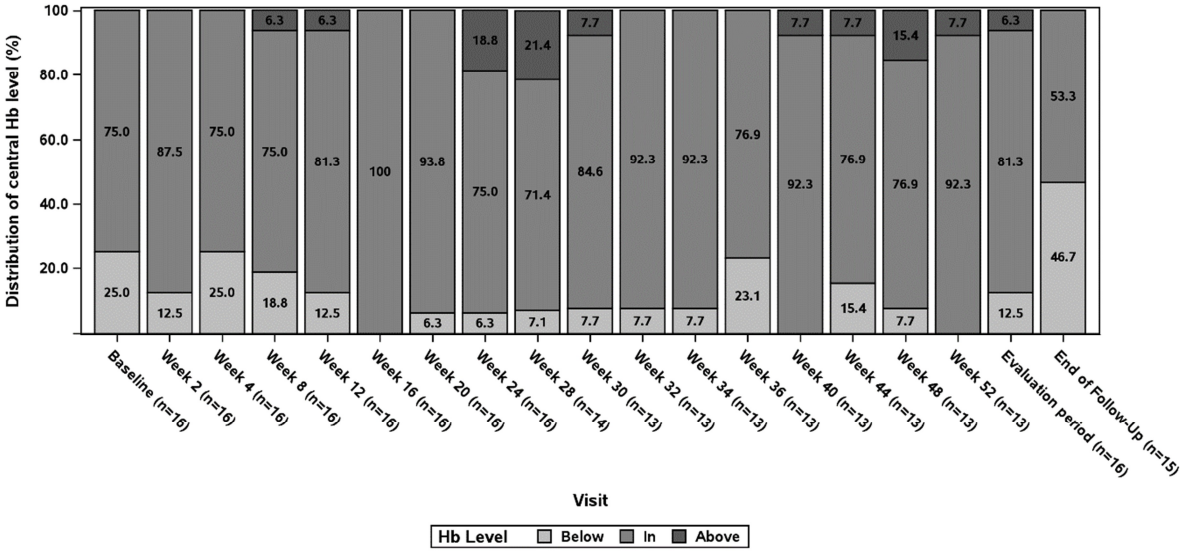
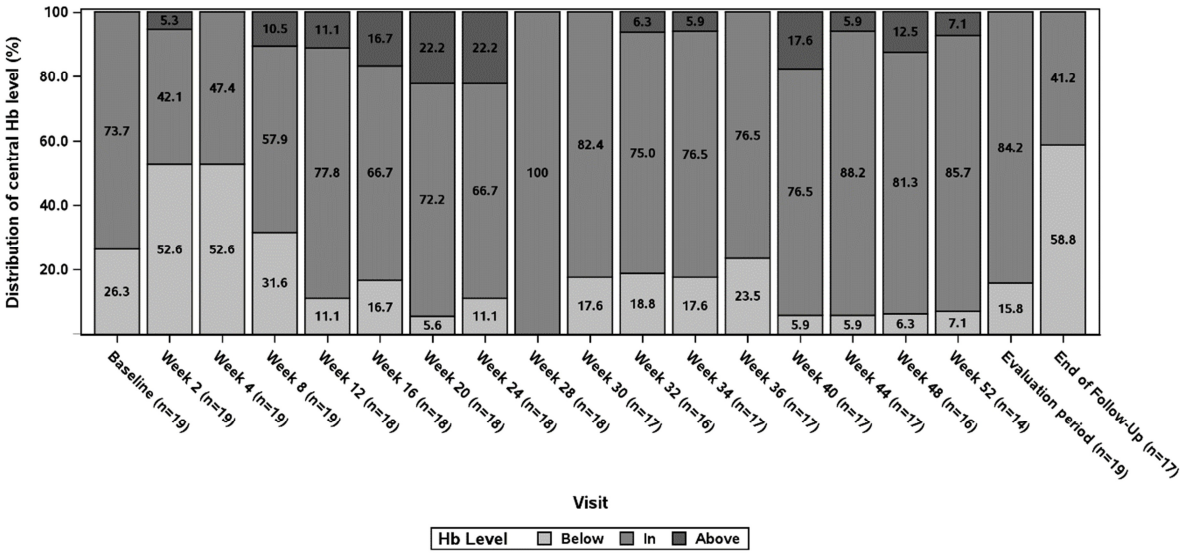
Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: Low (<= 7.5 ug/week)
Planned Treatment: Molidustat

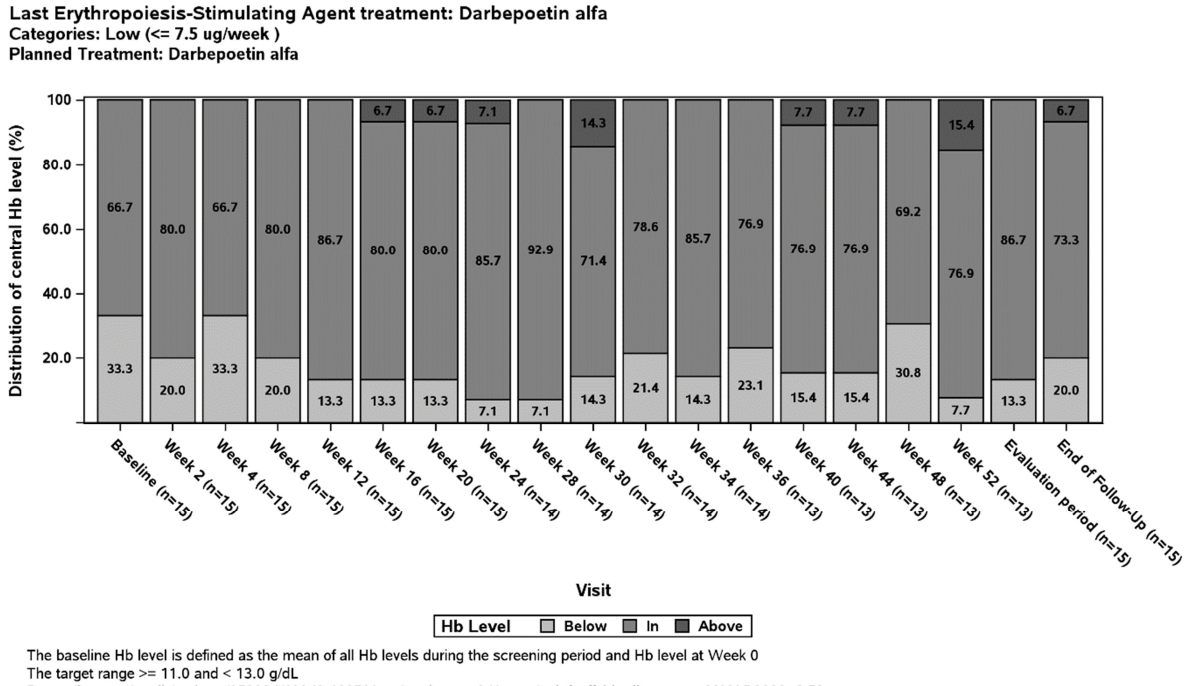


The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
The target range >= 11.0 and < 13.0 g/dL

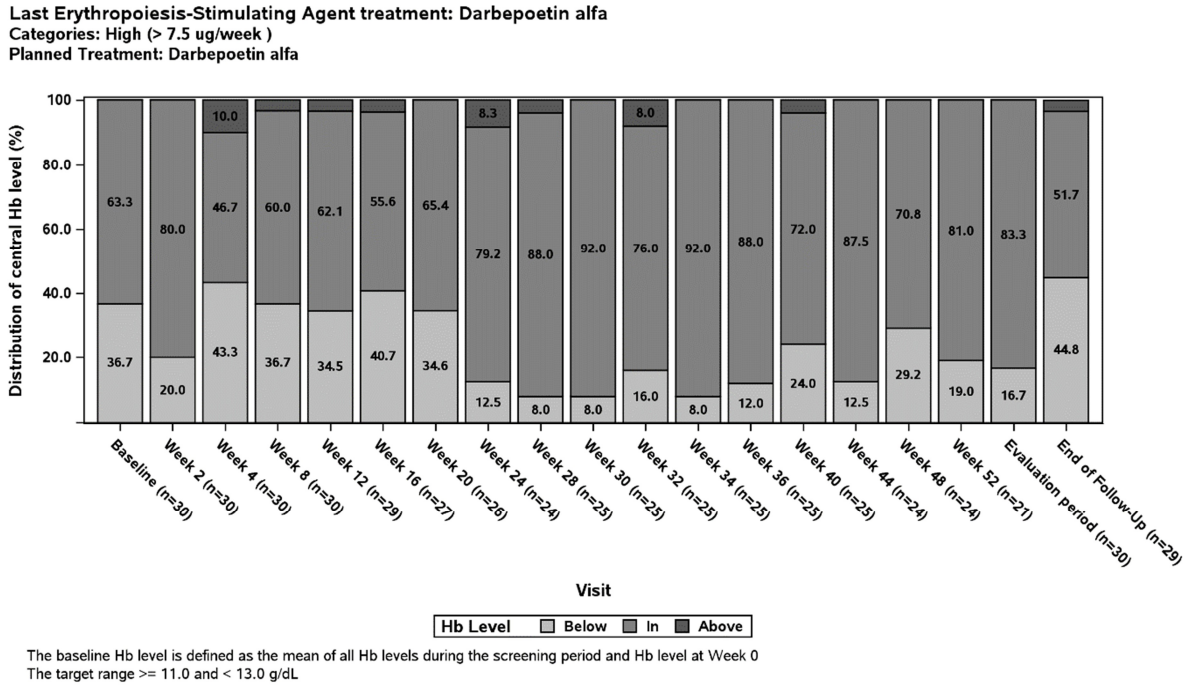
Last Erythropoiesis-Stimulating Agent treatment: Darbepoetin alfa
Categories: High (> 7.5 ug/week)
Planned Treatment: Molidustat



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



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



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

図 2.7.3.6-26 前治療として使用した DA の用量別（低用量又は高用量）の各来院時の Hb 値が目標 Hb 値内、上限以上又は下限未満に該当する被験者の割合（試験 19350、FAS）

表 2.7.3.6-67 前治療として使用した DA の用量別（低用量又は高用量）の各来院時の Hb 値が目標 Hb 値内、上限以上又は下限未満に該当する被験者の割合（試験 19350、FAS）

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

Visit	Hb Level	Molidustat (N=16)	Darbepoetin alfa (N=15)
Baseline	n	16	15
	Below	4 (25.0%)	5 (33.3%)
	In	12 (75.0%)	10 (66.7%)
	Above	0 (0.0%)	0 (0.0%)
Week 2	n	16	15
	Below	2 (12.5%)	3 (20.0%)
	In	14 (87.5%)	12 (80.0%)
	Above	0 (0.0%)	0 (0.0%)
Week 4	n	16	15
	Below	4 (25.0%)	5 (33.3%)
	In	12 (75.0%)	10 (66.7%)
	Above	0 (0.0%)	0 (0.0%)
Week 8	n	16	15
	Below	3 (18.8%)	3 (20.0%)
	In	12 (75.0%)	12 (80.0%)
	Above	1 (6.3%)	0 (0.0%)
Week 12	n	16	15
	Below	2 (12.5%)	2 (13.3%)
	In	13 (81.3%)	13 (86.7%)
	Above	1 (6.3%)	0 (0.0%)
Week 16	n	16	15
	Below	0 (0.0%)	2 (13.3%)
	In	16 (100.0%)	12 (80.0%)
	Above	0 (0.0%)	1 (6.7%)
Week 20	n	16	15
	Below	1 (6.3%)	2 (13.3%)
	In	15 (93.8%)	12 (80.0%)
	Above	0 (0.0%)	1 (6.7%)
Week 24	n	16	14
	Below	1 (6.3%)	1 (7.1%)
	In	12 (75.0%)	12 (85.7%)
	Above	3 (18.8%)	1 (7.1%)
Week 28	n	14	14
	Below	1 (7.1%)	1 (7.1%)
	In	10 (71.4%)	13 (92.9%)
	Above	3 (21.4%)	0 (0.0%)
Week 30	n	13	14
	Below	1 (7.7%)	2 (14.3%)
	In	11 (84.6%)	10 (71.4%)
	Above	1 (7.7%)	2 (14.3%)
Week 32	n	13	14
	Below	1 (7.7%)	3 (21.4%)
	In	12 (92.3%)	11 (78.6%)
	Above	0 (0.0%)	0 (0.0%)
Week 34	n	13	14
	Below	1 (7.7%)	2 (14.3%)
	In	12 (92.3%)	12 (85.7%)
	Above	0 (0.0%)	0 (0.0%)
Week 36	n	13	13
	Below	3 (23.1%)	3 (23.1%)
	In	10 (76.9%)	10 (76.9%)
	Above	0 (0.0%)	0 (0.0%)
Week 40	n	13	13
	Below	0 (0.0%)	2 (15.4%)

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

Visit	Hb Level	Molidustat (N=16)	Darbepoetin alfa (N=15)
	In	12 (92.3%)	10 (76.9%)
	Above	1 (7.7%)	1 (7.7%)
Week 44	n	13	13
	Below	2 (15.4%)	2 (15.4%)
	In	10 (76.9%)	10 (76.9%)
	Above	1 (7.7%)	1 (7.7%)
Week 48	n	13	13
	Below	1 (7.7%)	4 (30.8%)
	In	10 (76.9%)	9 (69.2%)
	Above	2 (15.4%)	0 (0.0%)
Week 52	n	13	13
	Below	0 (0.0%)	1 (7.7%)
	In	12 (92.3%)	10 (76.9%)
	Above	1 (7.7%)	2 (15.4%)
Evaluation period	n	16	15
	Below	2 (12.5%)	2 (13.3%)
	In	13 (81.3%)	13 (86.7%)
	Above	1 (6.3%)	0 (0.0%)
End of Follow-Up	n	15	15
	Below	7 (46.7%)	3 (20.0%)
	In	8 (53.3%)	11 (73.3%)
	Above	0 (0.0%)	1 (6.7%)

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

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

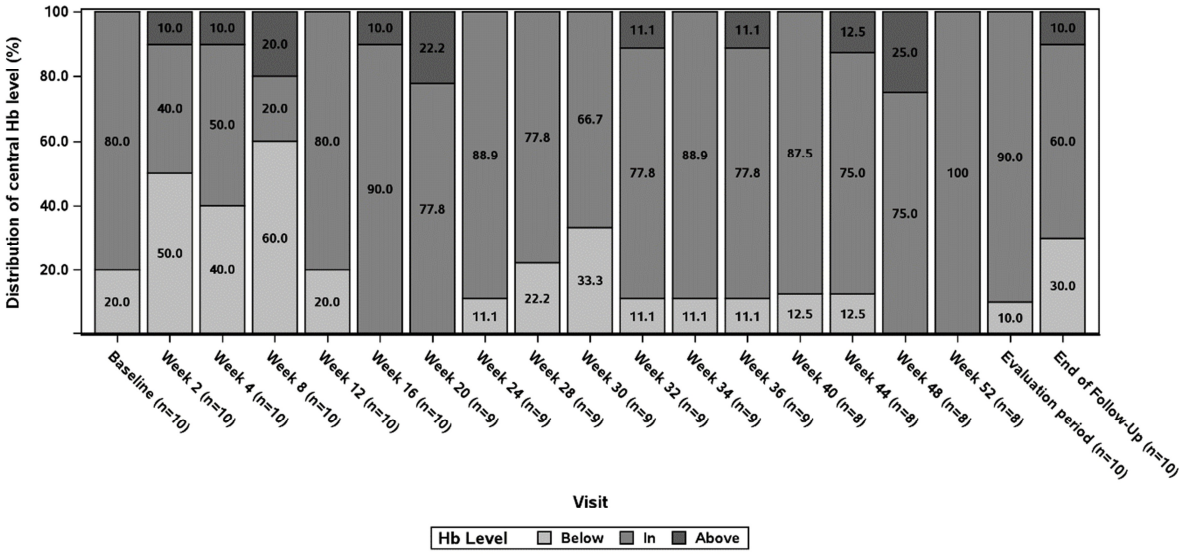
Visit	Hb Level	Molidustat (N=19)	Darbepoetin alfa (N=30)
Baseline	n	19	30
	Below	5 (26.3%)	11 (36.7%)
	In	14 (73.7%)	19 (63.3%)
	Above	0 (0.0%)	0 (0.0%)
Week 2	n	19	30
	Below	10 (52.6%)	6 (20.0%)
	In	8 (42.1%)	24 (80.0%)
	Above	1 (5.3%)	0 (0.0%)
Week 4	n	19	30
	Below	10 (52.6%)	13 (43.3%)
	In	9 (47.4%)	14 (46.7%)
	Above	0 (0.0%)	3 (10.0%)
Week 8	n	19	30
	Below	6 (31.6%)	11 (36.7%)
	In	11 (57.9%)	18 (60.0%)
	Above	2 (10.5%)	1 (3.3%)
Week 12	n	18	29
	Below	2 (11.1%)	10 (34.5%)
	In	14 (77.8%)	18 (62.1%)
	Above	2 (11.1%)	1 (3.4%)
Week 16	n	18	27
	Below	3 (16.7%)	11 (40.7%)
	In	12 (66.7%)	15 (55.6%)
	Above	3 (16.7%)	1 (3.7%)
Week 20	n	18	26
	Below	1 (5.6%)	9 (34.6%)
	In	13 (72.2%)	17 (65.4%)
	Above	4 (22.2%)	0 (0.0%)
Week 24	n	18	24
	Below	2 (11.1%)	3 (12.5%)
	In	12 (66.7%)	19 (79.2%)
	Above	4 (22.2%)	2 (8.3%)
Week 28	n	18	25
	Below	0 (0.0%)	2 (8.0%)
	In	18 (100.0%)	22 (88.0%)
	Above	0 (0.0%)	1 (4.0%)
Week 30	n	17	25
	Below	3 (17.6%)	2 (8.0%)
	In	14 (82.4%)	23 (92.0%)
	Above	0 (0.0%)	0 (0.0%)
Week 32	n	16	25
	Below	3 (18.8%)	4 (16.0%)
	In	12 (75.0%)	19 (76.0%)
	Above	1 (6.3%)	2 (8.0%)
Week 34	n	17	25
	Below	3 (17.6%)	2 (8.0%)
	In	13 (76.5%)	23 (92.0%)
	Above	1 (5.9%)	0 (0.0%)
Week 36	n	17	25
	Below	4 (23.5%)	3 (12.0%)
	In	13 (76.5%)	22 (88.0%)
	Above	0 (0.0%)	0 (0.0%)
Week 40	n	17	25
	Below	1 (5.9%)	6 (24.0%)
	In	13 (76.5%)	18 (72.0%)
	Above	3 (17.6%)	1 (4.0%)

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

Visit	Hb Level	Molidustat (N=19)	Darbepoetin alfa (N=30)
Week 44	n	17	24
	Below	1 (5.9%)	3 (12.5%)
	In	15 (88.2%)	21 (87.5%)
	Above	1 (5.9%)	0 (0.0%)
Week 48	n	16	24
	Below	1 (6.3%)	7 (29.2%)
	In	13 (81.3%)	17 (70.8%)
	Above	2 (12.5%)	0 (0.0%)
Week 52	n	14	21
	Below	1 (7.1%)	4 (19.0%)
	In	12 (85.7%)	17 (81.0%)
	Above	1 (7.1%)	0 (0.0%)
Evaluation period	n	19	30
	Below	3 (15.8%)	5 (16.7%)
	In	16 (84.2%)	25 (83.3%)
	Above	0 (0.0%)	0 (0.0%)
End of Follow-Up	n	17	29
	Below	10 (58.8%)	13 (44.8%)
	In	7 (41.2%)	15 (51.7%)
	Above	0 (0.0%)	1 (3.4%)

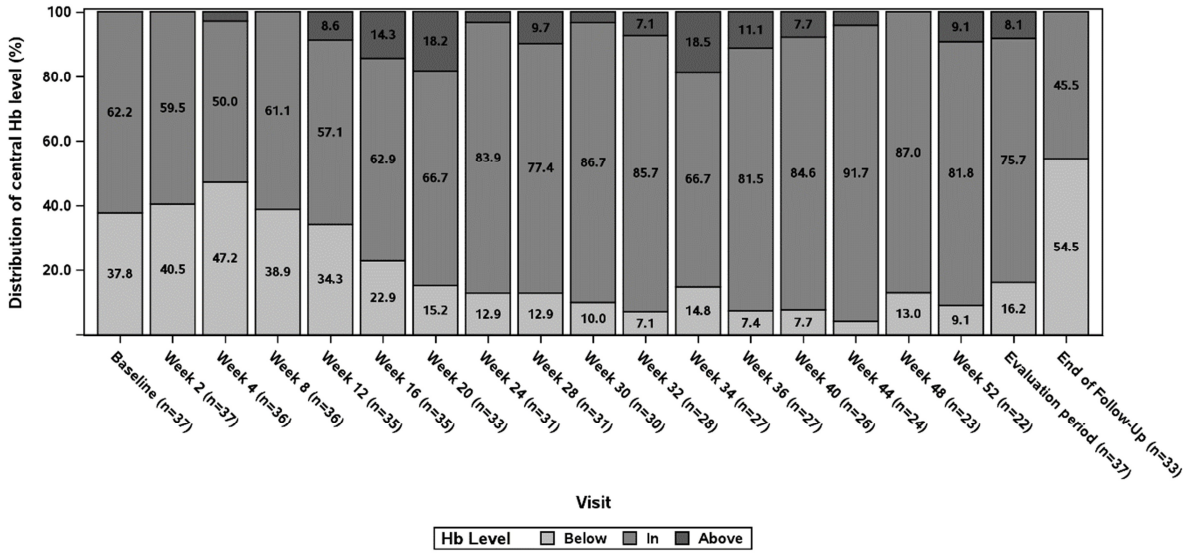
The target range >= 11.0 and < 13.0 g/dL
n: The number of subjects who had a valid Hb level
The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0

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

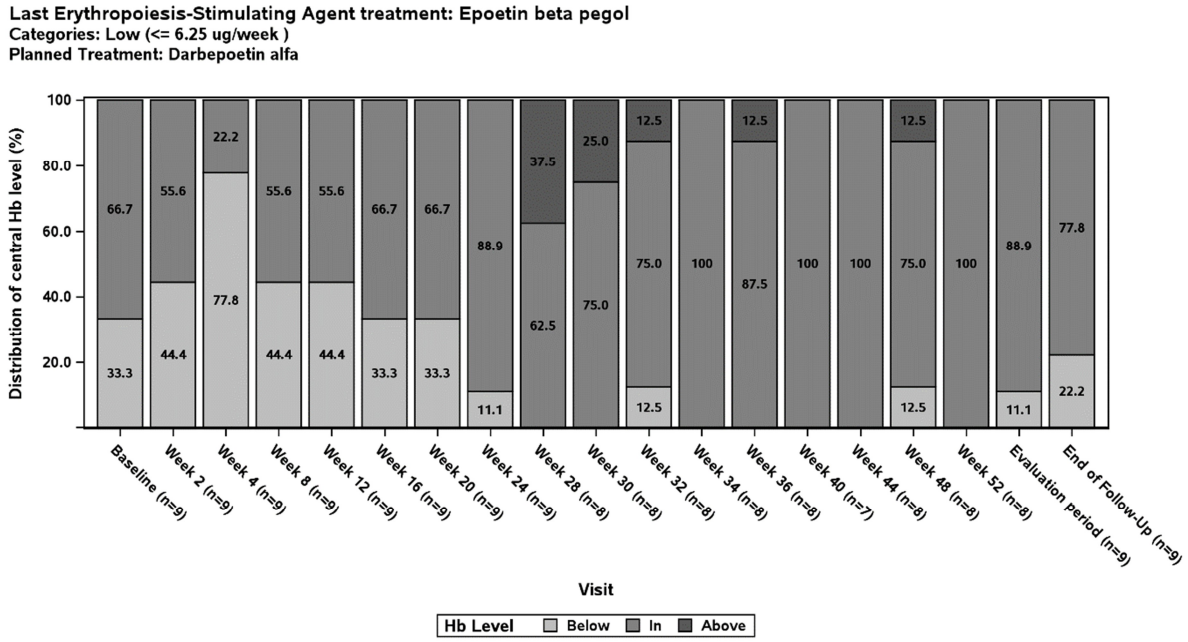


The baseline Hb level is defined as the mean of all Hb levels during the screening period and Hb level at Week 0
The target range >= 11.0 and < 13.0 g/dL

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



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



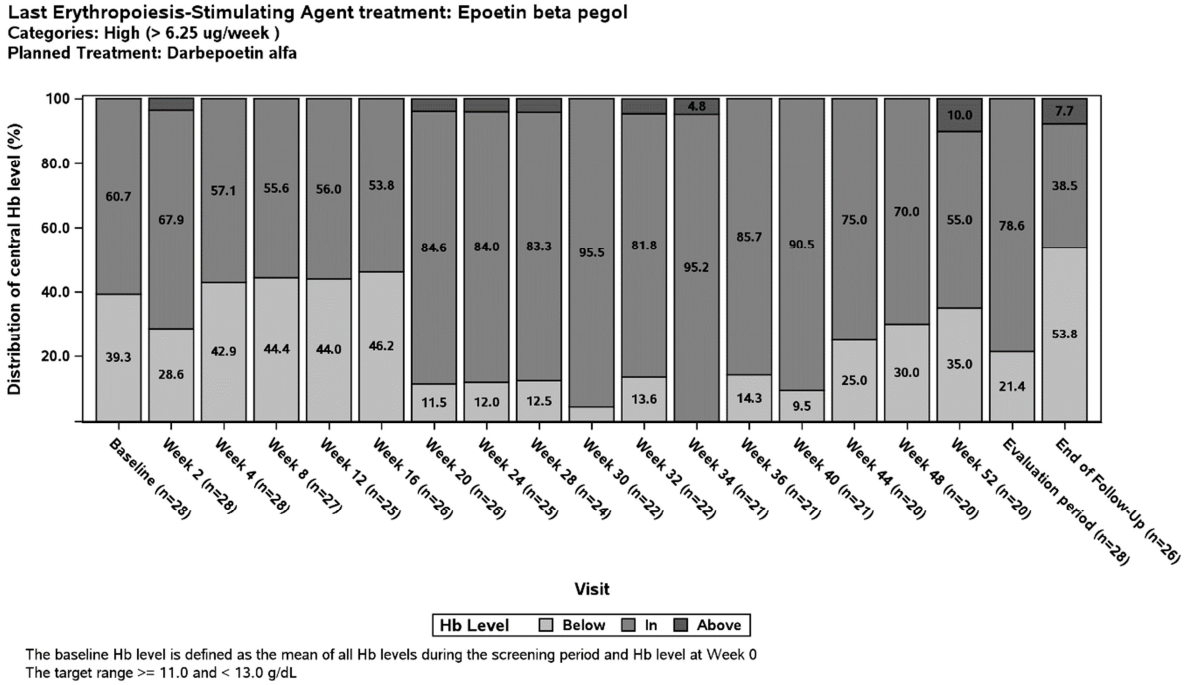


図 2.7.3.6-27 前治療として使用した PEGOL の用量別（低用量又は高用量）の各来院時の Hb 値が目標 Hb 値内、上限以上又は下限未満に該当する被験者の割合（試験 19350、FAS）

表 2.7.3.6-68 前治療として使用した PEGOL の用量（低用量又は高用量）の各来院時の Hb 値が目標 Hb 値内、上限以上又は下限未満に該当する被験者の割合（試験 19350、FAS）

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

Visit	Hb Level	Molidustat (N=10)	Darbepoetin alfa (N=9)
Baseline	n	10	9
	Below	2 (20.0%)	3 (33.3%)
	In	8 (80.0%)	6 (66.7%)
	Above	0 (0.0%)	0 (0.0%)
Week 2	n	10	9
	Below	5 (50.0%)	4 (44.4%)
	In	4 (40.0%)	5 (55.6%)
	Above	1 (10.0%)	0 (0.0%)
Week 4	n	10	9
	Below	4 (40.0%)	7 (77.8%)
	In	5 (50.0%)	2 (22.2%)
	Above	1 (10.0%)	0 (0.0%)
Week 8	n	10	9
	Below	6 (60.0%)	4 (44.4%)
	In	2 (20.0%)	5 (55.6%)
	Above	2 (20.0%)	0 (0.0%)
Week 12	n	10	9
	Below	2 (20.0%)	4 (44.4%)
	In	8 (80.0%)	5 (55.6%)
	Above	0 (0.0%)	0 (0.0%)
Week 16	n	10	9
	Below	0 (0.0%)	3 (33.3%)
	In	9 (90.0%)	6 (66.7%)
	Above	1 (10.0%)	0 (0.0%)
Week 20	n	9	9
	Below	0 (0.0%)	3 (33.3%)
	In	7 (77.8%)	6 (66.7%)
	Above	2 (22.2%)	0 (0.0%)
Week 24	n	9	9
	Below	1 (11.1%)	1 (11.1%)
	In	8 (88.9%)	8 (88.9%)
	Above	0 (0.0%)	0 (0.0%)
Week 28	n	9	8
	Below	2 (22.2%)	0 (0.0%)
	In	7 (77.8%)	5 (62.5%)
	Above	0 (0.0%)	3 (37.5%)
Week 30	n	9	8
	Below	3 (33.3%)	0 (0.0%)
	In	6 (66.7%)	6 (75.0%)
	Above	0 (0.0%)	2 (25.0%)
Week 32	n	9	8
	Below	1 (11.1%)	1 (12.5%)
	In	7 (77.8%)	6 (75.0%)
	Above	1 (11.1%)	1 (12.5%)
Week 34	n	9	8
	Below	1 (11.1%)	0 (0.0%)
	In	8 (88.9%)	8 (100.0%)
	Above	0 (0.0%)	0 (0.0%)
Week 36	n	9	8
	Below	1 (11.1%)	0 (0.0%)
	In	7 (77.8%)	7 (87.5%)
	Above	1 (11.1%)	1 (12.5%)

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

Visit	Hb Level	Molidustat (N=10)	Darbepoetin alfa (N=9)
Week 40	n	8	7
	Below	1 (12.5%)	0 (0.0%)
	In	7 (87.5%)	7 (100.0%)
	Above	0 (0.0%)	0 (0.0%)
Week 44	n	8	8
	Below	1 (12.5%)	0 (0.0%)
	In	6 (75.0%)	8 (100.0%)
	Above	1 (12.5%)	0 (0.0%)
Week 48	n	8	8
	Below	0 (0.0%)	1 (12.5%)
	In	6 (75.0%)	6 (75.0%)
	Above	2 (25.0%)	1 (12.5%)
Week 52	n	8	8
	Below	0 (0.0%)	0 (0.0%)
	In	8 (100.0%)	8 (100.0%)
	Above	0 (0.0%)	0 (0.0%)
Evaluation period	n	10	9
	Below	1 (10.0%)	1 (11.1%)
	In	9 (90.0%)	8 (88.9%)
	Above	0 (0.0%)	0 (0.0%)
End of Follow-Up	n	10	9
	Below	3 (30.0%)	2 (22.2%)
	In	6 (60.0%)	7 (77.8%)
	Above	1 (10.0%)	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 all Hb levels during the screening period and Hb level at Week 0

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

Visit	Hb Level	Molidustat (N=37)	Darbepoetin alfa (N=28)
Baseline	n	37	28
	Below	14 (37.8%)	11 (39.3%)
	In	23 (62.2%)	17 (60.7%)
	Above	0 (0.0%)	0 (0.0%)
Week 2	n	37	28
	Below	15 (40.5%)	8 (28.6%)
	In	22 (59.5%)	19 (67.9%)
	Above	0 (0.0%)	1 (3.6%)
Week 4	n	36	28
	Below	17 (47.2%)	12 (42.9%)
	In	18 (50.0%)	16 (57.1%)
	Above	1 (2.8%)	0 (0.0%)
Week 8	n	36	27
	Below	14 (38.9%)	12 (44.4%)
	In	22 (61.1%)	15 (55.6%)
	Above	0 (0.0%)	0 (0.0%)
Week 12	n	35	25
	Below	12 (34.3%)	11 (44.0%)
	In	20 (57.1%)	14 (56.0%)
	Above	3 (8.6%)	0 (0.0%)
Week 16	n	35	26
	Below	8 (22.9%)	12 (46.2%)
	In	22 (62.9%)	14 (53.8%)
	Above	5 (14.3%)	0 (0.0%)
Week 20	n	33	26
	Below	5 (15.2%)	3 (11.5%)
	In	22 (66.7%)	22 (84.6%)
	Above	6 (18.2%)	1 (3.8%)
Week 24	n	31	25
	Below	4 (12.9%)	3 (12.0%)
	In	26 (83.9%)	21 (84.0%)
	Above	1 (3.2%)	1 (4.0%)
Week 28	n	31	24
	Below	4 (12.9%)	3 (12.5%)
	In	24 (77.4%)	20 (83.3%)
	Above	3 (9.7%)	1 (4.2%)
Week 30	n	30	22
	Below	3 (10.0%)	1 (4.5%)
	In	26 (86.7%)	21 (95.5%)
	Above	1 (3.3%)	0 (0.0%)
Week 32	n	28	22
	Below	2 (7.1%)	3 (13.6%)
	In	24 (85.7%)	18 (81.8%)
	Above	2 (7.1%)	1 (4.5%)
Week 34	n	27	21
	Below	4 (14.8%)	0 (0.0%)
	In	18 (66.7%)	20 (95.2%)
	Above	5 (18.5%)	1 (4.8%)
Week 36	n	27	21
	Below	2 (7.4%)	3 (14.3%)
	In	22 (81.5%)	18 (85.7%)
	Above	3 (11.1%)	0 (0.0%)
Week 40	n	26	21
	Below	2 (7.7%)	2 (9.5%)
	In	22 (84.6%)	19 (90.5%)

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

Visit	Hb Level	Molidustat (N=37)	Darbepoetin alfa (N=28)
	Above	2 (7.7%)	0 (0.0%)
Week 44	n	24	20
	Below	1 (4.2%)	5 (25.0%)
	In	22 (91.7%)	15 (75.0%)
	Above	1 (4.2%)	0 (0.0%)
Week 48	n	23	20
	Below	3 (13.0%)	6 (30.0%)
	In	20 (87.0%)	14 (70.0%)
	Above	0 (0.0%)	0 (0.0%)
Week 52	n	22	20
	Below	2 (9.1%)	7 (35.0%)
	In	18 (81.8%)	11 (55.0%)
	Above	2 (9.1%)	2 (10.0%)
Evaluation period	n	37	28
	Below	6 (16.2%)	6 (21.4%)
	In	28 (75.7%)	22 (78.6%)
	Above	3 (8.1%)	0 (0.0%)
End of Follow-Up	n	33	26
	Below	18 (54.5%)	14 (53.8%)
	In	15 (45.5%)	10 (38.5%)
	Above	0 (0.0%)	2 (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 all Hb levels during the screening period and Hb level at Week 0