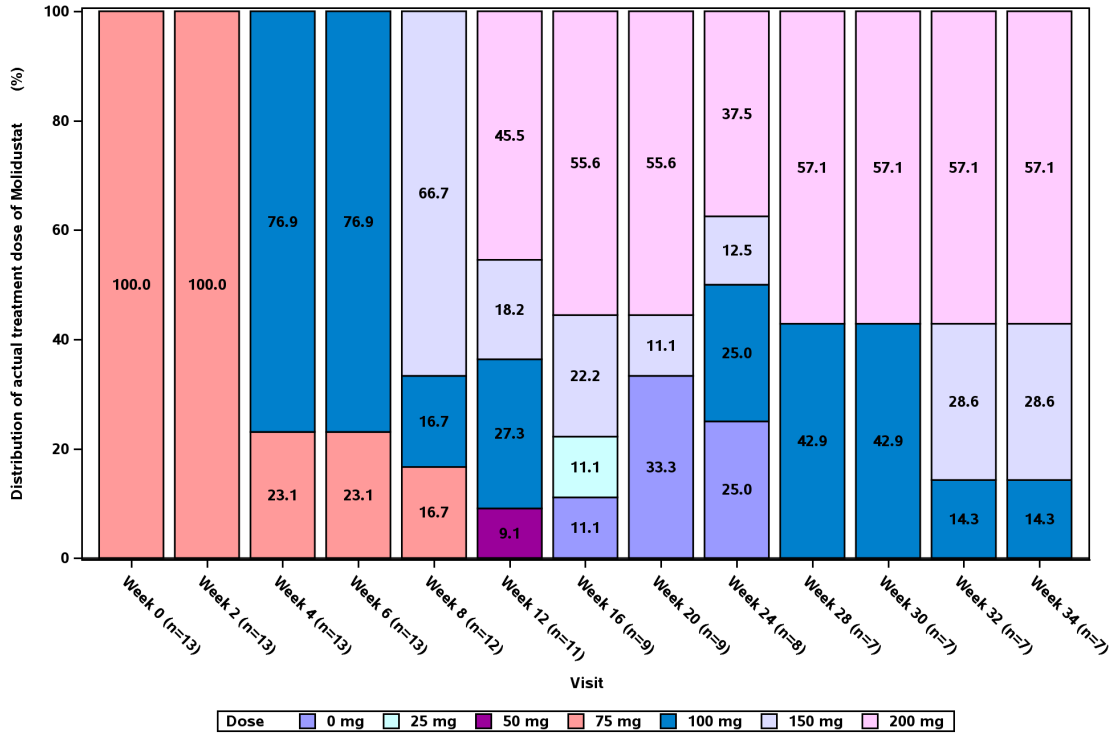



Last Erythropoiesis-Stimulating Agent treatment:Darbepoetin alfa
Categories:Total
Distribution of actual treatment dose of Molidustat (%)
Visit
Week 0 (n=22)
Week 2 (n=22)
Week 4 (n=22)
Week 6 (n=20)
Week 8 (n=20)
Week 12 (n=20)
Week 16 (n=20)
Week 20 (n=20)
Week 24 (n=19)
Week 28 (n=19)
Week 30 (n=19)
Week 32 (n=19)
Week 34 (n=19)
Dose
0 mg
5 mg
12.5 mg
25 mg
50 mg
75 mg
100 mg
150 mg
200 mg

Last Erythropoiesis-Stimulating Agent treatment:Epoetin beta pegol
Categories:Low (<= 18.750 ug/week)



Last Erythropoiesis-Stimulating Agent treatment:Epoetin beta pegol
Categories:High (> 18.750 ug/week)



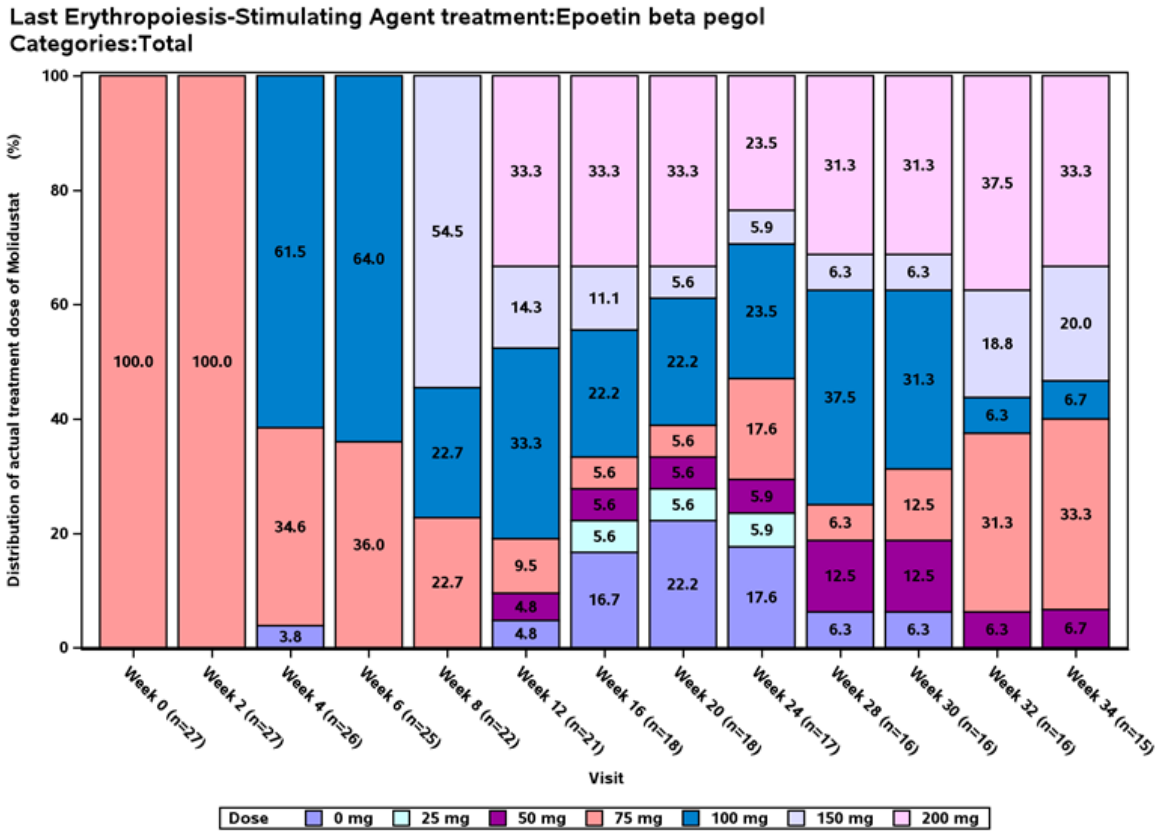


図 2.7.3.6-47　前治療として使用した ESA の種類別のモリデュスタットの各来院での用量（試験 19353、FAS）

表 2.7.3.6-88　前治療として使用したESAの種類別のモリデュスタットの各来院での用量（試験19353、FAS）

Actual Treatment: Molidustat
Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Low (<= 30.000 ug/week)

Visit	n	0 mg	5 mg	12.5 mg	25 mg	50 mg	75 mg	100 mg	150 mg	200 mg
Week 0	17	0	0	0	0	0	17 (100.0%)	0	0	0
Week 2	17	0	0	0	0	0	17 (100.0%)	0	0	0
Week 4	17	1 (5.9%)	0	0	0	2 (11.8%)	4 (23.5%)	10 (58.8%)	0	0
Week 6	16	1 (6.3%)	0	0	0	3 (18.8%)	4 (25.0%)	8 (50.0%)	0	0
Week 8	16	3 (18.8%)	0	0	0	1 (6.3%)	4 (25.0%)	2 (12.5%)	6 (37.5%)	0
Week 12	16	2 (12.5%)	0	0	3 (18.8%)	0	2 (12.5%)	3 (18.8%)	1 (6.3%)	5 (31.3%)
Week 16	16	3 (18.8%)	0	1 (6.3%)	2 (12.5%)	2 (12.5%)	1 (6.3%)	0	3 (18.8%)	4 (25.0%)
Week 20	16	3 (18.8%)	0	3 (18.8%)	0	1 (6.3%)	3 (18.8%)	1 (6.3%)	2 (12.5%)	3 (18.8%)
Week 24	15	2 (13.3%)	1 (6.7%)	0	3 (20.0%)	1 (6.7%)	0	3 (20.0%)	4 (26.7%)	1 (6.7%)
Week 28	15	3 (20.0%)	0	0	2 (13.3%)	3 (20.0%)	0	3 (20.0%)	2 (13.3%)	2 (13.3%)
Week 30	15	3 (20.0%)	0	1 (6.7%)	1 (6.7%)	3 (20.0%)	0	2 (13.3%)	3 (20.0%)	2 (13.3%)
Week 32	15	2 (13.3%)	0	1 (6.7%)	0	3 (20.0%)	2 (13.3%)	1 (6.7%)	5 (33.3%)	1 (6.7%)
Week 34	15	2 (13.3%)	0	1 (6.7%)	0	3 (20.0%)	2 (13.3%)	1 (6.7%)	5 (33.3%)	1 (6.7%)

Actual Treatment: Molidustat
Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: High (> 30.000 ug/week)

Visit	n	0 mg	5 mg	12.5 mg	25 mg	50 mg	75 mg	100 mg	150 mg	200 mg
Week 0	5	0	0	0	0	0	5 (100.0%)	0	0	0
Week 2	5	0	0	0	0	0	5 (100.0%)	0	0	0
Week 4	5	0	0	0	0	1 (20.0%)	0	4 (80.0%)	0	0
Week 6	4	0	0	0	0	1 (25.0%)	0	3 (75.0%)	0	0
Week 8	4	0	0	0	0	1 (25.0%)	0	0	3 (75.0%)	0
Week 12	4	0	0	0	0	1 (25.0%)	0	0	1 (25.0%)	2 (50.0%)
Week 16	4	0	0	0	0	1 (25.0%)	0	0	1 (25.0%)	2 (50.0%)
Week 20	4	1 (25.0%)	0	0	0	0	1 (25.0%)	0	1 (25.0%)	1 (25.0%)
Week 24	4	1 (25.0%)	0	0	0	0	0	1 (25.0%)	1 (25.0%)	1 (25.0%)
Week 28	4	0	0	0	0	0	1 (25.0%)	2 (50.0%)	0	1 (25.0%)
Week 30	4	1 (25.0%)	0	0	0	0	0	2 (50.0%)	0	1 (25.0%)
Week 32	4	2 (50.0%)	0	0	0	0	1 (25.0%)	0	0	1 (25.0%)
Week 34	4	1 (25.0%)	0	0	0	1 (25.0%)	1 (25.0%)	0	0	1 (25.0%)

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

Visit	n	0 mg	5 mg	12.5 mg	25 mg	50 mg	75 mg	100 mg	150 mg	200 mg
Week 0	22	0	0	0	0	0	22 (100.0%)	0	0	0
Week 2	22	0	0	0	0	0	22 (100.0%)	0	0	0
Week 4	22	1 (4.5%)	0	0	0	3 (13.6%)	4 (18.2%)	14 (63.6%)	0	0
Week 6	20	1 (5.0%)	0	0	0	4 (20.0%)	4 (20.0%)	11 (55.0%)	0	0
Week 8	20	3 (15.0%)	0	0	0	2 (10.0%)	4 (20.0%)	2 (10.0%)	9 (45.0%)	0
Week 12	20	2 (10.0%)	0	0	3 (15.0%)	1 (5.0%)	2 (10.0%)	3 (15.0%)	2 (10.0%)	7 (35.0%)
Week 16	20	3 (15.0%)	0	1 (5.0%)	2 (10.0%)	3 (15.0%)	1 (5.0%)	0	4 (20.0%)	6 (30.0%)
Week 20	20	4 (20.0%)	0	3 (15.0%)	0	1 (5.0%)	4 (20.0%)	1 (5.0%)	3 (15.0%)	4 (20.0%)
Week 24	19	3 (15.8%)	1 (5.3%)	0	3 (15.8%)	1 (5.3%)	0	4 (21.1%)	5 (26.3%)	2 (10.5%)
Week 28	19	3 (15.8%)	0	0	2 (10.5%)	3 (15.8%)	1 (5.3%)	5 (26.3%)	2 (10.5%)	3 (15.8%)
Week 30	19	4 (21.1%)	0	1 (5.3%)	1 (5.3%)	3 (15.8%)	0	4 (21.1%)	3 (15.8%)	3 (15.8%)
Week 32	19	4 (21.1%)	0	1 (5.3%)	0	3 (15.8%)	3 (15.8%)	1 (5.3%)	5 (26.3%)	2 (10.5%)
Week 34	19	3 (15.8%)	0	1 (5.3%)	0	4 (21.1%)	3 (15.8%)	1 (5.3%)	5 (26.3%)	2 (10.5%)

Actual Treatment: Molidustat
Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: Low (<= 18.750 ug/week)

Visit	n	0 mg	25 mg	50 mg	75 mg	100 mg	150 mg	200 mg
Week 0	14	0	0	0	14 (100.0%)	0	0	0
Week 2	14	0	0	0	14 (100.0%)	0	0	0
Week 4	13	1 (7.7%)	0	0	6 (46.2%)	6 (46.2%)	0	0
Week 6	12	0	0	0	6 (50.0%)	6 (50.0%)	0	0
Week 8	10	0	0	0	3 (30.0%)	3 (30.0%)	4 (40.0%)	0
Week 12	10	1 (10.0%)	0	0	2 (20.0%)	4 (40.0%)	1 (10.0%)	2 (20.0%)
Week 16	9	2 (22.2%)	0	1 (11.1%)	1 (11.1%)	4 (44.4%)	0	1 (11.1%)
Week 20	9	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	4 (44.4%)	0	1 (11.1%)
Week 24	9	1 (11.1%)	1 (11.1%)	1 (11.1%)	3 (33.3%)	2 (22.2%)	0	1 (11.1%)
Week 28	9	1 (11.1%)	0	2 (22.2%)	1 (11.1%)	3 (33.3%)	1 (11.1%)	1 (11.1%)
Week 30	9	1 (11.1%)	0	2 (22.2%)	2 (22.2%)	2 (22.2%)	1 (11.1%)	1 (11.1%)
Week 32	9	0	0	1 (11.1%)	5 (55.6%)	0	1 (11.1%)	2 (22.2%)
Week 34	8	0	0	1 (12.5%)	5 (62.5%)	0	1 (12.5%)	1 (12.5%)

Actual Treatment: Molidustat
Last Erythropoiesis-Stimulating Agent treatment: Epoetin beta pegol
Categories: High (> 18.750 ug/week)

Visit	n	0 mg	25 mg	50 mg	75 mg	100 mg	150 mg	200 mg
Week 0	13	0	0	0	13 (100.0%)	0	0	0
Week 2	13	0	0	0	13 (100.0%)	0	0	0
Week 4	13	0	0	0	3 (23.1%)	10 (76.9%)	0	0
Week 6	13	0	0	0	3 (23.1%)	10 (76.9%)	0	0
Week 8	12	0	0	0	2 (16.7%)	2 (16.7%)	8 (66.7%)	0
Week 12	11	0	0	1 (9.1%)	0	3 (27.3%)	2 (18.2%)	5 (45.5%)
Week 16	9	1 (11.1%)	1 (11.1%)	0	0	0	2 (22.2%)	5 (55.6%)
Week 20	9	3 (33.3%)	0	0	0	0	1 (11.1%)	5 (55.6%)
Week 24	8	2 (25.0%)	0	0	0	2 (25.0%)	1 (12.5%)	3 (37.5%)
Week 28	7	0	0	0	0	3 (42.9%)	0	4 (57.1%)
Week 30	7	0	0	0	0	3 (42.9%)	0	4 (57.1%)
Week 32	7	0	0	0	0	1 (14.3%)	2 (28.6%)	4 (57.1%)
Week 34	7	0	0	0	0	1 (14.3%)	2 (28.6%)	4 (57.1%)

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

Visit	n	0 mg	25 mg	50 mg	75 mg	100 mg	150 mg	200 mg
Week 0	27	0	0	0	27 (100.0%)	0	0	0
Week 2	27	0	0	0	27 (100.0%)	0	0	0
Week 4	26	1 (3.8%)	0	0	9 (34.6%)	16 (61.5%)	0	0
Week 6	25	0	0	0	9 (36.0%)	16 (64.0%)	0	0
Week 8	22	0	0	0	5 (22.7%)	5 (22.7%)	12 (54.5%)	0
Week 12	21	1 (4.8%)	0	1 (4.8%)	2 (9.5%)	7 (33.3%)	3 (14.3%)	7 (33.3%)
Week 16	18	3 (16.7%)	1 (5.6%)	1 (5.6%)	1 (5.6%)	4 (22.2%)	2 (11.1%)	6 (33.3%)
Week 20	18	4 (22.2%)	1 (5.6%)	1 (5.6%)	1 (5.6%)	4 (22.2%)	1 (5.6%)	6 (33.3%)
Week 24	17	3 (17.6%)	1 (5.9%)	1 (5.9%)	3 (17.6%)	4 (23.5%)	1 (5.9%)	4 (23.5%)
Week 28	16	1 (6.3%)	0	2 (12.5%)	1 (6.3%)	6 (37.5%)	1 (6.3%)	5 (31.3%)
Week 30	16	1 (6.3%)	0	2 (12.5%)	2 (12.5%)	5 (31.3%)	1 (6.3%)	5 (31.3%)
Week 32	16	0	0	1 (6.3%)	5 (31.3%)	1 (6.3%)	3 (18.8%)	6 (37.5%)
Week 34	15	0	0	1 (6.7%)	5 (33.3%)	1 (6.7%)	3 (20.0%)	5 (33.3%)

表 2.7.3.6-89 部分集団解析：人口統計学的特性（試験 19351、FAS）

Rescue Treatment untill evaluation period: NO

	Molidustat N=20 (100%)
Sex	
Male	13 (65.0%)
Female	7 (35.0%)
Race	
ASIAN	20 (100.0%)
Ethnicity	
NOT HISPANIC OR LATINO	20 (100.0%)
Age(years)	
n	20
Mean	65.2
SD	10.9
Min	45
Median	66.5
Max	86
Age(years) group 01	
< 65	8 (40.0%)
>= 65	12 (60.0%)
Age(years) group 02	
< 75	16 (80.0%)
>= 75	4 (20.0%)
Baseline Weight (kg)	
n	20
Mean	59.83
SD	11.51
Min	40.6
Median	59.15
Max	79.4
Baseline Weight (kg) group	
< 55	5 (25.0%)
>= 55	15 (75.0%)
Baseline Height (cm)	
n	20
Mean	162.76
SD	10.82
Min	140.8
Median	161.80
Max	180.0
Baseline Body Mass Index (kg/m2)	
n	20
Mean	22.53
SD	3.51
Min	17.4
Median	22.10
Max	29.2
Smoking History	
NEVER	11 (55.0%)
FORMER	8 (40.0%)
CURRENT	1 (5.0%)
Alcohol consumption	
ABSTINENT	16 (80.0%)
LIGHT	3 (15.0%)
MODERATE	1 (5.0%)

Rescue Treatment untill evaluation period: YES

	Molidustat N=5 (100%)
Sex	
Male	2 (40.0%)
Female	3 (60.0%)
Race	
ASIAN	5 (100.0%)
Ethnicity	
NOT HISPANIC OR LATINO	5 (100.0%)
Age(years)	
n	5
Mean	68.6
SD	7.7
Min	59
Median	71.0
Max	76
Age(years) group 01	
< 65	2 (40.0%)
>= 65	3 (60.0%)
Age(years) group 02	
< 75	3 (60.0%)
>= 75	2 (40.0%)
Baseline Weight (kg)	
n	5
Mean	57.28
SD	13.06
Min	43.3
Median	55.00
Max	70.8
Baseline Weight (kg) group	
< 55	2 (40.0%)
>= 55	3 (60.0%)
Baseline Height (cm)	
n	5
Mean	157.62
SD	10.70
Min	148.1
Median	153.30
Max	170.0
Baseline Body Mass Index (kg/m2)	
n	5
Mean	22.80
SD	2.84
Min	19.6
Median	24.50
Max	25.1
Smoking History	
NEVER	3 (60.0%)
FORMER	2 (40.0%)
CURRENT	0
Alcohol consumption	
ABSTINENT	1 (20.0%)
LIGHT	4 (80.0%)
MODERATE	0

表 2.7.3.6-90 部分集団解析：ベースラインの特性（試験 19351、FAS）

Rescue Treatment untill evaluation period: NO

	Molidustat N=20 (100%)
Baseline central Hb level (g/dL)	
n	20
Mean	9.24
SD	0.55
Min	7.8
Median	9.43
Max	9.8
Baseline central Hb level (g/dL) group	
< 9.0	4 (20.0%)
>= 9.0	16 (80.0%)
Baseline Local Hemoglobin (g/dL)	
n	19
Mean	9.22
SD	0.61
Min	7.9
Median	9.33
Max	10.0
Central mean screening Hb level (g/dL)	
n	20
Mean	9.45
SD	0.50
Min	8.1
Median	9.63
Max	10.0
Central Hb level (g/dL) at Week0	
n	20
Mean	8.83
SD	0.70
Min	7.3
Median	9.05
Max	10.0
First central Hb level (g/dL) after last ESA (within 1 week)	
n	14
Mean	10.78
SD	1.01
Min	9.2
Median	10.65
Max	13.2
Rate of rise in central Hb level (g/dL/week) during the screening period	
n	20
Mean	-0.364
SD	0.198
Min	-0.85
Median	-0.317
Max	-0.05
Prior Thromboembolic Event	
NO	17 (85.0%)
YES	3 (15.0%)
History of ESA treatment after initiation of dialysis	
NO	0
YES	20 (100.0%)
Use of ESAs within 8 weeks prior to the start of the study drug	
NO	7 (35.0%)
YES	13 (65.0%)

Rescue Treatment untill evaluation period: NO

	Molidustat N=20 (100%)
Last ESA Dose prior to administration(IU/week)	
n	20
Mean	2554.2
SD	1810.5
Min	0
Median	2000.0
Max	8000
Last ESA Dose prior to administration(IU/week/kg)	
n	20
Mean	43.9
SD	29.8
Min	0
Median	36.0
Max	111
Duration of washout (week)	
n	20
Mean	7.0
SD	2.7
Min	3
Median	6.9
Max	12
Main cause of CKD	
IgA nephropathy	1 (5.0%)
chronic glomerulonephritis	4 (20.0%)
diabetic nephropathy	9 (45.0%)
nephrosclerosis	2 (10.0%)
polycystic kidney disease	2 (10.0%)
unknown	2 (10.0%)
Main cause of CKD group	
diabetic nephropathy	9 (45.0%)
other	9 (45.0%)
unknown	2 (10.0%)
Duration of CKD (years)	
n	20
Mean	10.871
SD	8.056
Min	1.32
Median	9.196
Max	32.19
Duration of dialysis (years)	
n	20
Mean	5.987
SD	5.234
Min	0.41
Median	3.969
Max	19.87
Duration of dialysis (years) group	
< 5	13 (65.0%)
>= 5	7 (35.0%)
Duration of dialysis (years) group by median safety populations of the study	
< median (3.9)	9 (45.0%)
>= median (3.9)	11 (55.0%)

Rescue Treatment untill evaluation period: NO

	Molidustat N=20 (100%)
Baseline total iron binding capacity (umol/L)	
n	20
Mean	37.5
SD	4.5
Min	28
Median	38.2
Max	45
Baseline unsaturated iron binding capacity (umol/L)	
n	20
Mean	22.3
SD	5.3
Min	11
Median	22.1
Max	31
Baseline Transferrin Saturation (%)	
n	20
Mean	40.8
SD	11.4
Min	23
Median	40.6
Max	67
Baseline Transferrin Saturation (%) group	
>= 20	20 (100.0%)
Baseline Hepcidin (ng/mL)	
n	20
Mean	110.1
SD	42.7
Min	45
Median	100.2
Max	224
Baseline total iron (ug/dL)	
n	20
Mean	84.8
SD	23.6
Min	42
Median	83.0
Max	125
Baseline ferritin (ng/mL)	
n	20
Mean	195.7
SD	79.8
Min	71
Median	185.0
Max	376
Baseline Ferritin (ng/mL) group	
< 100	2 (10.0%)
>= 100	18 (90.0%)
Baseline Vitamin B12 (pmol/L)	
n	20
Mean	433.5
SD	270.3
Min	142
Median	331.6
Max	1011

Rescue Treatment untill evaluation period: NO

	Molidustat N=20 (100%)
Baseline folate (nmol/L)	
n	20
Mean	187.3
SD	745.7
Min	9
Median	15.1
Max	3354

Mean of last two HB in screening period
Duration of washout (week): 12 (week) was imputed for the subjects who did not receive ESA.
Median: based on safety analysis set.
ESA treatment : Epoetin alfa (including Epoetin kappa) , Epoetin beta, Darbepoetin alfa and Epoetin beta pegol.

Rescue Treatment untill evaluation period: YES

	Molidustat N=5 (100%)
Baseline central Hb level (g/dL)	
n	5
Mean	9.11
SD	0.59
Min	8.1
Median	9.37
Max	9.4
Baseline central Hb level (g/dL) group	
< 9.0	1 (20.0%)
>= 9.0	4 (80.0%)
Baseline Local Hemoglobin (g/dL)	
n	5
Mean	9.09
SD	0.60
Min	8.1
Median	9.27
Max	9.5
Central mean screening Hb level (g/dL)	
n	5
Mean	9.34
SD	0.65
Min	8.3
Median	9.40
Max	9.9
Central Hb level (g/dL) at Week0	
n	5
Mean	8.66
SD	0.62
Min	7.7
Median	8.60
Max	9.3
First central Hb level (g/dL) after last ESA (within 1 week)	
n	4
Mean	10.68
SD	1.27
Min	8.9
Median	11.00
Max	11.8
Rate of rise in central Hb level (g/dL/week) during the screening period	
n	5
Mean	-0.374
SD	0.184
Min	-0.61
Median	-0.400
Max	-0.10
Prior Thromboembolic Event	
NO	5 (100.0%)
YES	0
History of ESA treatment after initiation of dialysis	
NO	1 (20.0%)
YES	4 (80.0%)
Use of ESAs within 8 weeks prior to the start of the study drug	
NO	2 (40.0%)
YES	3 (60.0%)

Rescue Treatment untill evaluation period: YES

	Molidustat N=5 (100%)
Last ESA Dose prior to administration(IU/week)	
n	5
Mean	4550.0
SD	3063.9
Min	1000
Median	3750.0
Max	9000
Last ESA Dose prior to administration(IU/week/kg)	
n	5
Mean	77.8
SD	52.9
Min	23
Median	64.5
Max	164
Duration of washout (week)	
n	5
Mean	6.2
SD	2.5
Min	3
Median	6.7
Max	9
Main cause of CKD	
IgA nephropathy	1 (20.0%)
chronic glomerulonephritis	3 (60.0%)
diabetic nephropathy	0
nephrosclerosis	0
polycystic kidney disease	0
unknown	1 (20.0%)
Main cause of CKD group	
diabetic nephropathy	0
other	4 (80.0%)
unknown	1 (20.0%)
Duration of CKD (years)	
n	5
Mean	16.395
SD	14.257
Min	3.20
Median	15.477
Max	36.92
Duration of dialysis (years)	
n	5
Mean	12.854
SD	15.521
Min	0.07
Median	3.047
Max	35.17
Duration of dialysis (years) group	
< 5	3 (60.0%)
>= 5	2 (40.0%)
Duration of dialysis (years) group by median safety populations of the study	
< median (3.9)	3 (60.0%)
>= median (3.9)	2 (40.0%)

Rescue Treatment untill evaluation period: YES

	Molidustat N=5 (100%)
Baseline total iron binding capacity (umol/L)	
n	5
Mean	36.6
SD	4.3
Min	32
Median	35.6
Max	43
Baseline unsaturated iron binding capacity (umol/L)	
n	5
Mean	15.9
SD	6.3
Min	5
Median	19.0
Max	20
Baseline Transferrin Saturation (%)	
n	5
Mean	54.8
SD	19.7
Min	40
Median	48.1
Max	89
Baseline Transferrin Saturation (%) group	
>= 20	5 (100.0%)
Baseline Hepcidin (ng/mL)	
n	5
Mean	146.8
SD	18.5
Min	115
Median	153.2
Max	159
Baseline total iron (ug/dL)	
n	5
Mean	115.6
SD	57.4
Min	72
Median	93.0
Max	216
Baseline ferritin (ng/mL)	
n	5
Mean	251.7
SD	162.7
Min	95
Median	207.0
Max	524
Baseline Ferritin (ng/mL) group	
< 100	1 (20.0%)
>= 100	4 (80.0%)
Baseline Vitamin B12 (pmol/L)	
n	5
Mean	420.5
SD	253.6
Min	185
Median	312.8
Max	725

Rescue Treatment untill evaluation period: YES

	Molidustat N=5 (100%)
Baseline folate (nmol/L)	
n	5
Mean	155.0
SD	297.2
Min	14
Median	23.6
Max	687

Mean of last two HB in screening period
Duration of washout (week): 12 (week) was imputed for the subjects who did not receive ESA.
Median: based on safety analysis set.
ESA treatment : Epoetin alfa (including Epoetin kappa) , Epoetin beta, Darbepoetin alfa and Epoetin beta pegol.

表 2.7.3.6-91 部分集団解析：人口統計学的特性（試験 19352、FAS）

Rescue Treatment: NO

	Molidustat N=136 (100%)	Darbepoetin alfa N=75 (100%)	Total N=211 (100%)
Sex			
Male	87 (64.0%)	48 (64.0%)	135 (64.0%)
Female	49 (36.0%)	27 (36.0%)	76 (36.0%)
Race			
ASIAN	136 (100.0%)	75 (100.0%)	211 (100.0%)
Ethnicity			
NOT HISPANIC OR LATINO	136 (100.0%)	75 (100.0%)	211 (100.0%)
Age(years)			
n	136	75	211
Mean	66.0	64.6	65.5
SD	10.5	10.6	10.5
Min	32	36	32
Median	66.0	65.0	66.0
Max	86	84	86
Age(years) group 01			
< 65	52 (38.2%)	34 (45.3%)	86 (40.8%)
>= 65	84 (61.8%)	41 (54.7%)	125 (59.2%)
Age(years) group 02			
< 75	104 (76.5%)	62 (82.7%)	166 (78.7%)
>= 75	32 (23.5%)	13 (17.3%)	45 (21.3%)
Baseline Weight (kg)			
n	136	75	211
Mean	58.61	58.69	58.64
SD	10.39	12.45	11.13
Min	41.3	40.5	40.5
Median	57.90	56.00	57.70
Max	92.1	127.5	127.5
Baseline Weight (kg) group			
< 55	52 (38.2%)	35 (46.7%)	87 (41.2%)
>= 55	84 (61.8%)	40 (53.3%)	124 (58.8%)
Baseline Height (cm)			
n	136	75	211
Mean	161.30	161.73	161.45
SD	8.59	8.49	8.54
Min	141.0	141.8	141.0
Median	161.95	162.10	162.10
Max	183.3	182.6	183.3
Baseline Body Mass Index (kg/m2)			
n	135	75	210
Mean	22.50	22.28	22.42
SD	3.21	3.13	3.18
Min	15.9	17.2	15.9
Median	22.00	22.10	22.00
Max	33.7	38.2	38.2
Baseline Body Mass Index group (kg/m2)			
missing	1 (0.7%)	0	1 (0.5%)
< 25	111 (81.6%)	64 (85.3%)	175 (82.9%)
>= 25	24 (17.6%)	11 (14.7%)	35 (16.6%)

Rescue Treatment: NO

	Molidustat N=136 (100%)	Darbepoetin alfa N=75 (100%)	Total N=211 (100%)
Smoking History			
NEVER	63 (46.3%)	33 (44.0%)	96 (45.5%)
FORMER	56 (41.2%)	30 (40.0%)	86 (40.8%)
CURRENT	17 (12.5%)	12 (16.0%)	29 (13.7%)
Alcohol consumption			
ABSTINENT	72 (52.9%)	41 (54.7%)	113 (53.6%)
LIGHT	59 (43.4%)	33 (44.0%)	92 (43.6%)
MODERATE	4 (2.9%)	1 (1.3%)	5 (2.4%)
HEAVY	1 (0.7%)	0	1 (0.5%)

Rescue Treatment: YES

	Molidustat N=17 (100%)	Darbepoetin alfa N=1 (100%)	Total N=18 (100%)
Sex			
Male	4 (23.5%)	1 (100.0%)	5 (27.8%)
Female	13 (76.5%)	0	13 (72.2%)
Race			
ASIAN	17 (100.0%)	1 (100.0%)	18 (100.0%)
Ethnicity			
NOT HISPANIC OR LATINO	17 (100.0%)	1 (100.0%)	18 (100.0%)
Age(years)			
n	17	1	18
Mean	67.5	76.0	68.0
SD	9.5	.	9.5
Min	46	76	46
Median	69.0	76.0	69.5
Max	80	76	80
Age(years) group 01			
< 65	6 (35.3%)	0	6 (33.3%)
>= 65	11 (64.7%)	1 (100.0%)	12 (66.7%)
Age(years) group 02			
< 75	13 (76.5%)	0	13 (72.2%)
>= 75	4 (23.5%)	1 (100.0%)	5 (27.8%)
Baseline Weight (kg)			
n	17	1	18
Mean	57.79	53.50	57.55
SD	9.32	.	9.10
Min	43.3	53.5	43.3
Median	56.20	53.50	56.10
Max	78.0	53.5	78.0
Baseline Weight (kg) group			
< 55	7 (41.2%)	1 (100.0%)	8 (44.4%)
>= 55	10 (58.8%)	0	10 (55.6%)
Baseline Height (cm)			
n	17	1	18
Mean	157.39	163.50	157.73
SD	6.64	.	6.60
Min	145.8	163.5	145.8
Median	156.10	163.50	156.15
Max	170.4	163.5	170.4
Baseline Body Mass Index (kg/m2)			
n	17	1	18
Mean	23.45	20.00	23.26
SD	4.21	.	4.17
Min	16.5	20.0	16.5
Median	22.70	20.00	22.60
Max	32.1	20.0	32.1
Baseline Body Mass Index group (kg/m2)			
missing	0	0	0
< 25	12 (70.6%)	1 (100.0%)	13 (72.2%)
>= 25	5 (29.4%)	0	5 (27.8%)
Smoking History			
NEVER	12 (70.6%)	0	12 (66.7%)
FORMER	4 (23.5%)	0	4 (22.2%)
CURRENT	1 (5.9%)	1 (100.0%)	2 (11.1%)

Rescue Treatment: YES

	Molidustat N=17 (100%)	Darbepoetin alfa N=1 (100%)	Total N=18 (100%)
Alcohol consumption			
ABSTINENT	14 (82.4%)	1 (100.0%)	15 (83.3%)
LIGHT	3 (17.6%)	0	3 (16.7%)
MODERATE	0	0	0
HEAVY	0	0	0

表 2.7.3.6-92 部分集団解析：ベースラインの特性（試験 19352、FAS）

Rescue Treatment: NO

	Molidustat N=136 (100%)	Darbepoetin alfa N=75 (100%)	Total N=211 (100%)
Baseline central Hb level (g/dL)			
n	136	75	211
Mean	10.79	10.85	10.81
SD	0.64	0.66	0.64
Min	9.5	9.5	9.5
Median	10.77	10.90	10.80
Max	11.9	12.0	12.0
Baseline central Hb level (g/dL) group			
< 11.0	85 (62.5%)	43 (57.3%)	128 (60.7%)
>= 11.0	51 (37.5%)	32 (42.7%)	83 (39.3%)
Baseline local Hb level (g/dL)			
n	136	75	211
Mean	10.85	10.86	10.85
SD	0.66	0.64	0.65
Min	9.4	9.7	9.4
Median	10.77	10.87	10.80
Max	12.3	12.4	12.4
Baseline local Hb level (g/dL) group			
< 11.0	84 (61.8%)	39 (52.0%)	123 (58.3%)
>= 11.0	52 (38.2%)	36 (48.0%)	88 (41.7%)
Central mean screening Hb level (g/dL)			
n	136	75	211
Mean	10.81	10.88	10.84
SD	0.66	0.65	0.65
Min	9.6	9.5	9.5
Median	10.75	10.85	10.75
Max	12.0	12.0	12.0
Previous ESA dose group			
LOW	135 (99.3%)	75 (100.0%)	210 (99.5%)
HIGH	1 (0.7%)	0	1 (0.5%)
Previous ESA dose group recorded in IxRS			
LOW	135 (99.3%)	75 (100.0%)	210 (99.5%)
HIGH	1 (0.7%)	0	1 (0.5%)
Prior Thromboembolic Event			
NO	126 (92.6%)	68 (90.7%)	194 (91.9%)
YES	10 (7.4%)	7 (9.3%)	17 (8.1%)
Prior Thromboembolic Event in IxRS			
NO	126 (92.6%)	69 (92.0%)	195 (92.4%)
YES	10 (7.4%)	6 (8.0%)	16 (7.6%)

Rescue Treatment: NO

	Molidustat N=136 (100%)	Darbepoetin alfa N=75 (100%)	Total N=211 (100%)
Main cause of CKD			
Gouty nephropathy	0	1 (1.3%)	1 (0.5%)
IgA nephropathy	0	3 (4.0%)	3 (1.4%)
Membranous nephropathy	0	1 (1.3%)	1 (0.5%)
Nephorotic syndrome	1 (0.7%)	0	1 (0.5%)
Nephrotic syndrome	1 (0.7%)	1 (1.3%)	2 (0.9%)
Reflux nephropathy	0	1 (1.3%)	1 (0.5%)
Renal failure due to Nephrectomy	1 (0.7%)	0	1 (0.5%)
Renal failure due to nephrectomy	1 (0.7%)	0	1 (0.5%)
Renal sclerosis	0	0	0
Vesicoureteral reflux	0	1 (1.3%)	1 (0.5%)
chronic glomerulonephritis	45 (33.1%)	25 (33.3%)	70 (33.2%)
chronic pyelonephritis	1 (0.7%)	0	1 (0.5%)
diabetic nephropathy	40 (29.4%)	23 (30.7%)	63 (29.9%)
nephrosclerosis	22 (16.2%)	15 (20.0%)	37 (17.5%)
nephrotic syndrome	1 (0.7%)	0	1 (0.5%)
polycystic kidney disease	13 (9.6%)	2 (2.7%)	15 (7.1%)
rapidly progressive glomerulonephritis	0	1 (1.3%)	1 (0.5%)
unknown	10 (7.4%)	1 (1.3%)	11 (5.2%)
Main cause of CKD group			
diabetic nephropathy	40 (29.4%)	23 (30.7%)	63 (29.9%)
other	86 (63.2%)	51 (68.0%)	137 (64.9%)
unknown	10 (7.4%)	1 (1.3%)	11 (5.2%)
Duration of CKD (years)			
n	136	75	211
Mean	12.330	10.832	11.798
SD	9.535	8.900	9.321
Min	1.03	1.10	1.03
Median	9.932	7.830	8.884
Max	39.75	36.79	39.75
Medical History of Atrial fibrillation			
NO	129 (94.9%)	72 (96.0%)	201 (95.3%)
YES	7 (5.1%)	3 (4.0%)	10 (4.7%)
Baseline Pulse Rate (BEATS/MIN)			
n	136	75	211
Mean	72.5	71.8	72.3
SD	10.9	11.4	11.0
Min	48	48	48
Median	72.0	71.0	72.0
Max	106	107	107
Baseline Systolic Blood Pressure (mmHg)			
n	136	75	211
Mean	149.4	148.3	149.0
SD	17.6	18.5	17.9
Min	105	107	105
Median	149.0	148.0	149.0
Max	197	191	197
Baseline Diastolic Blood Pressure (mmHg)			
n	136	75	211
Mean	78.9	80.0	79.3
SD	11.4	10.0	10.9
Min	49	53	49
Median	78.0	80.0	79.0
Max	112	100	112

Rescue Treatment: NO

	Molidustat N=136 (100%)	Darbepoetin alfa N=75 (100%)	Total N=211 (100%)
Duration of dialysis (years)			
n	136	75	211
Mean	8.091	7.783	7.982
SD	7.601	7.465	7.536
Min	0.31	0.24	0.24
Median	5.596	5.752	5.695
Max	34.39	32.59	34.39
Baseline total iron binding capacity (umol/L)			
n	136	75	211
Mean	42.5	42.1	42.4
SD	6.6	7.0	6.8
Min	22	28	22
Median	41.8	41.6	41.7
Max	63	67	67
Baseline unsaturated iron binding capacity (umol/L)			
n	136	75	211
Mean	30.4	29.5	30.1
SD	6.6	6.5	6.6
Min	10	14	10
Median	30.8	29.0	30.4
Max	49	48	49
Baseline Transferrin Saturation (%)			
n	136	75	211
Mean	28.7	29.9	29.2
SD	9.6	10.0	9.7
Min	11	14	11
Median	26.7	29.1	27.3
Max	57	59	59
Baseline Transferrin Saturation (%) group			
< 20	19 (14.0%)	11 (14.7%)	30 (14.2%)
>= 20	117 (86.0%)	64 (85.3%)	181 (85.8%)
Baseline Hepcidin (ng/mL)			
n	136	75	211
Mean	45.4	49.3	46.8
SD	38.3	41.7	39.5
Min	1	3	1
Median	32.0	39.9	33.9
Max	169	230	230
Baseline total iron (ug/dL)			
n	136	75	211
Mean	67.4	70.3	68.5
SD	22.1	27.2	24.0
Min	21	27	21
Median	64.5	64.0	64.0
Max	145	171	171
Baseline ferritin (ng/mL)			
n	136	75	211
Mean	111.3	116.2	113.0
SD	96.9	119.7	105.3
Min	11	8	8
Median	75.9	82.2	76.7
Max	469	803	803
Baseline Ferritin (ng/mL) group			
< 100	82 (60.3%)	43 (57.3%)	125 (59.2%)
>= 100	54 (39.7%)	32 (42.7%)	86 (40.8%)

Rescue Treatment: NO

	Molidustat N=136 (100%)	Darbepoetin alfa N=75 (100%)	Total N=211 (100%)
Baseline Vitamin B12 (pmol/L)			
n	128	72	200
Mean	333.7	318.4	328.2
SD	180.2	164.8	174.6
Min	134	142	134
Median	288.1	264.9	279.3
Max	1070	989	1070
Baseline folate (nmol/L)			
n	136	75	211
Mean	200.3	168.2	188.9
SD	596.0	600.2	596.2
Min	9	9	9
Median	15.2	15.0	15.2
Max	3218	3603	3603
Baseline Potassium (mmol/L) in Serum			
n	136	75	211
Mean	4.67	4.70	4.68
SD	0.66	0.58	0.64
Min	2.9	3.5	2.9
Median	4.70	4.70	4.70
Max	6.4	6.2	6.4
Baseline Hemoglobin A1C (%) in Blood - Calculated			
n	136	75	211
Mean	5.72	5.66	5.70
SD	0.85	0.65	0.79
Min	4.4	4.7	4.4
Median	5.50	5.50	5.50
Max	9.7	8.0	9.7
Baseline LDL Cholesterol (mg/dL) in Serum			
n	136	75	211
Mean	91.9	87.4	90.3
SD	26.3	27.0	26.6
Min	31	35	31
Median	90.5	86.0	88.0
Max	200	143	200
Baseline HDL Cholesterol (mg/dL) in Serum			
n	136	75	211
Mean	49.6	51.3	50.2
SD	16.4	17.9	16.9
Min	21	19	19
Median	47.5	46.0	47.0
Max	101	117	117
Baseline Triglycerides (mg/dL) in Serum			
n	136	75	211
Mean	115.2	108.3	112.7
SD	83.6	61.6	76.4
Min	30	31	30
Median	94.0	91.0	94.0
Max	551	362	551
Baseline C Reactive Protein (mg/dL) in Serum			
n	136	75	211
Mean	0.272	0.219	0.253
SD	0.658	0.633	0.648
Min	0.02	0.02	0.02
Median	0.080	0.080	0.080
Max	5.69	5.38	5.69

Rescue Treatment: NO

	Molidustat N=136 (100%)	Darbepoetin alfa N=75 (100%)	Total N=211 (100%)
Baseline Erythropoietin (IU/L) in Serum			
n	136	75	211
Mean	11.135	12.263	11.536
SD	8.048	13.538	10.320
Min	2.30	2.22	2.22
Median	8.565	7.840	8.470
Max	50.56	94.17	94.17

Median: based on safety analysis set.
ESA treatment: Epoetin alfa (including Epoetin kappa) , Epoetin beta, Darbepoetin alfa and Epoetin beta pegol.
Central mean screening Hb level: Mean of all Hb in screening period

Rescue Treatment: YES

	Molidustat N=17 (100%)	Darbepoetin alfa N=1 (100%)	Total N=18 (100%)
Baseline central Hb level (g/dL)			
n	17	1	18
Mean	10.55	10.40	10.55
SD	0.62	.	0.60
Min	9.6	10.4	9.6
Median	10.60	10.40	10.50
Max	11.8	10.4	11.8
Baseline central Hb level (g/dL) group			
< 11.0	12 (70.6%)	1 (100.0%)	13 (72.2%)
>= 11.0	5 (29.4%)	0	5 (27.8%)
Baseline local Hb level (g/dL)			
n	17	1	18
Mean	10.58	10.27	10.56
SD	0.62	.	0.61
Min	9.4	10.3	9.4
Median	10.60	10.27	10.55
Max	12.0	10.3	12.0
Baseline local Hb level (g/dL) group			
< 11.0	14 (82.4%)	1 (100.0%)	15 (83.3%)
>= 11.0	3 (17.6%)	0	3 (16.7%)
Central mean screening Hb level (g/dL)			
n	17	1	18
Mean	10.64	10.40	10.63
SD	0.62	.	0.60
Min	9.6	10.4	9.6
Median	10.70	10.40	10.55
Max	12.0	10.4	12.0
Previous ESA dose group			
LOW	17 (100.0%)	1 (100.0%)	18 (100.0%)
HIGH	0	0	0
Previous ESA dose group recorded in IxRS			
LOW	17 (100.0%)	1 (100.0%)	18 (100.0%)
HIGH	0	0	0
Prior Thromboembolic Event			
NO	15 (88.2%)	1 (100.0%)	16 (88.9%)
YES	2 (11.8%)	0	2 (11.1%)
Prior Thromboembolic Event in IxRS			
NO	15 (88.2%)	1 (100.0%)	16 (88.9%)
YES	2 (11.8%)	0	2 (11.1%)

Rescue Treatment: YES

	Molidustat N=17 (100%)	Darbepoetin alfa N=1 (100%)	Total N=18 (100%)
Main cause of CKD			
Gouty nephropathy	0	0	0
IgA nephropathy	1 (5.9%)	0	1 (5.6%)
Membranous nephropathy	0	0	0
Nephorotic syndrome	0	0	0
Nephrotic syndrome	0	0	0
Reflux nephropathy	0	0	0
Renal failure due to Nephrectomy	0	0	0
Renal failure due to nephrectomy	0	0	0
Renal sclerosis	1 (5.9%)	0	1 (5.6%)
Vesicoureteral reflux	0	0	0
chronic glomerulonephritis	2 (11.8%)	0	2 (11.1%)
chronic pyelonephritis	0	0	0
diabetic nephropathy	8 (47.1%)	1 (100.0%)	9 (50.0%)
nephrosclerosis	3 (17.6%)	0	3 (16.7%)
nephrotic syndrome	0	0	0
polycystic kidney disease	0	0	0
rapidly progressive glomerulonephritis	0	0	0
unknown	2 (11.8%)	0	2 (11.1%)
Main cause of CKD group			
diabetic nephropathy	8 (47.1%)	1 (100.0%)	9 (50.0%)
other	7 (41.2%)	0	7 (38.9%)
unknown	2 (11.8%)	0	2 (11.1%)
Duration of CKD (years)			
n	17	1	18
Mean	9.960	11.589	10.051
SD	8.070	.	7.839
Min	2.54	11.59	2.54
Median	5.903	11.589	6.110
Max	25.89	11.59	25.89
Medical History of Atrial fibrillation			
NO	17 (100.0%)	1 (100.0%)	18 (100.0%)
YES	0	0	0
Baseline Pulse Rate (BEATS/MIN)			
n	17	1	18
Mean	69.6	80.0	70.2
SD	10.1	.	10.1
Min	58	80	58
Median	67.0	80.0	67.0
Max	88	80	88
Baseline Systolic Blood Pressure (mmHg)			
n	17	1	18
Mean	153.1	134.0	152.1
SD	13.4	.	13.8
Min	133	134	133
Median	150.0	134.0	150.0
Max	177	134	177
Baseline Diastolic Blood Pressure (mmHg)			
n	17	1	18
Mean	76.7	57.0	75.6
SD	9.9	.	10.7
Min	57	57	57
Median	76.0	57.0	75.5
Max	95	57	95

Rescue Treatment: YES

	Molidustat N=17 (100%)	Darbepoetin alfa N=1 (100%)	Total N=18 (100%)
Duration of dialysis (years)			
n	17	1	18
Mean	7.858	1.914	7.528
SD	7.710	.	7.610
Min	1.51	1.91	1.51
Median	4.038	1.914	3.992
Max	26.00	1.91	26.00
Baseline total iron binding capacity (umol/L)			
n	17	1	18
Mean	39.2	41.0	39.3
SD	5.7	.	5.5
Min	30	41	30
Median	37.8	41.0	39.0
Max	51	41	51
Baseline unsaturated iron binding capacity (umol/L)			
n	17	1	18
Mean	26.7	31.2	27.0
SD	8.9	.	8.7
Min	3	31	3
Median	27.6	31.2	28.1
Max	39	31	39
Baseline Transferrin Saturation (%)			
n	17	1	18
Mean	32.6	24.0	32.1
SD	19.3	.	18.9
Min	15	24	15
Median	25.8	24.0	25.6
Max	90	24	90
Baseline Transferrin Saturation (%) group			
< 20	2 (11.8%)	0	2 (11.1%)
>= 20	15 (88.2%)	1 (100.0%)	16 (88.9%)
Baseline Hepcidin (ng/mL)			
n	17	1	18
Mean	68.8	23.3	66.3
SD	48.6	.	48.4
Min	14	23	14
Median	53.2	23.3	50.2
Max	196	23	196
Baseline total iron (ug/dL)			
n	17	1	18
Mean	69.4	55.0	68.6
SD	37.1	.	36.1
Min	38	55	38
Median	62.0	55.0	58.5
Max	170	55	170
Baseline ferritin (ng/mL)			
n	17	1	18
Mean	177.9	57.1	171.2
SD	208.2	.	204.0
Min	39	57	39
Median	101.0	57.1	93.0
Max	741	57	741
Baseline Ferritin (ng/mL) group			
< 100	8 (47.1%)	1 (100.0%)	9 (50.0%)
>= 100	9 (52.9%)	0	9 (50.0%)

Rescue Treatment: YES

	Molidustat N=17 (100%)	Darbepoetin alfa N=1 (100%)	Total N=18 (100%)
Baseline Vitamin B12 (pmol/L)			
n	14	1	15
Mean	363.3	789.4	391.7
SD	221.9	.	240.4
Min	102	789	102
Median	326.1	789.4	353.4
Max	944	789	944
Baseline folate (nmol/L)			
n	17	1	18
Mean	420.4	13.6	397.8
SD	884.0	.	862.9
Min	9	14	9
Median	14.5	13.6	14.4
Max	2719	14	2719
Baseline Potassium (mmol/L) in Serum			
n	17	1	18
Mean	4.64	4.60	4.63
SD	0.74	.	0.72
Min	3.2	4.6	3.2
Median	4.80	4.60	4.70
Max	5.8	4.6	5.8
Baseline Hemoglobin A1C (%) in Blood - Calculated			
n	17	1	18
Mean	5.69	5.90	5.70
SD	1.10	.	1.06
Min	4.8	5.9	4.8
Median	5.30	5.90	5.40
Max	8.7	5.9	8.7
Baseline LDL Cholesterol (mg/dL) in Serum			
n	17	1	18
Mean	83.8	84.0	83.8
SD	27.3	.	26.5
Min	35	84	35
Median	83.0	84.0	83.5
Max	129	84	129
Baseline HDL Cholesterol (mg/dL) in Serum			
n	17	1	18
Mean	52.7	44.0	52.2
SD	12.7	.	12.5
Min	34	44	34
Median	51.0	44.0	51.0
Max	74	44	74
Baseline Triglycerides (mg/dL) in Serum			
n	17	1	18
Mean	87.9	76.0	87.3
SD	58.0	.	56.3
Min	36	76	36
Median	63.0	76.0	69.5
Max	251	76	251
Baseline C Reactive Protein (mg/dL) in Serum			
n	17	1	18
Mean	0.132	0.030	0.127
SD	0.162	.	0.159
Min	0.02	0.03	0.02
Median	0.080	0.030	0.080
Max	0.70	0.03	0.70

Rescue Treatment: YES

	Molidustat N=17 (100%)	Darbepoetin alfa N=1 (100%)	Total N=18 (100%)
Baseline Erythropoietin (IU/L) in Serum			
n	17	1	18
Mean	13.322	6.710	12.954
SD	16.782	.	16.355
Min	1.67	6.71	1.67
Median	6.960	6.710	6.835
Max	66.04	6.71	66.04

Median: based on safety analysis set.
ESA treatment: Epoetin alfa (including Epoetin kappa) , Epoetin beta, Darbepoetin alfa and Epoetin beta pegol.
Central mean screening Hb level: Mean of all Hb in screening period

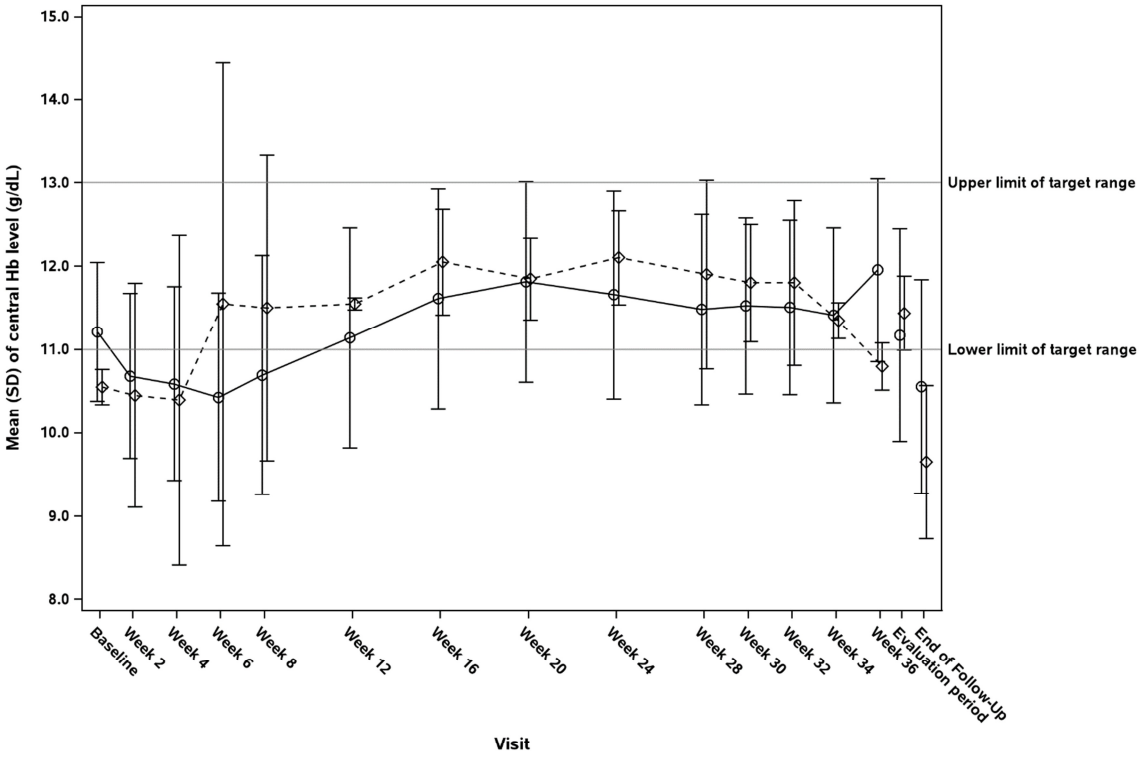
表 2.7.3.6-93　緊急治療の有無別治験薬割付前の ESA の週当たりの平均投与量及び体重換算した週当たりの平均投与量（試験 19352、SAF）

Rescue Treatment: NO

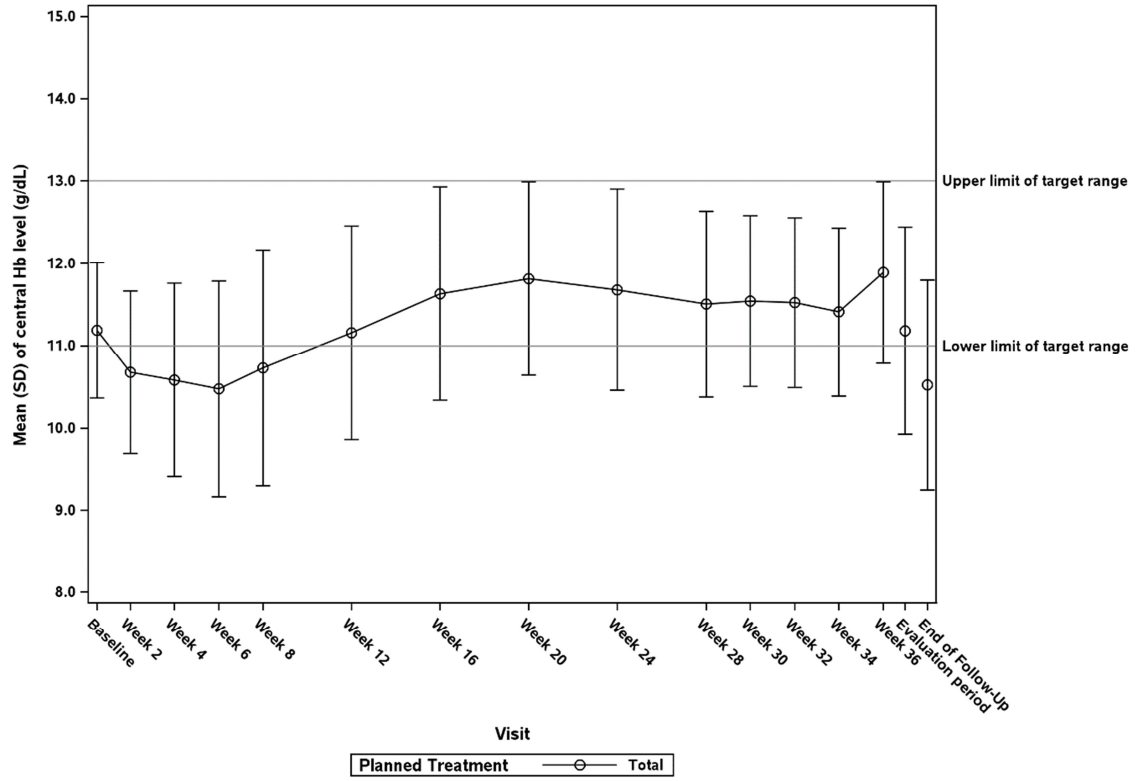
		Molidustat (N=136)	Darbepoetin alfa (N=75)	Total (N=211)
Last ESA Dose prior to administration(IU/week)	n	136	75	211
	Mean	3297.8	3230.0	3273.7
	SD	2273.9	2027.9	2185.0
	Min	625	625	625
	Median	2500.0	2500.0	2500.0
	Max	12000	9000	12000
Last ESA Dose prior to administration(IU/week/kg)	n	136	75	211
	Mean	56.9	56.6	56.8
	SD	38.3	37.1	37.8
	Min	10	11	10
	Median	43.2	47.0	45.5
	Max	198	198	198

Rescue Treatment: YES

		Molidustat (N=17)	Darbepoetin alfa (N=1)	Total (N=18)
Last ESA Dose prior to administration(IU/week)	n	17	1	18
	Mean	4323.5	9000.0	4583.3
	SD	2690.8	.	2833.6
	Min	1500	9000	1500
	Median	4000.0	9000.0	4000.0
	Max	9000	9000	9000
Last ESA Dose prior to administration(IU/week/kg)	n	17	1	18
	Mean	78.4	168.2	83.4
	SD	52.4	.	55.1
	Min	26	168	26
	Median	70.2	168.2	70.8
	Max	174	168	174



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



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 2.7.3.6-48　Hb 値（平均値±SD）の推移（試験 19353、FAS）

表 2.7.3.6-94 各来院時の Hb 値及びベースラインからの変化量（試験 19353、FAS）

		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)	Screening -2	49	11.26	0.98	9.8	11.20	13.1						
	Screening -1	49	11.30	0.88	9.7	11.30	13.1						
	Week 0	49	11.07	0.88	9.3	11.00	12.6						
	Baseline	49	11.21	0.83	9.8	11.10	12.7						
	Week 2	49	10.68	0.99	8.5	10.80	12.6	49	-0.53	0.67	-1.8	-0.50	1.0
	Week 4	49	10.59	1.16	8.5	10.50	13.4	49	-0.62	0.98	-2.3	-0.87	1.3
	Week 6	48	10.43	1.25	7.9	10.55	12.9	48	-0.76	1.08	-2.9	-0.63	1.3
	Week 8	45	10.70	1.43	7.3	10.50	13.7	45	-0.54	1.35	-3.5	-0.37	2.3
	Week 12	42	11.14	1.32	8.6	11.40	15.0	42	-0.13	1.38	-2.9	-0.32	3.6
	Week 16	41	11.61	1.32	8.2	11.90	13.7	41	0.37	1.44	-3.3	0.63	2.6
	Week 20	38	11.81	1.20	8.3	11.80	13.8	38	0.58	1.31	-3.2	0.60	3.8
	Week 24	38	11.66	1.25	8.2	11.60	14.1	38	0.42	1.70	-3.3	0.50	3.8
	Week 28	35	11.48	1.14	8.6	11.50	14.2	35	0.24	1.52	-3.2	0.57	3.4
	Week 30	35	11.53	1.06	8.3	11.50	13.5	35	0.28	1.50	-3.2	0.47	2.8
	Week 32	35	11.51	1.05	8.6	11.50	13.3	35	0.26	1.46	-2.9	0.63	3.3
	Week 34	35	11.41	1.05	8.0	11.40	13.0	35	0.17	1.38	-3.5	-0.03	3.0
	Week 36	34	11.95	1.10	9.8	11.80	14.7	34	0.71	1.36	-1.5	0.45	3.8
	End of Follow-Up	48	10.56	1.28	7.6	10.55	13.9	48	-0.65	1.31	-3.5	-0.95	3.6
Untreated with ESAs in Molidustat group (N=2)	Screening -2	2	10.90	0.71	10.4	10.90	11.4						
	Screening -1	2	10.55	0.21	10.4	10.55	10.7						
	Week 0	2	10.20	0.14	10.1	10.20	10.3						
	Baseline	2	10.55	0.21	10.4	10.55	10.7						
	Week 2	2	10.45	1.34	9.5	10.45	11.4	2	-0.10	1.56	-1.2	-0.10	1.0
	Week 4	2	10.40	1.98	9.0	10.40	11.8	2	-0.15	2.19	-1.7	-0.15	1.4
	Week 6	2	11.55	2.90	9.5	11.55	13.6	2	1.00	3.11	-1.2	1.00	3.2
	Week 8	2	11.50	1.84	10.2	11.50	12.8	2	0.95	2.05	-0.5	0.95	2.4
	Week 12	2	11.55	0.07	11.5	11.55	11.6	2	1.00	0.28	0.8	1.00	1.2
	Week 16	2	12.05	0.64	11.6	12.05	12.5	2	1.50	0.42	1.2	1.50	1.8
	Week 20	2	11.85	0.49	11.5	11.85	12.2	2	1.30	0.71	0.8	1.30	1.8
	Week 24	2	12.10	0.57	11.7	12.10	12.5	2	1.55	0.35	1.3	1.55	1.8
	Week 28	2	11.90	1.13	11.1	11.90	12.7	2	1.35	0.92	0.7	1.35	2.0
	Week 30	2	11.80	0.71	11.3	11.80	12.3	2	1.25	0.49	0.9	1.25	1.6
	Week 32	2	11.80	0.99	11.1	11.80	12.5	2	1.25	0.78	0.7	1.25	1.8
	Week 34	2	11.35	0.21	11.2	11.35	11.5	2	0.80	0.42	0.5	0.80	1.1
	Week 36	2	10.80	0.28	10.6	10.80	11.0	2	0.25	0.07	0.2	0.25	0.3
	End of Follow-Up	2	9.65	0.92	9.0	9.65	10.3	2	-0.90	1.13	-1.7	-0.90	-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)	Screening -2	51	11.25	0.97	9.8	11.20	13.1						
	Screening -1	51	11.27	0.88	9.7	11.20	13.1						
	Week 0	51	11.04	0.88	9.3	11.00	12.6						
	Baseline	51	11.19	0.82	9.8	11.07	12.7						
	Week 2	51	10.67	0.99	8.5	10.80	12.6	51	-0.51	0.70	-1.8	-0.50	1.0
	Week 4	51	10.58	1.18	8.5	10.50	13.4	51	-0.60	1.01	-2.3	-0.87	1.4
	Week 6	50	10.47	1.31	7.9	10.55	13.6	50	-0.69	1.20	-2.9	-0.63	3.2
	Week 8	47	10.73	1.43	7.3	10.50	13.7	47	-0.48	1.38	-3.5	-0.37	2.4
	Week 12	44	11.16	1.30	8.6	11.40	15.0	44	-0.08	1.37	-2.9	-0.18	3.6
	Week 16	43	11.63	1.29	8.2	11.90	13.7	43	0.42	1.43	-3.3	0.63	2.6
	Week 20	40	11.82	1.18	8.3	11.80	13.8	40	0.61	1.29	-3.2	0.70	3.8
	Week 24	40	11.68	1.22	8.2	11.60	14.1	40	0.48	1.67	-3.3	0.53	3.8
	Week 28	37	11.51	1.13	8.6	11.50	14.2	37	0.30	1.51	-3.2	0.67	3.4
	Week 30	37	11.54	1.04	8.3	11.50	13.5	37	0.33	1.48	-3.2	0.80	2.8
	Week 32	37	11.52	1.03	8.6	11.50	13.3	37	0.32	1.44	-2.9	0.67	3.3
	Week 34	37	11.41	1.02	8.0	11.40	13.0	37	0.20	1.35	-3.5	0.23	3.0
	Week 36	36	11.89	1.10	9.8	11.75	14.7	36	0.69	1.33	-1.5	0.43	3.8
	End of Follow-Up	50	10.52	1.28	7.6	10.50	13.9	50	-0.66	1.29	-3.5	-0.95	3.6

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 2.7.3.6-95 治験薬割当て時の ESA 治療の有無別の 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 19353、FAS）

Visit	Hb Level	Pre-treatment with ESAs in Molidustat group (N=49)	Untreated with ESAs in Molidustat group (N=2)	Total (N=51)
Baseline	n	49	2	51
	Below	23 (46.9%)	2 (100.0%)	25 (49.0%)
	In	26 (53.1%)	0 (0.0%)	26 (51.0%)
	Above	0 (0.0%)	0 (0.0%)	0 (0.0%)
Week 2	n	49	2	51
	Below	28 (57.1%)	1 (50.0%)	29 (56.9%)
	In	21 (42.9%)	1 (50.0%)	22 (43.1%)
	Above	0 (0.0%)	0 (0.0%)	0 (0.0%)
Week 4	n	49	2	51
	Below	30 (61.2%)	1 (50.0%)	31 (60.8%)
	In	18 (36.7%)	1 (50.0%)	19 (37.3%)
	Above	1 (2.0%)	0 (0.0%)	1 (2.0%)
Week 6	n	48	2	50
	Below	31 (64.6%)	1 (50.0%)	32 (64.0%)
	In	17 (35.4%)	0 (0.0%)	17 (34.0%)
	Above	0 (0.0%)	1 (50.0%)	1 (2.0%)
Week 8	n	45	2	47
	Below	25 (55.6%)	1 (50.0%)	26 (55.3%)
	In	17 (37.8%)	1 (50.0%)	18 (38.3%)
	Above	3 (6.7%)	0 (0.0%)	3 (6.4%)
Week 12	n	42	2	44
	Below	18 (42.9%)	0 (0.0%)	18 (40.9%)
	In	21 (50.0%)	2 (100.0%)	23 (52.3%)
	Above	3 (7.1%)	0 (0.0%)	3 (6.8%)
Week 16	n	41	2	43
	Below	12 (29.3%)	0 (0.0%)	12 (27.9%)
	In	22 (53.7%)	2 (100.0%)	24 (55.8%)
	Above	7 (17.1%)	0 (0.0%)	7 (16.3%)
Week 20	n	38	2	40
	Below	7 (18.4%)	0 (0.0%)	7 (17.5%)
	In	25 (65.8%)	2 (100.0%)	27 (67.5%)
	Above	6 (15.8%)	0 (0.0%)	6 (15.0%)
Week 24	n	38	2	40
	Below	7 (18.4%)	0 (0.0%)	7 (17.5%)
	In	25 (65.8%)	2 (100.0%)	27 (67.5%)
	Above	6 (15.8%)	0 (0.0%)	6 (15.0%)
Week 28	n	35	2	37
	Below	10 (28.6%)	0 (0.0%)	10 (27.0%)
	In	22 (62.9%)	2 (100.0%)	24 (64.9%)
	Above	3 (8.6%)	0 (0.0%)	3 (8.1%)
Week 30	n	35	2	37
	Below	9 (25.7%)	0 (0.0%)	9 (24.3%)
	In	24 (68.6%)	2 (100.0%)	26 (70.3%)
	Above	2 (5.7%)	0 (0.0%)	2 (5.4%)
Week 32	n	35	2	37
	Below	9 (25.7%)	0 (0.0%)	9 (24.3%)
	In	22 (62.9%)	2 (100.0%)	24 (64.9%)
	Above	4 (11.4%)	0 (0.0%)	4 (10.8%)
Week 34	n	35	2	37
	Below	9 (25.7%)	0 (0.0%)	9 (24.3%)
	In	24 (68.6%)	2 (100.0%)	26 (70.3%)
	Above	2 (5.7%)	0 (0.0%)	2 (5.4%)

Visit	Hb Level	Pre-treatment with ESAs in Molidustat group (N=49)	Untreated with ESAs in Molidustat group (N=2)	Total (N=51)
Week 36	n	34	2	36
	Below	6 (17.6%)	1 (50.0%)	7 (19.4%)
	In	22 (64.7%)	1 (50.0%)	23 (63.9%)
	Above	6 (17.6%)	0 (0.0%)	6 (16.7%)
Evaluation period	n	49	2	51
	Below	16 (32.7%)	0 (0.0%)	16 (31.4%)
	In	32 (65.3%)	2 (100.0%)	34 (66.7%)
	Above	1 (2.0%)	0 (0.0%)	1 (2.0%)
End of Follow-Up	n	48	2	50
	Below	31 (64.6%)	2 (100.0%)	33 (66.0%)
	In	15 (31.3%)	0 (0.0%)	15 (30.0%)
	Above	2 (4.2%)	0 (0.0%)	2 (4.0%)

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 the last two Hb levels during the screening period and Hb level at Week 0

表 2.7.3.6-96 治験薬投与 4 週目から 8 週目まで Hb 値が目標範囲の下限を 2 回以上連続して下回った被人口統計学的、ベースライン特性及び前治療として使用した ESA（試験 19353、FAS）

	Pre-treatment with ESAs in Molidustat group N=28 (100%)	Untreated with ESAs in Molidustat group N=1 (100%)	Total N=29 (100%)
Sex			
Male	16 (57.1%)	0	16 (55.2%)
Female	12 (42.9%)	1 (100.0%)	13 (44.8%)
Race			
ASIAN	28 (100.0%)	1 (100.0%)	29 (100.0%)
Ethnicity			
NOT HISPANIC OR LATINO	28 (100.0%)	1 (100.0%)	29 (100.0%)
Age(years)			
n	28	1	29
Mean	64.0	76.0	64.4
SD	12.2	.	12.2
Min	34	76	34
Median	67.5	76.0	68.0
Max	85	76	85
Age(years) group 01			
< 65	11 (39.3%)	0	11 (37.9%)
>= 65	17 (60.7%)	1 (100.0%)	18 (62.1%)
Age(years) group 02			
< 75	24 (85.7%)	0	24 (82.8%)
>= 75	4 (14.3%)	1 (100.0%)	5 (17.2%)
Baseline Weight (kg)			
n	28	1	29
Mean	64.08	47.10	63.49
SD	11.69	.	11.90
Min	41.2	47.1	41.2
Median	63.30	47.10	62.00
Max	87.1	47.1	87.1
Baseline Weight (kg) group			
< 55	7 (25.0%)	1 (100.0%)	8 (27.6%)
>= 55	21 (75.0%)	0	21 (72.4%)
Baseline Height (cm)			
n	28	1	29
Mean	160.60	152.20	160.31
SD	8.44	.	8.44
Min	146.8	152.2	146.8
Median	159.25	152.20	159.00
Max	177.2	152.2	177.2
Baseline Body Mass Index (kg/m2)			
n	28	1	29
Mean	24.83	20.30	24.67
SD	4.10	.	4.12
Min	16.8	20.3	16.8
Median	23.80	20.30	23.70
Max	34.0	20.3	34.0
Baseline Body Mass Index group (kg/m2)			
< 25	17 (60.7%)	1 (100.0%)	18 (62.1%)
>= 25	11 (39.3%)	0	11 (37.9%)
Smoking History			
NEVER	16 (57.1%)	1 (100.0%)	17 (58.6%)
FORMER	11 (39.3%)	0	11 (37.9%)
CURRENT	1 (3.6%)	0	1 (3.4%)
Alcohol consumption			
ABSTINENT	14 (50.0%)	1 (100.0%)	15 (51.7%)

	Pre-treatment with ESAs in Molidustat group N=28 (100%)	Untreated with ESAs in Molidustat group N=1 (100%)	Total N=29 (100%)
LIGHT	14 (50.0%)	0	14 (48.3%)
Baseline central Hb level (g/dL)			
n	28	1	29
Mean	10.87	10.70	10.86
SD	0.76	.	0.75
Min	9.8	10.7	9.8
Median*	10.65	10.70	10.67
Max	12.7	10.7	12.7
Baseline central Hb level (g/dL) group			
< 11.0	20 (71.4%)	1 (100.0%)	21 (72.4%)
>= 11.0	8 (28.6%)	0	8 (27.6%)
Baseline local Hb level (g/dL)			
n	28	1	29
Mean	10.88	10.87	10.88
SD	0.74	.	0.73
Min	9.9	10.9	9.9
Median*	10.75	10.87	10.80
Max	12.6	10.9	12.6
Baseline local Hb level (g/dL) group			
< 11.0	18 (64.3%)	1 (100.0%)	19 (65.5%)
>= 11.0	10 (35.7%)	0	10 (34.5%)
Central mean screening Hb level (g/dL)			
n	28	1	29
Mean	10.92	10.90	10.92
SD	0.83	.	0.82
Min	10.0	10.9	10.0
Median*	10.65	10.90	10.65
Max	13.0	10.9	13.0
Prior Thromboembolic Event			
NO	26 (92.9%)	1 (100.0%)	27 (93.1%)
YES	2 (7.1%)	0	2 (6.9%)
Pre-treatment of ESAs for 19353			
PRE-TREATED AT ASSIGNMENT	28 (100.0%)	0	28 (96.6%)
UNTREATED AT ASSIGNMENT	0	1 (100.0%)	1 (3.4%)
Pre-treatment of ESAs recorded in IxRS			
Subjects pre treated with ESA (IxRS)	28 (100.0%)	0	28 (96.6%)
Subjects untreated with ESA (IxRS)	0	1 (100.0%)	1 (3.4%)
Use of ESAs within 8 weeks prior to the start of the study drug			
NO	0	1 (100.0%)	1 (3.4%)
YES	28 (100.0%)	0	28 (96.6%)
History of ESA treatment after initiation of dialysis			
YES	28 (100.0%)	1 (100.0%)	29 (100.0%)
Main cause of CKD			
IgA nephropathy	2 (7.1%)	0	2 (6.9%)
chronic glomerulonephritis	6 (21.4%)	0	6 (20.7%)
diabetic nephropathy	7 (25.0%)	0	7 (24.1%)
nephrosclerosis	7 (25.0%)	1 (100.0%)	8 (27.6%)
polycystic kidney disease	2 (7.1%)	0	2 (6.9%)
unknown	4 (14.3%)	0	4 (13.8%)
Main cause of CKD group			
diabetic nephropathy	7 (25.0%)	0	7 (24.1%)

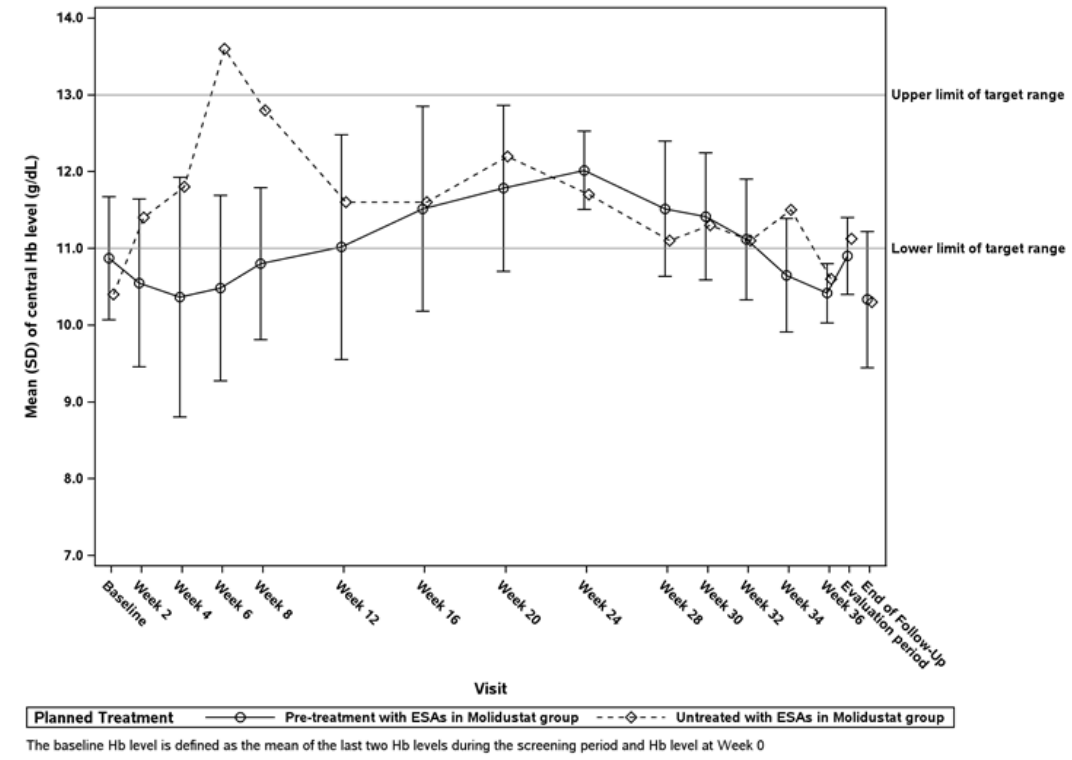
	Pre-treatment with ESAs in Molidustat group N=28 (100%)	Untreated with ESAs in Molidustat group N=1 (100%)	Total N=29 (100%)
other	17 (60.7%)	1 (100.0%)	18 (62.1%)
unknown	4 (14.3%)	0	4 (13.8%)
Duration of CKD (years)			
n	28	1	29
Mean	11.742	4.342	11.487
SD	8.693	.	8.646
Min	0.56	4.34	0.56
Median*	9.848	4.342	9.164
Max	39.63	4.34	39.63
Duration of peritoneal dialysis (years)			
n	28	1	29
Mean	2.8736	1.6400	2.8310
SD	1.8651	.	1.8458
Min	0.444	1.640	0.444
Median*	2.4339	1.6400	2.4038
Max	6.220	1.640	6.220
Duration of peritoneal dialysis (years) group			
< 5	23 (82.1%)	1 (100.0%)	24 (82.8%)
>= 5	5 (17.9%)	0	5 (17.2%)
Baseline Pulse Rate (BEATS/MIN)			
n	28	1	29
Mean	77.3	65.0	76.9
SD	9.9	.	10.0
Min	63	65	63
Median*	76.0	65.0	76.0
Max	94	65	94
Baseline Systolic Blood Pressure (mmHg)			
n	28	1	29
Mean	144.1	131.0	143.7
SD	18.5	.	18.3
Min	110	131	110
Median*	145.5	131.0	145.0
Max	179	131	179
Baseline Diastolic Blood Pressure (mmHg)			
n	28	1	29
Mean	84.6	75.0	84.3
SD	15.6	.	15.5
Min	50	75	50
Median*	88.5	75.0	88.0
Max	124	75	124
Baseline total iron binding capacity (umol/L)			
n	28	1	29
Mean	43.4	42.6	43.4
SD	6.3	.	6.2
Min	26	43	26
Median*	43.1	42.6	43.0
Max	55	43	55
Baseline unsaturated iron binding capacity (umol/L)			
n	28	1	29
Mean	27.7	16.7	27.3
SD	8.3	.	8.4
Min	3	17	3
Median*	27.2	16.7	27.0
Max	42	17	42

	Pre-treatment with ESAs in Molidustat group N=28 (100%)	Untreated with ESAs in Molidustat group N=1 (100%)	Total N=29 (100%)
Baseline Transferrin Saturation (%)			
n	28	1	29
Mean	36.6	60.9	37.5
SD	16.2	.	16.6
Min	15	61	15
Median*	35.3	60.9	35.4
Max	92	61	92
Baseline Transferrin Saturation (%) group			
< 20	3 (10.7%)	0	3 (10.3%)
>= 20	25 (89.3%)	1 (100.0%)	26 (89.7%)
Baseline Hepcidin (ng/mL)			
n	28	1	29
Mean	125.6	279.0	130.9
SD	51.7	.	58.2
Min	41	279	41
Median*	133.8	279.0	137.6
Max	226	279	279
Baseline total iron (ug/dL)			
n	28	1	29
Mean	87.8	145.0	89.8
SD	34.9	.	35.9
Min	21	145	21
Median*	82.5	145.0	83.0
Max	187	145	187
Baseline ferritin (ng/mL)			
n	28	1	29
Mean	190.6	369.0	196.8
SD	134.7	.	136.3
Min	39	369	39
Median*	177.0	369.0	179.0
Max	726	369	726
Baseline Ferritin (ng/mL) group			
< 100	7 (25.0%)	0	7 (24.1%)
>= 100	21 (75.0%)	1 (100.0%)	22 (75.9%)
Baseline Vitamin B12 (pmol/L)			
n	27	1	28
Mean	400.9	422.0	401.7
SD	163.8	.	160.8
Min	146	422	146
Median*	363.7	422.0	375.5
Max	841	422	841
Baseline folate (nmol/L)			
n	28	1	29
Mean	64.7	13.8	63.0
SD	264.0	.	259.4
Min	9	14	9
Median*	14.5	13.8	14.5
Max	1412	14	1412
Baseline Potassium (mmol/L) in Serum			
n	28	1	29
Mean	4.39	4.80	4.41
SD	0.77	.	0.76
Min	3.2	4.8	3.2
Median*	4.40	4.80	4.40
Max	6.0	4.8	6.0
Baseline Hemoglobin A1C (%) in Blood - Calculated			
n	28	1	29

	Pre-treatment with ESAs in Molidustat group N=28 (100%)	Untreated with ESAs in Molidustat group N=1 (100%)	Total N=29 (100%)
Mean	5.75	4.80	5.72
SD	0.65	.	0.66
Min	4.5	4.8	4.5
Median*	5.60	4.80	5.60
Max	7.4	4.8	7.4
Baseline LDL Cholesterol (mg/dL) in Serum			
n	28	1	29
Mean	106.1	125.0	106.8
SD	29.8	.	29.4
Min	54	125	54
Median*	109.5	125.0	110.0
Max	155	125	155
Baseline HDL Cholesterol (mg/dL) in Serum			
n	28	1	29
Mean	50.4	63.0	50.9
SD	15.6	.	15.5
Min	28	63	28
Median*	48.0	63.0	48.0
Max	87	63	87
Baseline Triglycerides (mg/dL) in Serum			
n	28	1	29
Mean	145.2	143.0	145.1
SD	82.9	.	81.5
Min	34	143	34
Median*	125.5	143.0	130.0
Max	473	143	473
Baseline C Reactive Protein (mg/dL) in Serum			
n	28	1	29
Mean	0.255	0.040	0.247
SD	0.406	.	0.401
Min	0.02	0.04	0.02
Median*	0.110	0.040	0.100
Max	1.98	0.04	1.98
Baseline Erythropoietin (IU/L) in Serum			
n	28	1	29
Mean	15.062	6.190	14.756
SD	13.287	.	13.151
Min	3.94	6.19	3.94
Median*	7.640	6.190	7.100
Max	52.26	6.19	52.26
Darbepoetin alfa (ug/week)			
n	12	0	12
Mean	31.93	.	31.93
SD	9.80	.	9.80
Min	15.0		15.0
Median	30.00	.	30.00
Max	45.0		45.0
Epoetin beta pegol (ug/week)			
n	16	1	17
Mean	28.438	37.500	28.971
SD	17.130	.	16.731
Min	6.25	37.50	6.25
Median	25.000	37.500	25.000
Max	62.50	37.50	62.50
Epoetin alfa or beta (IU/week)			

	Pre-treatment with ESAs in Molidustat group N=28 (100%)	Untreated with ESAs in Molidustat group N=1 (100%)	Total N=29 (100%)
n	0	0	0
Mean	.	.	.
SD	.	.	.
Min			
Median	.	.	.
Max			
Conversed to Erythropoietin dose per week (IU/week)			
n	28	1	29
Mean	4361.7	3750.0	4340.6
SD	2526.2	.	2483.3
Min	625	3750	625
Median	3875.0	3750.0	3750.0
Max	9000	3750	9000
Categories (IU/week)			
< 3000	10 (35.7%)	0	10 (34.5%)
>= 3000 to < 4500	6 (21.4%)	1 (100.0%)	7 (24.1%)
>= 4500 to < 6000	0	0	0
>= 6000	12 (42.9%)	0	12 (41.4%)

Median: based on safety analysis set.
ESA treatment: Epoetin alfa (including Epoetin kappa) , Epoetin beta, Darbepoetin alfa and Epoetin beta pegol.
Duration of washout (week): 12 (week) was imputed for the subjects who did not receive ESA.
Central mean screening Hb level: Mean of all Hb in screening period



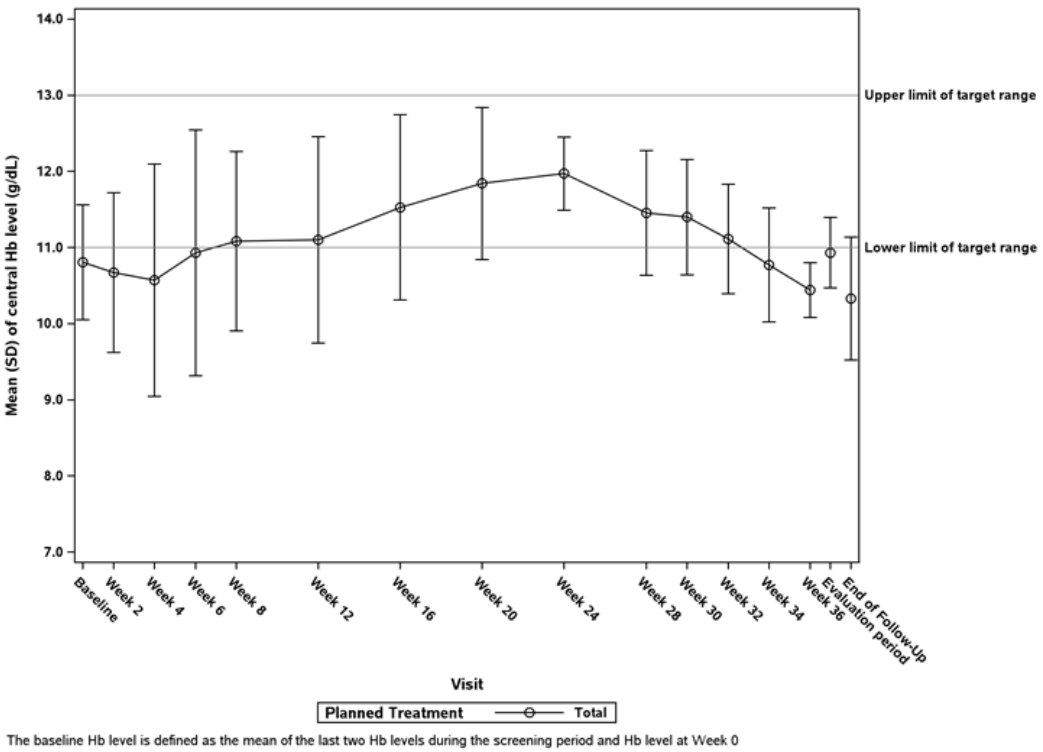


図 2.7.3.6-49　EOT に目標 Hb 値を下回った被験者での Hb 値の推移（試験 19353）

表 2.7.3.6-97 治験薬投与 30 週目から 40 週目まで Hb 値が目標範囲の下限を 2 回以上連続して下回った被験者における各来院時の Hb 値が目標範囲内、上限以上又は下限未満に該当する被験者の割合（試験 19349）

Visit	Hb Level	Molidustat (N=16)	Darbepoetin alfa (N=7)
Baseline	n	16	7
	Below	16 (100.0%)	7 (100.0%)
	In	0 (0.0%)	0 (0.0%)
	Above	0 (0.0%)	0 (0.0%)
Week 2	n	16	7
	Below	16 (100.0%)	7 (100.0%)
	In	0 (0.0%)	0 (0.0%)
	Above	0 (0.0%)	0 (0.0%)
Week 4	n	16	7
	Below	14 (87.5%)	6 (85.7%)
	In	2 (12.5%)	1 (14.3%)
	Above	0 (0.0%)	0 (0.0%)
Week 8	n	16	7
	Below	9 (56.3%)	3 (42.9%)
	In	7 (43.8%)	4 (57.1%)
	Above	0 (0.0%)	0 (0.0%)
Week 12	n	16	7
	Below	5 (31.3%)	1 (14.3%)
	In	11 (68.8%)	5 (71.4%)
	Above	0 (0.0%)	1 (14.3%)
Week 16	n	16	7
	Below	4 (25.0%)	1 (14.3%)
	In	11 (68.8%)	6 (85.7%)
	Above	1 (6.3%)	0 (0.0%)
Week 20	n	16	7
	Below	2 (12.5%)	0 (0.0%)
	In	12 (75.0%)	6 (85.7%)
	Above	2 (12.5%)	1 (14.3%)
Week 24	n	16	7
	Below	2 (12.5%)	1 (14.3%)
	In	14 (87.5%)	5 (71.4%)
	Above	0 (0.0%)	1 (14.3%)
Week 28	n	16	7
	Below	7 (43.8%)	2 (28.6%)
	In	8 (50.0%)	5 (71.4%)
	Above	1 (6.3%)	0 (0.0%)
Week 30	n	16	7
	Below	12 (75.0%)	2 (28.6%)
	In	3 (18.8%)	5 (71.4%)
	Above	1 (6.3%)	0 (0.0%)
Week 32	n	16	7
	Below	15 (93.8%)	4 (57.1%)
	In	1 (6.3%)	3 (42.9%)
	Above	0 (0.0%)	0 (0.0%)
Week 34	n	15	7
	Below	11 (73.3%)	2 (28.6%)
	In	4 (26.7%)	5 (71.4%)
	Above	0 (0.0%)	0 (0.0%)
Week 36	n	15	7
	Below	8 (53.3%)	4 (57.1%)
	In	7 (46.7%)	3 (42.9%)
	Above	0 (0.0%)	0 (0.0%)

Visit	Hb Level	Molidustat (N=16)	Darbepoetin alfa (N=7)
Week 40	n	15	7
	Below	7 (46.7%)	6 (85.7%)
	In	7 (46.7%)	0 (0.0%)
	Above	1 (6.7%)	1 (14.3%)
Week 44	n	12	7
	Below	3 (25.0%)	3 (42.9%)
	In	7 (58.3%)	4 (57.1%)
	Above	2 (16.7%)	0 (0.0%)
Week 48	n	11	6
	Below	4 (36.4%)	2 (33.3%)
	In	7 (63.6%)	3 (50.0%)
	Above	0 (0.0%)	1 (16.7%)
Week 52	n	10	4
	Below	3 (30.0%)	3 (75.0%)
	In	7 (70.0%)	1 (25.0%)
	Above	0 (0.0%)	0 (0.0%)
Evaluation period	n	16	7
	Below	12 (75.0%)	2 (28.6%)
	In	4 (25.0%)	5 (71.4%)
	Above	0 (0.0%)	0 (0.0%)
End of Follow-Up	n	16	7
	Below	12 (75.0%)	6 (85.7%)
	In	4 (25.0%)	1 (14.3%)
	Above	0 (0.0%)	0 (0.0%)

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 the last two Hb levels during the screening period and Hb level at Week 0

表 2.7.3.6-98 第 30 週から第 40 週までで Hb 値が目標範囲の下限を 2 回以上連続して下回った被験者の各来院時の Hb 値（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=16)	Screening -2	16	9.81	0.80	8.4	9.75	11.3						
	Screening -1	16	9.70	0.91	7.9	9.85	10.9						
	Week 0	16	9.69	0.74	8.2	9.90	10.5						
	Baseline	16	9.73	0.78	8.3	9.88	10.7						
	Week 2	16	9.70	0.87	8.3	9.95	10.9	16	-0.03	0.36	-0.8	-0.03	0.6
	Week 4	16	9.90	1.06	7.7	10.10	11.8	16	0.17	0.56	-0.9	0.20	1.1
	Week 8	16	10.44	0.97	8.5	10.35	11.8	16	0.71	0.49	-0.2	0.70	1.6
	Week 12	16	11.16	0.98	8.7	11.25	12.7	16	1.42	0.78	-0.2	1.52	2.5
	Week 16	16	11.44	0.90	9.9	11.50	13.2	16	1.71	1.09	-0.8	1.70	3.5
	Week 20	16	12.14	0.80	10.6	12.20	13.3	16	2.40	1.16	0.2	2.65	4.0
	Week 24	16	11.71	0.64	10.6	11.75	12.8	16	1.97	1.16	-0.1	1.82	4.3
	Week 28	16	11.04	0.99	9.1	11.05	13.5	16	1.30	1.46	-1.1	1.20	4.6
	Week 30	16	10.47	1.21	7.9	10.60	13.1	16	0.74	1.62	-2.3	0.92	4.2
	Week 32	16	10.19	0.83	8.0	10.50	11.1	16	0.45	1.26	-2.2	0.58	2.6
	Week 34	15	10.36	0.70	8.8	10.40	11.4	15	0.67	1.06	-1.4	0.77	2.4
	Week 36	15	11.02	0.96	9.6	10.90	12.5	15	1.32	1.22	-0.4	1.47	3.5
	Week 40	15	11.09	1.30	8.9	11.60	13.5	15	1.39	1.37	-0.8	1.27	3.8
	Week 44	12	11.70	1.32	8.6	11.75	13.8	12	1.93	1.86	-1.9	1.80	4.9
	Week 48	11	11.37	1.22	8.9	11.30	12.8	11	1.67	1.47	-1.1	1.43	4.5
	Week 52	10	11.46	0.99	10.1	11.60	12.8	10	1.78	1.15	-0.1	1.53	3.7
	End of Follow-Up	16	10.16	1.43	7.4	10.55	12.7	16	0.43	1.41	-3.1	0.88	2.4

Planned Treatment	Visit	Value at visit						Change from Baseline					
		n	Mean	SD	Min	Median	Max	n	Mean	SD	Min	Median	Max
Darbepoetin alfa (N=7)	Screening -2	7	9.60	0.56	8.8	9.80	10.3						
	Screening -1	7	9.57	0.94	8.3	9.40	10.8						
	Week 0	7	9.40	0.90	8.1	9.50	10.6						
	Baseline	7	9.52	0.78	8.4	9.57	10.4						
	Week 2	7	9.66	0.92	8.2	9.40	10.8	7	0.13	0.40	-0.4	0.17	0.7
	Week 4	7	10.33	0.71	9.3	10.60	11.1	7	0.80	0.50	-0.1	1.00	1.5
	Week 8	7	10.97	0.64	10.3	11.10	11.9	7	1.45	0.43	0.9	1.53	2.0
	Week 12	7	11.76	0.95	10.4	11.90	13.3	7	2.23	0.53	1.6	2.03	2.9
	Week 16	7	11.67	0.87	10.2	12.00	12.6	7	2.15	1.21	0.9	1.57	4.2
	Week 20	7	11.94	0.72	11.1	11.60	13.0	7	2.42	1.15	1.1	2.33	4.3
	Week 24	7	12.07	1.01	10.2	12.10	13.2	7	2.55	1.37	1.0	2.13	4.3
	Week 28	7	10.96	1.15	9.2	11.20	12.2	7	1.43	1.63	-1.2	1.43	3.6
	Week 30	7	11.13	1.27	9.2	11.60	12.3	7	1.60	1.61	-1.2	1.90	3.4
	Week 32	7	11.11	0.74	10.3	10.80	12.1	7	1.59	1.15	-0.1	2.23	2.8
	Week 34	7	11.51	0.68	10.7	11.70	12.4	7	1.99	0.92	0.4	2.30	3.0
	Week 36	7	10.93	0.93	9.9	10.70	12.8	7	1.40	0.69	0.6	1.50	2.4
	Week 40	7	10.74	1.26	9.5	10.60	13.4	7	1.22	0.91	0.3	1.10	3.0
	Week 44	7	11.03	0.80	9.9	11.00	12.2	7	1.50	1.07	0.3	1.37	3.4
	Week 48	6	11.47	1.56	9.5	11.60	13.6	6	1.95	1.33	0.7	1.58	3.7
	Week 52	4	10.85	0.85	10.0	10.70	12.0	4	1.48	1.27	0.5	1.12	3.2
	End of Follow-Up	7	9.94	1.47	7.3	10.50	11.5	7	0.42	1.37	-1.9	0.40	2.1

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 2.7.3.6-99 第 30 週から 40 週までで Hb 値が目標範囲の下限を 2 回以上連続して下回った被験者での評価期間中の Hb 値（試験 19349）

		Value during period							Change from Baseline						
Planned Treatment	Period	n	Mean	SD	Min	Median	Max	95%CI	n	Mean	SD	Min	Median	Max	95%CI
Molidustat (N=16)	Baseline	16	9.73	0.78	8.3	9.88	10.7								
	Evaluation period	16	10.44	0.86	8.2	10.64	11.4	9.99, 10.90	16	0.71	1.27	-2.0	0.89	2.5	0.03, 1.39
Darbepoetin alfa (N=7)	Baseline	7	9.52	0.78	8.4	9.57	10.4								
	Evaluation period	7	11.17	0.34	10.7	11.23	11.6	10.86, 11.49	7	1.65	0.75	0.7	1.43	2.7	0.96, 2.34

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
95% CI: The two-sided 95% confidence intervals estimated using one-sample t-statistics.
Detail of 95% CI of value during evaluation period
Molidustat : 9.9887 - 10.9009
Darbepoetin alfa : 10.8557 - 11.4872

表 2.7.3.6-100　治験薬投与 30 週目から 40 週目まで Hb 値が目標範囲の下限を 2 回連続して下回った被験者の TEAE の概要（試験 19349、SAF）

	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
Number (%) of subjects with treatment-emergent adverse events			
Any AE	15 (93.8%)	7 (100.0%)	22 (95.7%)
Maximum intensity for any AE			
MILD	5 (31.3%)	3 (42.9%)	8 (34.8%)
MODERATE	7 (43.8%)	3 (42.9%)	10 (43.5%)
SEVERE	3 (18.8%)	1 (14.3%)	4 (17.4%)
Any study drug-related AE	2 (12.5%)	1 (14.3%)	3 (13.0%)
Maximum intensity for study drug related AE			
MILD	1 (6.3%)	1 (14.3%)	2 (8.7%)
MODERATE	1 (6.3%)	0	1 (4.3%)
SEVERE	0	0	0
Any AE related to procedures required by the protocol	0	0	0
Any AE leading to discontinuation of study drug	2 (12.5%)	2 (28.6%)	4 (17.4%)
Any AE leading to dose interruption	3 (18.8%)	0	3 (13.0%)
Any SAE	8 (50.0%)	4 (57.1%)	12 (52.2%)
Any study drug-related SAE	1 (6.3%)	0	1 (4.3%)
Any SAE related to procedures required by the protocol	0	0	0
Any SAE leading to discontinuation of study drug	1 (6.3%)	2 (28.6%)	3 (13.0%)
AE with outcome death	0	0	0

表 2.7.3.6-101　治験薬投与 30 週目から 40 週目まで Hb 値が目標範囲の下限を 2 回連続して下回った被験者のすべての TEAE（試験 19349、SAF）

Primary system organ class Preferred term MedDRA version 22.0	MedDRA-J	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
Number (%) of subjects with at least one adverse event		15 (93.8%)	7 (100.0%)	22 (95.7%)
Blood and lymphatic system disorders	血液およびリンパ系障害	1 (6.3%)	0	1 (4.3%)
Iron deficiency anaemia	鉄欠乏性貧血	1 (6.3%)	0	1 (4.3%)
Cardiac disorders	心臓障害	2 (12.5%)	1 (14.3%)	3 (13.0%)
Bradycardia	徐脈	0	1 (14.3%)	1 (4.3%)
Cardiac failure	心不全	1 (6.3%)	0	1 (4.3%)
Cardiac failure chronic	慢性心不全	0	1 (14.3%)	1 (4.3%)
Cardiac failure congestive	うっ血性心不全	1 (6.3%)	0	1 (4.3%)
Endocrine disorders	内分泌障害	1 (6.3%)	2 (28.6%)	3 (13.0%)
Hyperparathyroidism	副甲状腺機能亢進症	1 (6.3%)	0	1 (4.3%)
Hyperthyroidism	甲状腺機能亢進症	0	1 (14.3%)	1 (4.3%)
Thyroiditis subacute	亜急性甲状腺炎	0	1 (14.3%)	1 (4.3%)
Eye disorders	眼障害	5 (31.3%)	1 (14.3%)	6 (26.1%)
Cataract	白内障	1 (6.3%)	1 (14.3%)	2 (8.7%)
Macular oedema	黄斑浮腫	1 (6.3%)	0	1 (4.3%)
Normal tension glaucoma	正常眼圧緑内障	1 (6.3%)	0	1 (4.3%)
Posterior capsule opacification	後嚢部混濁	1 (6.3%)	0	1 (4.3%)
Retinal haemorrhage	網膜出血	1 (6.3%)	0	1 (4.3%)
Gastrointestinal disorders	胃腸障害	6 (37.5%)	3 (42.9%)	9 (39.1%)
Chronic gastritis	慢性胃炎	0	1 (14.3%)	1 (4.3%)
Constipation	便秘	4 (25.0%)	2 (28.6%)	6 (26.1%)
Diarrhoea	下痢	2 (12.5%)	0	2 (8.7%)
Large intestine perforation	大腸穿孔	1 (6.3%)	0	1 (4.3%)
Stomatitis	口内炎	0	1 (14.3%)	1 (4.3%)

Primary system organ class Preferred term MedDRA version 22.0	MedDRA-J	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
General disorders and administration site conditions	一般・全身障害および投与部位の状態	2 (12.5%)	1 (14.3%)	3 (13.0%)
Oedema	浮腫	1 (6.3%)	0	1 (4.3%)
Oedema peripheral	末梢性浮腫	1 (6.3%)	0	1 (4.3%)
Pyrexia	発熱	0	1 (14.3%)	1 (4.3%)
Infections and infestations	感染症および寄生虫症	8 (50.0%)	4 (57.1%)	12 (52.2%)
Abscess limb	四肢膿瘍	1 (6.3%)	0	1 (4.3%)
Bronchitis	気管支炎	1 (6.3%)	0	1 (4.3%)
Cellulitis	蜂巣炎	0	1 (14.3%)	1 (4.3%)
Conjunctivitis bacterial	細菌性結膜炎	1 (6.3%)	0	1 (4.3%)
Cystitis	膀胱炎	1 (6.3%)	0	1 (4.3%)
Herpes zoster	帯状疱疹	1 (6.3%)	0	1 (4.3%)
Nasopharyngitis	上咽頭炎	3 (18.8%)	2 (28.6%)	5 (21.7%)
Otitis media	中耳炎	1 (6.3%)	0	1 (4.3%)
Pneumonia	肺炎	2 (12.5%)	0	2 (8.7%)
Pyelonephritis	腎盂腎炎	0	1 (14.3%)	1 (4.3%)
Pyelonephritis acute	急性腎盂腎炎	1 (6.3%)	0	1 (4.3%)
Streptococcal infection	レンサ球菌感染	1 (6.3%)	0	1 (4.3%)
Injury, poisoning and procedural complications	傷害、中毒および処置合併症	8 (50.0%)	1 (14.3%)	9 (39.1%)
Arthropod sting	節足動物刺傷	1 (6.3%)	0	1 (4.3%)
Contusion	挫傷	4 (25.0%)	0	4 (17.4%)
Face injury	顔面損傷	0	1 (14.3%)	1 (4.3%)
Fall	転倒	2 (12.5%)	0	2 (8.7%)
Joint dislocation	関節脱臼	1 (6.3%)	0	1 (4.3%)
Limb injury	四肢損傷	0	1 (14.3%)	1 (4.3%)
Shunt blood flow excessive	シャント血流過剰	1 (6.3%)	0	1 (4.3%)
Shunt stenosis	シャント狭窄	1 (6.3%)	0	1 (4.3%)
Skin abrasion	皮膚擦過傷	1 (6.3%)	0	1 (4.3%)
Skin laceration	皮膚裂傷	1 (6.3%)	0	1 (4.3%)
Spinal compression fracture	脊椎圧迫骨折	1 (6.3%)	0	1 (4.3%)

Primary system organ class Preferred term MedDRA version 22.0	MedDRA-J	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
Investigations	臨床検査	1 (6.3%)	2 (28.6%)	3 (13.0%)
Blood alkaline phosphatase increased	血中アルカリホスファターゼ増加	1 (6.3%)	0	1 (4.3%)
Blood creatine phosphokinase increased	血中クレアチンホスホキナーゼ増加	0	1 (14.3%)	1 (4.3%)
Blood thyroid stimulating hormone increased	血中甲状腺刺激ホルモン増加	0	1 (14.3%)	1 (4.3%)
Electrocardiogram QT prolonged	心電図ＱＴ延長	1 (6.3%)	0	1 (4.3%)
Metabolism and nutrition disorders	代謝および栄養障害	6 (37.5%)	3 (42.9%)	9 (39.1%)
Decreased appetite	食欲減退	2 (12.5%)	0	2 (8.7%)
Fluid retention	体液貯留	1 (6.3%)	0	1 (4.3%)
Gout	痛風	1 (6.3%)	0	1 (4.3%)
Hyperkalaemia	高カリウム血症	3 (18.8%)	2 (28.6%)	5 (21.7%)
Hyperuricaemia	高尿酸血症	0	1 (14.3%)	1 (4.3%)
Hypokalaemia	低カリウム血症	0	1 (14.3%)	1 (4.3%)
Metabolic acidosis	代謝性アシドーシス	1 (6.3%)	0	1 (4.3%)
Musculoskeletal and connective tissue disorders	筋骨格系および結合組織障害	5 (31.3%)	3 (42.9%)	8 (34.8%)
Arthralgia	関節痛	1 (6.3%)	0	1 (4.3%)
Back pain	背部痛	2 (12.5%)	0	2 (8.7%)
Bursitis	滑液包炎	0	1 (14.3%)	1 (4.3%)
Chondrocalcinosis pyrophosphate	ピロリン酸カルシウム結晶性軟骨石灰化症	1 (6.3%)	0	1 (4.3%)
Gouty arthritis	痛風性関節炎	0	1 (14.3%)	1 (4.3%)
Joint swelling	関節腫脹	0	1 (14.3%)	1 (4.3%)
Muscle spasms	筋痙縮	0	1 (14.3%)	1 (4.3%)
Osteoarthritis	変形性関節症	1 (6.3%)	0	1 (4.3%)
Osteoporosis	骨粗鬆症	1 (6.3%)	0	1 (4.3%)
Nervous system disorders	神経系障害	4 (25.0%)	0	4 (17.4%)
Cerebral infarction	脳梗塞	1 (6.3%)	0	1 (4.3%)
Dizziness	浮動性めまい	1 (6.3%)	0	1 (4.3%)
Headache	頭痛	1 (6.3%)	0	1 (4.3%)
Sciatica	坐骨神経痛	1 (6.3%)	0	1 (4.3%)
Psychiatric disorders	精神障害	2 (12.5%)	0	2 (8.7%)
Abnormal behaviour	異常行動	1 (6.3%)	0	1 (4.3%)
Insomnia	不眠症	2 (12.5%)	0	2 (8.7%)

Primary system organ class Preferred term MedDRA version 22.0	MedDRA-J	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
Renal and urinary disorders	腎および尿路障害	5 (31.3%)	3 (42.9%)	8 (34.8%)
Acute kidney injury	急性腎障害	1 (6.3%)	0	1 (4.3%)
Chronic kidney disease	慢性腎臓病	4 (25.0%)	3 (42.9%)	7 (30.4%)
Dysuria	排尿困難	0	1 (14.3%)	1 (4.3%)
Renal cyst haemorrhage	腎嚢胞出血	1 (6.3%)	0	1 (4.3%)
Respiratory, thoracic and mediastinal disorders	呼吸器、胸郭および縦隔障害	3 (18.8%)	2 (28.6%)	5 (21.7%)
Cough	咳嗽	1 (6.3%)	0	1 (4.3%)
Dyspnoea	呼吸困難	0	1 (14.3%)	1 (4.3%)
Interstitial lung disease	間質性肺疾患	1 (6.3%)	0	1 (4.3%)
Pleural effusion	胸水	0	1 (14.3%)	1 (4.3%)
Upper respiratory tract inflammation	上気道の炎症	1 (6.3%)	1 (14.3%)	2 (8.7%)
Skin and subcutaneous tissue disorders	皮膚および皮下組織障害	0	2 (28.6%)	2 (8.7%)
Rash	発疹	0	1 (14.3%)	1 (4.3%)
Urticaria	蕁麻疹	0	1 (14.3%)	1 (4.3%)
Surgical and medical procedures	外科および内科処置	2 (12.5%)	1 (14.3%)	3 (13.0%)
Arteriovenous fistula operation	動静脈瘻手術	1 (6.3%)	1 (14.3%)	2 (8.7%)
Surgical vascular shunt	外科的血管シャント	1 (6.3%)	0	1 (4.3%)
Vascular disorders	血管障害	2 (12.5%)	0	2 (8.7%)
Hypertension	高血圧	2 (12.5%)	0	2 (8.7%)

Adverse events are sorted in alphabetical order by primary SOC and preferred term.
A subject is counted only once within each preferred term or any primary SOC.

表 2.7.3.6-102 治験薬投与 30 週目から 40 週目まで Hb 値が目標範囲の下限を 2 回連続して下回った被験者の人口統計学的及びベースライン特性（試験 19349、FAS）

	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
Sex			
Male	9 (56.3%)	4 (57.1%)	13 (56.5%)
Female	7 (43.8%)	3 (42.9%)	10 (43.5%)
Race			
ASIAN	16 (100.0%)	7 (100.0%)	23 (100.0%)
Ethnicity			
NOT HISPANIC OR LATINO	16 (100.0%)	7 (100.0%)	23 (100.0%)
Age(years)			
n	16	7	23
Mean	71.9	75.4	73.0
SD	9.5	4.4	8.3
Min	50	67	50
Median	73.0	77.0	75.0
Max	84	80	84
Age(years) group 01			
< 65	4 (25.0%)	0	4 (17.4%)
>= 65	12 (75.0%)	7 (100.0%)	19 (82.6%)
Age(years) group 02			
< 75	8 (50.0%)	2 (28.6%)	10 (43.5%)
>= 75	8 (50.0%)	5 (71.4%)	13 (56.5%)
Baseline Weight (kg)			
n	16	7	23
Mean	62.29	58.41	61.11
SD	10.83	7.29	9.89
Min	45.6	46.9	45.6
Median	62.40	60.00	62.20
Max	89.8	67.1	89.8
Baseline Weight (kg) group			
< 55	3 (18.8%)	2 (28.6%)	5 (21.7%)
>= 55	13 (81.3%)	5 (71.4%)	18 (78.3%)
Baseline Height (cm)			
n	16	7	23
Mean	157.89	158.76	158.15
SD	6.76	12.49	8.60
Min	145.1	136.6	136.6
Median	159.05	161.70	160.00
Max	167.6	174.7	174.7
Baseline Body Mass Index (kg/m2)			
n	16	7	23
Mean	24.96	23.21	24.43
SD	3.93	2.16	3.53
Min	20.3	20.5	20.3
Median	23.85	22.90	23.10
Max	34.6	27.3	34.6
Baseline Body Mass Index group (kg/m2)			
< 25	10 (62.5%)	6 (85.7%)	16 (69.6%)
>= 25	6 (37.5%)	1 (14.3%)	7 (30.4%)
Smoking History			
NEVER	7 (43.8%)	3 (42.9%)	10 (43.5%)
FORMER	6 (37.5%)	4 (57.1%)	10 (43.5%)
CURRENT	3 (18.8%)	0	3 (13.0%)
Alcohol consumption			
ABSTINENT	9 (56.3%)	4 (57.1%)	13 (56.5%)
LIGHT	7 (43.8%)	3 (42.9%)	10 (43.5%)

	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
Baseline central Hb level (g/dL)			
n	16	7	23
Mean	9.73	9.52	9.67
SD	0.78	0.78	0.77
Min	8.3	8.4	8.3
Median	9.88	9.57	9.80
Max	10.7	10.4	10.7
Baseline central Hb level (g/dL) group			
< 9.0	3 (18.8%)	2 (28.6%)	5 (21.7%)
>= 9.0	13 (81.3%)	5 (71.4%)	18 (78.3%)
Baseline central Hb level (g/dL) recorded in IxRS			
n	16	7	23
Mean	9.73	9.52	9.67
SD	0.78	0.78	0.77
Min	8.3	8.4	8.3
Median	9.88	9.57	9.80
Max	10.7	10.4	10.7
Baseline central Hb level (g/dL) recorded in IxRS group			
< 9.0	3 (18.8%)	2 (28.6%)	5 (21.7%)
>= 9.0	13 (81.3%)	5 (71.4%)	18 (78.3%)
Baseline local Hb level (g/dL)			
n	16	7	23
Mean	9.79	9.63	9.74
SD	0.85	0.73	0.80
Min	8.3	8.6	8.3
Median	9.95	9.70	9.77
Max	10.8	10.7	10.8
Baseline local Hb level (g/dL) group			
< 9.0	4 (25.0%)	2 (28.6%)	6 (26.1%)
>= 9.0	12 (75.0%)	5 (71.4%)	17 (73.9%)
Central mean screening Hb level (g/dL)			
n	16	7	23
Mean	9.76	9.59	9.70
SD	0.82	0.72	0.78
Min	8.4	8.6	8.4
Median	9.88	9.60	9.75
Max	10.9	10.5	10.9
Central screening Hb level (g/dL) recorded in IxRS			
n	16	7	23
Mean	9.76	9.59	9.70
SD	0.82	0.72	0.78
Min	8.4	8.6	8.4
Median	9.88	9.60	9.75
Max	10.9	10.5	10.9
Prior Thromboembolic Event			
NO	16 (100.0%)	6 (85.7%)	22 (95.7%)
YES	0	1 (14.3%)	1 (4.3%)
Prior Thromboembolic Event in IxRS			
NO	15 (93.8%)	6 (85.7%)	21 (91.3%)
YES	1 (6.3%)	1 (14.3%)	2 (8.7%)
Baseline eGFR (mL/min/1.73m2)			
n	16	7	23
Mean	17.3	19.1	17.9
SD	6.7	7.9	7.0
Min	8	8	8
Median	16.0	19.0	16.0
Max	31	28	31
Baseline eGFR (mL/min/1.73m2) group			
< 15	7 (43.8%)	2 (28.6%)	9 (39.1%)
>= 15 < 30	7 (43.8%)	5 (71.4%)	12 (52.2%)
>= 30	2 (12.5%)	0	2 (8.7%)
Stage of CKD based on eGFR			
G3b	2 (12.5%)	0	2 (8.7%)
G4	7 (43.8%)	5 (71.4%)	12 (52.2%)
G5	7 (43.8%)	2 (28.6%)	9 (39.1%)

	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
Stage of CKD based on eGFR and UACR			
G3bA1	1 (6.3%)	0	1 (4.3%)
G3bA2	1 (6.3%)	0	1 (4.3%)
G4A1	0	3 (42.9%)	3 (13.0%)
G4A3	7 (43.8%)	2 (28.6%)	9 (39.1%)
G5A3	7 (43.8%)	2 (28.6%)	9 (39.1%)
Main cause of CKD			
Hypertension	0	1 (14.3%)	1 (4.3%)
chronic glomerulonephritis	6 (37.5%)	2 (28.6%)	8 (34.8%)
diabetes mellitus	1 (6.3%)	0	1 (4.3%)
diabetic nephropathy	5 (31.3%)	2 (28.6%)	7 (30.4%)
nephrosclerosis	2 (12.5%)	2 (28.6%)	4 (17.4%)
polycystic kidney disease	2 (12.5%)	0	2 (8.7%)
Main cause of CKD group			
diabetic nephropathy	5 (31.3%)	2 (28.6%)	7 (30.4%)
other	11 (68.8%)	5 (71.4%)	16 (69.6%)
Duration of CKD (years)			
n	16	7	23
Mean	10.921	7.779	9.965
SD	12.332	7.735	11.054
Min	0.49	1.11	0.49
Median	6.787	4.857	6.226
Max	48.45	19.09	48.45
Medical History of Atrial fibrillation			
NO	16 (100.0%)	6 (85.7%)	22 (95.7%)
YES	0	1 (14.3%)	1 (4.3%)
Baseline Pulse Rate (BEATS/MIN)			
n	16	7	23
Mean	70.8	72.3	71.2
SD	10.3	11.0	10.3
Min	55	63	55
Median	71.0	68.0	71.0
Max	93	96	96
Baseline Systolic Blood Pressure (mmHg)			
n	16	7	23
Mean	137.4	136.6	137.2
SD	14.7	9.9	13.2
Min	113	125	113
Median	142.5	131.0	142.0
Max	156	148	156
Baseline Diastolic Blood Pressure (mmHg)			
n	16	7	23
Mean	65.1	66.4	65.5
SD	12.7	8.9	11.5
Min	50	50	50
Median	64.5	69.0	68.0
Max	94	76	94
Baseline total iron binding capacity (umol/L)			
n	16	7	23
Mean	47.1	43.8	46.1
SD	4.4	5.3	4.8
Min	40	37	37
Median	47.2	41.4	46.6
Max	56	51	56
Baseline unsaturated iron binding capacity (umol/L)			
n	16	7	23
Mean	33.8	30.3	32.8
SD	6.5	7.9	7.0
Min	22	20	20
Median	34.6	28.3	34.2
Max	48	40	48
Baseline Transferrin Saturation (%)			
n	16	7	23
Mean	28.5	31.3	29.3
SD	10.4	12.2	10.8
Min	13	20	13
Median	27.5	24.0	26.9
Max	49	53	53

	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
Baseline Transferrin Saturation (%) group			
< 20	4 (25.0%)	0	4 (17.4%)
>= 20	12 (75.0%)	7 (100.0%)	19 (82.6%)
Baseline Hepcidin (ng/mL)			
n	16	7	23
Mean	51.5	60.9	54.3
SD	24.4	27.4	25.1
Min	24	29	24
Median	46.9	56.7	48.4
Max	114	110	114
Baseline total iron (ug/dL)			
n	16	7	23
Mean	74.2	75.0	74.4
SD	24.8	25.6	24.5
Min	31	50	31
Median	77.0	64.0	75.0
Max	124	121	124
Baseline ferritin (ng/mL)			
n	16	7	23
Mean	125.2	205.6	149.7
SD	83.5	194.5	128.5
Min	38	65	38
Median	97.6	135.0	98.1
Max	299	601	601
Baseline Ferritin (ng/mL) group			
< 100	9 (56.3%)	3 (42.9%)	12 (52.2%)
>= 100	7 (43.8%)	4 (57.1%)	11 (47.8%)
Baseline Vitamin B12 (pmol/L)			
n	15	6	21
Mean	256.9	288.7	266.0
SD	66.9	225.4	126.7
Min	137	167	137
Median	251.6	201.8	244.2
Max	336	745	745
Baseline folate (nmol/L)			
n	16	7	23
Mean	81.0	103.7	87.9
SD	233.7	209.4	222.1
Min	10	12	10
Median	21.3	25.2	22.7
Max	956	578	956
Baseline Potassium (mmol/L) in Serum			
n	16	7	23
Mean	4.65	4.73	4.67
SD	0.66	0.94	0.73
Min	3.5	3.4	3.4
Median	4.55	4.50	4.50
Max	5.6	6.3	6.3
Baseline Hemoglobin A1C (%) in Blood - Calculated			
n	16	7	23
Mean	5.80	5.71	5.77
SD	0.44	0.20	0.38
Min	5.2	5.5	5.2
Median	5.85	5.70	5.80
Max	6.5	6.0	6.5
Baseline LDL Cholesterol (mg/dL) in Serum			
n	16	7	23
Mean	112.9	92.3	106.7
SD	35.1	30.8	34.5
Min	54	35	35
Median	115.0	98.0	104.0
Max	161	125	161
Baseline HDL Cholesterol (mg/dL) in Serum			
n	16	7	23
Mean	46.8	49.0	47.5
SD	13.3	9.0	12.0
Min	31	41	31
Median	44.5	47.0	46.0
Max	80	68	80

	Molidustat N=16 (100%)	Darbepoetin alfa N=7 (100%)	Total N=23 (100%)
Baseline Triglycerides (mg/dL) in Serum			
n	16	7	23
Mean	156.6	135.9	150.3
SD	63.3	60.9	62.0
Min	58	50	50
Median	150.5	136.0	137.0
Max	299	221	299
Baseline C Reactive Protein (mg/dL) in Serum			
n	16	7	23
Mean	0.315	0.103	0.250
SD	0.561	0.115	0.478
Min	0.03	0.02	0.02
Median	0.150	0.080	0.110
Max	2.31	0.35	2.31
Baseline Erythropoietin (IU/L) in Serum			
n	16	0	16
Mean	10.509	.	10.509
SD	4.126	.	4.126
Min	4.53		4.53
Median	9.855	.	9.855
Max	17.66		17.66

Median: based on safety analysis set.
ESA treatment: Epoetin alfa (including Epoetin kappa) , Epoetin beta, Darbepoetin alfa and Epoetin beta pegol.
Duration of washout (week): 12 (week) was imputed for the subjects who did not receive ESA.
Central mean screening Hb level: Mean of last two Hb in screening period

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表2.7.3.6- 2	5.3.5.3.5 Ph2_adhoc15261_1 Table 11.2	
表2.7.3.6- 3	5.3.5.1.6 PH-404488Table14.1.5/7	5.3.5.1.9 Table 14.1.5 / 7
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表2.7.3.6- 22	5.3.5.3.3 IA-36w-3 part2/Table 1.1/11	5.3.5.3.7 IA 52w-2 Table 1.5 / 5
表2.7.3.6- 23	5.3.5.3.3 IA-36w-3 part2/Table 1.1/12	5.3.5.3.7 IA 52w-2 Table 1.7 / 5

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表2.7.3.6- 25	5.3.5.1.8 PH-40450 Table14.1.5/7	5.3.5.1.11 Table 14.1.5 / 7
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表2.7.3.6- 64	5.3.5.3.3 IA-36w-3 part1/1.2/1 DAの7.5cutoff	5.3.5.3.7 IA 52w-2 Table 1.6 / 3
表2.7.3.6- 65	5.3.5.3.3 IA-36w-3 part1/1.2/1 Pegolの6.25cutoff	5.3.5.3.7 IA 52w-2 Table 1.6 / 3
表2.7.3.6- 66	5.3.5.3.3 IA-36w-3 part1/1.2/4 DA/PegolのTotal	5.3.5.3.7 IA 52w-2 Table 1.5 / 2
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表2.7.3.6- 70	5.3.5.3.4 IA-36w-4 Table 1/24 DAのTotal/7.5cutoff PegolのTotal/6.25cutoff	5.3.5.3.7 IA 52w-2 Table 1.11 / 3
表2.7.3.6- 71	5.3.5.3.3 IA-36w-3 part1/Table 1.2/2 DA/Pegol/EPOのTotal	5.3.5.3.7 IA 52w-2 Table 1.6 / 4
表2.7.3.6- 72	5.3.5.3.3 IA-36w-3 part1/Table 1.2/2 DAの15cutoff	5.3.5.3.7 IA 52w-2 Table 1.6 / 4
表2.7.3.6- 73	5.3.5.3.3 IA-36w-3 part1/Table 1.2/2 Pegolの15.625cutoff	5.3.5.3.7 IA 52w-2 Table 1.6 / 4
表2.7.3.6- 74	5.3.5.3.3 IA-36w-3 part1/Table 1.2/2 EPOの3000cutoff	5.3.5.3.7 IA 52w-2 Table 1.6 / 4
表2.7.3.6- 75	5.3.5.3.3 IA-36w-3 part1/Table 1.2/5 DA/Pegol/EPOのTotal	5.3.5.3.7 IA 52w-2 Table 1.5 / 3
表2.7.3.6- 76	5.3.5.3.3 IA-36w-3 part1/Table 1.2/5 DAの15cutoff	5.3.5.3.7 IA 52w-2 Table 1.5 / 3
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表2.7.3.6- 78	5.3.5.3.3 IA-36w-3 part1/Table 1.2/5 EPOの3000cutoff	5.3.5.3.7 IA 52w-2 Table 1.5 / 3
表2.7.3.6- 79	5.3.5.3.4 IA-36w-4 Table 1/22 DAのTotal/15cutoff PegolのTotal/15.625cutoff EPOのTotal/3000cutoff	5.3.5.3.7 IA 52w-2 Table 1.11 / 2
表2.7.3.6- 80	5.3.5.3.4 IA-36w-4 Table 1/25 DAのTotal/15cutoff PegolのTotal/15.625cutoff EPOのTotal/3000cutoff	5.3.5.3.7 IA 52w-2 Table 1.11 / 4
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図2.7.3.6- 23	5.3.5.3.3 IA-36w-3　part1/Figure 1.2/1 DAの7.5cutoff	5.3.5.3.7 IA 52w-2 Figure 1.6 / 3

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図2.7.3.6- 24	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/1 Pegolの6.25cutoff	5.3.5.3.7 IA 52w-2 Figure 1.6 / 3
図2.7.3.6- 25	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/4 DA/PegolのTotal	5.3.5.3.7 IA 52w-2 Figure 1.5 / 2
図2.7.3.6- 26	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/4 DAの7.5cutoff	5.3.5.3.7 IA 52w-2 Figure 1.5 / 2
図2.7.3.6- 27	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/4 Pegolの6.25cutoff	5.3.5.3.7 IA 52w-2 Figure 1.5 / 2
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図2.7.3.6- 31	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/2 DAの15cutoff	5.3.5.3.7 IA 52w-2 Figure 1.6 / 4
図2.7.3.6- 32	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/2 Pegolの15.625cutoff	5.3.5.3.7 IA 52w-2 Figure 1.6 / 4
図2.7.3.6- 33	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/2 EPOの3000cutoff	5.3.5.3.7 IA 52w-2 Figure 1.6 / 4
図2.7.3.6- 34	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/5 DA/Pegol/EPOのTotal	5.3.5.3.7 IA 52w-2 Figure 1.5 / 3
図2.7.3.6- 35	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/5 DAの15cutoff	5.3.5.3.7 IA 52w-2 Figure 1.5 / 3
図2.7.3.6- 36	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/5 Pegolの15.625cutoff	5.3.5.3.7 IA 52w-2 Figure 1.5 / 3
図2.7.3.6- 37	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/5 EPOの3000cutoff	5.3.5.3.7 IA 52w-2 Figure 1.5 / 3
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図2.7.3.6- 42	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/3 Pegolの18.75cutoff	

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図2.7.3.6- 43	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/6 DA/PegolのTotal	
図2.7.3.6- 44	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/6 DAの30cutoff	
図2.7.3.6- 45	5.3.5.3.3 IA-36w-3	part1/Figure 1.2/6 Pegolの18.75cutoff	
図2.7.3.6- 46	5.3.5.3.4 IA-36w-4	Figure 1/12 DAのTotal/30cutoff PegolのTotal/18.75cutoff	
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