

Further details of reports included in Table, “Pooled Venous Thromboembolism (VTE) Rates Among 4068 Thalidomide-Treated and 1081 Lenalidomide-Treated Patients With Multiple Myeloma.” The table includes all studies that were included in the JAMA letter as well as additional studies that did not fit into any of the treatment regimens included in the JAMA letter.

Table 1. Venous thromboembolism (VTE) rates (%) among thalidomide treated patients

	Disease	Agent(s) other than thalidomide	Prophylaxis	VTE rate (Patients with VTE/Total patients)	Control arm VTE rate (if applicable)	Reference	
Untreated multiple myeloma patients that received dexamethasone ± chemotherapy and no prophylaxis (14% (109/795))	Untreated multiple myeloma	Dexamethasone	No prophylaxis	23% (3/13)		Abdelkefi et al. 2005. Bone Marrow Transplant, 36: 193.	1
	Untreated multiple myeloma	Dexamethasone	No prophylaxis	15% (15/100)	2% (2/100)	Cavo et al. Blood 2005; 106(1):35-9	2
	Untreated multiple myeloma	Dexamethasone	No prophylaxis	8% (7/93)		Ludwig et al. 2005. Proc. Am. Soc. Clin. Oncol. (abstr. 6537)	3
	Untreated multiple myeloma	Dexamethasone	No prophylaxis	7% (3/45)		Osman et al. N Engl J Med 2001;344(25):1951-2.	4
	Untreated multiple myeloma	Dexamethasone	No prophylaxis	12% (6/50)		Rajkumar et al. J Clin Oncol 2002;20(21):4319-23	5
	Untreated multiple myeloma	Dexamethasone	No prophylaxis	15% (36/235)	4% (10/235)	Rajkumar et al. J Clin Oncol 2006;24(18S):7517	6
	Untreated multiple myeloma	Dexamethasone	No prophylaxis	15% (6/40)		Klueppelberg et al. J Clin Oncol 2005;23(16S):6697	7
	Untreated multiple myeloma	Dexamethasone	No prophylaxis	20% (20/102)	3% (3/102)	Rajkumar et al. J Clin Oncol 2006;24(3):431-36	8
	Untreated multiple myeloma	Dexamethasone, melphalan	No prophylaxis	9% (4/46)		Dimopoulos et al. Haematologica 2006;91(2):252-4.	9
	Untreated multiple myeloma	Dexamethasone, epirubicin, vincristine	No prophylaxis	26% (8/31)		Schutt et al. Eur J Haematol 2005;74(1):40-6.	10
	Untreated multiple myeloma	Dexamethasone, cisplatin, cyclophosphamide, etoposide	No prophylaxis	3% (1/40)		Zangari et al. Blood 2002; 100(4):1168-71.	11

Untreated multiple myeloma patients that received dexamethasone ± chemotherapy and warfarin, 1 mg (15% (18/121))	Untreated multiple myeloma	Dexamethasone	Warfarin 1 mg	12% (10/81)		Cavo et al. Blood 2005; 106(1):35-9	12
	Untreated multiple myeloma	Dexamethasone	Warfarin 1 mg	25% (6/24)		Weber et al. J Clin Oncol 2003;21(1):16-19.	13
	Untreated multiple myeloma	Dexamethasone, vincristine, adriamycin	Warfarin 1 mg	13% (2/16)		Chanan-Khan et al. Blood 2004; 104: Abstract 3463	14
Untreated multiple myeloma patients that received dexamethasone ± chemotherapy and warfarin 2-3 INR or LMWH (0%(0/63))	Untreated multiple myeloma	Dexamethasone	Warfarin 2-3 INR or LMWH	0% (0/47)		Abdelkefi et al. 2005. Bone Marrow Transplant, 36: 193.	1
	Untreated multiple myeloma	Dexamethasone	Warfarin 2-3 INR or LMWH	0% (0/16)		Weber et al. J Clin Oncol 2003;21(1):16-9.	13
Relapsed/refractory multiple myeloma patients that received dexamethasone ± chemotherapy and no prophylaxis (6%(25/454))	Relapsed or refractory multiple myeloma	Dexamethasone	No prophylaxis	9% (4/47)		Anagnostopoulos et al. Br J Haematol 2003; 121(5):768-77	15
	Relapsed or refractory multiple myeloma	Dexamethasone	No prophylaxis	7% (3/44)		Dimopoulos et al. Ann Oncol 2001;12(7):991-5.	16
	Relapsed or refractory multiple myeloma	Dexamethasone	No prophylaxis	8% (2/25)		Huang et al. Ann Hematol 2003; 82: 558-565	17

	Relapsed or refractory multiple myeloma	Dexamethasone	No prophylaxis	2% (2/120)		Palumbo et al. The Hematology Journal (2004) 5, 318-324.	18
	Relapsed or refractory multiple myeloma	Dexamethasone	No prophylaxis	0% (0/20)		Tosi et al. Eur J Haematol 2004; 73: 98-103.	19
	Relapsed or refractory multiple myeloma	Dexamethasone, cyclophosphamide	No prophylaxis	2% (1/53)		Dimopoulos et al. Hematol J 2004;5(2):112-7.	20
	Relapsed or refractory multiple myeloma	Dexamethasone, cyclophosphamide	No prophylaxis	7% (5/71)		Garcia et al. Leukemia 2004;18(4):856-63.	21
	Relapsed or refractory multiple myeloma	Dexamethasone, cyclophosphamide	No prophylaxis	8% (5/60)		Kropff et al. Br J Haematol 2003;122(4):607-16	22
	Relapsed or refractory multiple myeloma	Dexamethasone, cytoxan, etoposide, cisplatinum	No prophylaxis	21% (3/14)		Urbauer et al. Blood 2002;99(11):4247-8	23
Relapsed/refractory multiple myeloma patients that received dexamethasone ± chemotherapy and warfarin, 1 mg (9%(8/85))	Relapsed or refractory multiple myeloma	Dexamethasone	Warfarin 1 mg	12% (6/52)		Kyriakou et al. Br J Haematol 2005;129(6):763-70	24
	Relapsed or refractory multiple myeloma	Dexamethasone, G3139	Warfarin 1 mg	6% (2/33)		Badros et al. J Clin Oncol 2005; 23(18):4089-99	25

Relapsed/refractory multiple myeloma patients that received dexamethasone ± chemotherapy and warfarin 2-3 INR or LMWH (8%(2/26))	Relapsed or refractory multiple myeloma	Dexamethasone	Warfarin 2-3 INR or LMWH	8% (2/26)		Wang et al. Am J Hematol 2005;79(3):194-7.	26
Relapsed/refractory multiple myeloma patients that received doxorubicin ± chemotherapy and no prophylaxis (12%(6/50))	Relapsed or refractory multiple myeloma	Doxorubicin	No prophylaxis	12% (6/50)		Offidani et al. Haematologica 2006;91(1):133-6	27
Untreated multiple myeloma patients that received dexamethasone, doxorubicin ± chemotherapy and no prophylaxis (24%(148/610))	Untreated multiple myeloma	Doxorubicin, dexamethasone	No prophylaxis	27% (4/15)		Osman et al. N Engl J Med 2001;344(25):1951-2.	4
	Untreated multiple myeloma	Doxorubicin, dexamethasone	No prophylaxis	28% (14/50)	4% (2/50)	Zangari et al. Blood 2001;98(5):1614-5.	28
	Untreated multiple myeloma	Doxorubicin, dexamethasone	No prophylaxis	30% (95/314)	17% (58/337)	Barlogie et al. N Engl J Med 2006; 354(10):1021-30	29

	Untreated multiple myeloma	Doxorubicin, dexamethasone, cisplatin, cyclophosphamide, etoposide	No prophylaxis	16% (31/192)		Zangari et al. Blood 2002; 100(4):1168-71.	11
	Untreated multiple myeloma	Vincristine, doxorubicin	No prophylaxis	10% (4/39)		Zervas et al. Ann Oncol 2004;15(1):134-8.	30
Untreated multiple myeloma patients that received dexamethasone, doxorubicin ± chemotherapy and aspirin (7% (3/45))	Untreated multiple myeloma	Doxorubicin, dexamethasone	Aspirin (81 mg/day)	7% (3/45)		Hassoun et al. Br J Haematol 2005;132:155-61.	31
Relapsed/refractory multiple myeloma patients that received dexamethasone, doxorubicin ± chemotherapy and no prophylaxis (17% (47/271))	Relapsed or refractory multiple myeloma	Doxorubicin, dexamethasone, cisplatin, cyclophosphamide, etoposide	No prophylaxis	16% (37/236)		Lee et al. J Clin Oncol 2003;21(14):2732-9	32
	Relapsed or refractory multiple myeloma	Doxorubicin, dexamethasone, vincristine, prednisone	No prophylaxis	40% (8/20)		Hussein. The Oncologist 2003;8(suppl 3):39-45.	33
	Relapsed or refractory multiple myeloma	Doxorubicin, dexamethasone, vincristine, prednisone, epoetin alfa	No prophylaxis	13% (2/15)		Hussein. The Oncologist 2003;8(suppl 3):39-45.	33

Untreated multiple myeloma patients that received dexamethasone, doxorubicin ± chemotherapy and LMWH (9%(19/211))	Untreated multiple myeloma	Doxorubicin, dexamethasone	LMWH	9% (19/211)	5% (11/201)	Minnema et al. Leukemia 2004;18(12):2044-6	34
Untreated multiple myeloma patients that received melphalan, prednisone ± chemotherapy and no prophylaxis (15% (43/287))	Untreated multiple myeloma	Melphalan, prednisone	No prophylaxis	16% (11/67)	0% (0/64)	Rus et al. J Thromb haemost 2004;2:2063-5	35
	Untreated multiple myeloma	Melphalan, prednisone	No prophylaxis	18% (9/49)		Palumbo et al. Cancer 2005;104(7):1428-33	36
	Untreated multiple myeloma	Melphalan, prednisone	No prophylaxis	19% (8/42)		Palumbo et al. J Clin Oncol 2004;2: 2063-5	37
	Untreated multiple myeloma	Melphalan, prednisone	No prophylaxis	12% (15/129)	2% (2/126)	Palumbo et al. Lancet 2006;367(9513):825-31	38
Untreated multiple myeloma patients that received melphalan, prednisone ± chemotherapy and LMWH (3% (2/64))	Untreated multiple myeloma	Melphalan, prednisone	LMWH	3% (2/64)		Palumbo et al. Lancet 2006;367(9513):825-30	38

Untreated multiple myeloma patients thalidomide monotherapy and no prophylaxis (3% (2/73))	Untreated multiple myeloma	Thalidomide monotherapy	No prophylaxis	0% (0/16)		Rajkumar et al. Leukemia (2001) 15, 1274-1276	39
	Untreated multiple myeloma	Thalidomide monotherapy	No prophylaxis	3% (1/29)		Rajkumar et al. Leukemia 2003;17(4):775-9	40
	Untreated multiple myeloma	Thalidomide monotherapy	No prophylaxis	4% (1/28)		Weber et al. J Clin Oncol 2003;21(1):16-9.	13
Relapsed/refractory multiple myeloma patients that received thalidomide monotherapy and no prophylaxis (3% (23/913))	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	4% (3/83)		Neben et al. Clinical Cancer Research 2002;8:3377-82	41
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	0% (0/84)		Singhal et al. N Engl J Med 1999;341(21):1565-71	42
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	2% (1/65)		Tosi et al. Haematologica 2002; 87: 408-414	43
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	3% (2/65)		Waage et al. Br J Haematol 2004;125(2):149-155	44
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	2% (3/169)		Barlogie et al. Blood 2001; 98(2): 492-4	45
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	0% (0/30)		Wechalekar et al. Leukemia and Lymphoma, 2003; 44(7): 1147-1149.	46
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	0% (0/27)		Yakoub-Agha et al. The Hematology Journal 2000: 1: 186-189.	47
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	0% (0/23)		Juliusson et al. BrJ Haematol; 2000, 109, 89-96.	48
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	0% (0/25)		Huang et al. Ann Hematol 2003; 82: 558-564	17
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	4% (2/53)		Hus et al. Haematologica 2001;86(4):404-8	49

	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	3% (1/32)		Kumar et al. Mayo Clin Proc 2003;78(1):34-9	50
	Relapsed or refractory multiple myeloma	Thalidomide monotherapy	No prophylaxis	5% (3/56)		Mileshkin et al. Blood 2003;102(1):69-77	51
	Maintenance therapy for multiple myeloma	Thalidomide monotherapy	No prophylaxis	4% (8/201)		Attal et al. Blood 2006; prepublished online.	52
	Untreated and relapsed or refractory multiple myeloma	Doxorubicin-containing	No prophylaxis	34% (30/87)		Zangari et al. British Journal of Haematology 2004;126(5):715-21.	53
	Untreated and relapsed or refractory multiple myeloma	Doxorubicin-containing	LMWH	15% (10/68)		Zangari et al. British Journal of Haematology 2004;126(5):715-21.	53
	Relapsed and refractory multiple myeloma	Chemotherapy	No prophylaxis	28% (5/18)		Camba et al. Haematologica 2001: 86: 1108.	54
	Untreated and relapsed or refractory multiple myeloma	Melphalan	No prophylaxis	11% (3/27)		Offidani et al. Eur J Haematol 2004: 72: 403-409.	55
Metastatic renal cell carcinoma patients that received thalidomide monotherapy and no prophylaxis (14% (12/84))	Renal cell carcinoma, metastatic	None	No prophylaxis	23% (9/40)		Escudier et al. Annals of Oncol 2002; 13:1029-1035	56
	Renal cell carcinoma, metastatic	None	No prophylaxis	16% (3/19)		Daliani et al. Cancer 2002; 95: 758-765	57
	Renal cell carcinoma, metastatic	None	No prophylaxis	0% (0/25)		Stebbing et al. British J of Cancer 2001; 85: 953-958	58
	Prostate Cancer, metastatic	Doxetaxel	No prophylaxis	28% (12/43)	0% (0/25)	Dahut et al. J Clin Oncol 2004; 22(13): 2532-2539	59

Metastatic melanoma patients that received temozolomide and no prophylaxis (4% (2/50))	Melanoma, metastatic	temozolomide	No prophylaxis	8% (1/12)		Hwu et al. J Clin Onc 2002; 20: 2610-2615.	60
	Melanoma, metastatic	temozolomide	No prophylaxis	3% (1/38)		Hwu et al. J Clin Oncol 2003; 21: 3351-3356	61
	Renal cell carcinoma, metastatic	gemcitabine-fluorouraci	warfarin - 1mg/d	43% (9/21)		Desai et al. Cancer. 2002 Oct 15;95(8):1629-36	62
Metastatic renal cell carcinoma patients that received alpha interferon and no prophylaxis (7% (3/43))	Renal cell carcinoma, metastatic	alpha interferon	No prophylaxis	0% (0/13)		Nathan et al. J Clin Oncol. 2002 Mar 1;20(5):1429-30.	63
	Renal cell carcinoma, metastatic	alpha interferon	No prophylaxis	10% (3/30)		Hernberg et al. J Clin Oncol 2003; 21: 3770-3776	64
	Prostate Cancer, metastatic	Doxetaxel	Prophylactic doses of LMWH	0% (0/6)		Dahut et al. J Clin Oncol 2004; 22(13): 2532-2539	59
	Myelodysplasia, previously treated	darbepoetin	No prophylaxis	43% (3/7)		Steurer et al. Br J of Haemato 2003; 121: 101-103	65
	NHL, relapsed	Rituximab	No prophylaxis	20% (2/10)		urbauer et al. Blood 2002; 99(11): 4247	23
	NHL, relapsed	Rituximab	No prophylaxis	13% (2/16)		Kaufmann et al. Blood 2004; 104: 2269-2271	66
	NHL, relapsed	Vinblastine	No prophylaxis	0% (0/11)		Kurvilla et al. Hematology 2006; 11: 25-29	67

Waldenstrom's macroglobulinemia patients that received dexamethasone, clarithromycin and no prophylaxis (1% (3/32))	Waldenstrom's macroglobulinemia	Dexamethasone, clarithromycin	No prophylaxis	10% (2/20)		Dimopoulos et al. Semin Oncol 2003; 30(2): 265-269	68
	Waldenstrom's macroglobulinemia	Dexamethasone, clarithromycin	No prophylaxis	8% (1/12)		Coleman et al. Seminars in Oncolo 2003; 30: 270-274	69
	Glioma, relapsed	Carmustine	No prophylaxis	30% (12/40)		Fine et al. J Clin Oncol. 2003 Jun 15;21(12):2299-304	70
	Colorectal carcinoma, relapsed	Capecitabine	No prophylaxis	12% (4/34)		McCollum et al. Am J Clin Onc 2006; 29: 40-44	71
	Solid tumors other than renal cell carcinoma, relapsed	None	No prophylaxis	0% (0/66)		Eisen et al. Br J Cancer 2000; 82: 812-817	72
	Chronic lymphocytic leukemia, newly diagnosed	Fludarabine	No prophylaxis	15% (2/13)		Chanan-Khan et al. Blood 2005; 106(10): 3348 - 52.	73

Table 2. Venous thromboembolism (VTE) rates (%) among lenalidomide treated patients

	Disease	Agent other than lenalidomide	Prophylaxis	VTE rate (Patients with VTE/Total patients)	VTE rate for control arm (if applicable)	Reference	
Untreated multiple myeloma patients that received dexamethasone ± chemotherapy and no prophylaxis (14% (38/278))	Untreated multiple myeloma	Dexamethasone	None	18% (24/132)		Rajkumar. 2006. NEJM. Volume 354:2079-2080	74
	Untreated multiple myeloma	Dexamethasone	None	75% (9/12)	0% (0/9)	Zonder et al. Blood 2006; 107: 403	75
	Untreated multiple myeloma	Dexamethasone (low dose)	None	4% (5/134)		Rajkumar. 2006. NEJM. Volume 354:2079-2080	74
Untreated multiple myeloma patients that received dexamethasone ± chemotherapy and aspirin (11% (10/88))	Untreated multiple myeloma	Dexamethasone	Aspirin (81mg/day)	19% (6/32)	7% (2/29)	Zonder et al. Blood 2006; 107: 403	75
	Untreated multiple myeloma	Dexamethasone	Aspirin	3% (1/34)		Rajkumar et al. Blood 2005; 106: 4050-53.	76
	Untreated multiple myeloma	Dexamethasone, clarithromycin	Aspirin (81mg/day)	14% (3/22)		Niesvizky et al. Blood 2005; 106: Abstract 642	77
Relapsed/refractory multiple myeloma	Relapsed or refractory multiple myeloma	Dexamethasone	None	9% (7/77)	1% (1/103)	Weber et al. The 10th International Myeloma Workshop 2005; Abstract 738.	78

	Relapsed or refractory multiple myeloma	Dexamethasone, erythropoietin support	None	28% (26/93)	7% (5/67)	Weber et al. The 10th International Myeloma Workshop 2005; Abstract 738.	78
	Relapsed or refractory multiple myeloma	Dexamethasone	None	9% (15/176)	5% (8/175)	Dimopoulos et al. Blood 2005; 106: Abstract 6	79
Relapsed/refractory multiple myeloma patients that received doxorubicin ± chemotherapy and aspirin (10% (2/21))	Relapsed or refractory multiple myeloma	Liposomal doxorubicin	Aspirin (81mg/day)	10% (2/21)		Hussein. Presented at the 46th annual meeting of ASH	80
Relapsed/refractory multiple myeloma patients that received melphalan, prednisone ± chemotherapy and aspirin (4% (1/24))	Untreated multiple myeloma	Melphalan, prednisone	Aspirin (81mg/day)	4% (1/24)		Palumbo et al. Blood 2005; 106: Abstract 785	81
Untreated multiple myeloma patients that received lenalidomide monotherapy and no prophylaxis (2% (4/222))	Untreated multiple myeloma	None	None	2% (4/222)		Richardson et al. Haematologica 2005; 90: 154	82

Relapsed/refractory multiple myeloma patients that received lenalidomide monotherapy and no prophylaxis (0% (0/102))	Relapsed or refractory multiple myeloma	None	None	0% (0/102)		Richardson et al. Blood 2006. July 18. Epub ahead of print.	83
	Relapsed or refractory multiple myeloma	Bortezomib	None	0% (0/19)		Richardson et al. Blood 2005; 106: Abstract 365.	84
	Myelodysplasia	None	None	2% (8/408)		FDA briefing document. NDA 21-880.	85

References

1. Abdelkefi A, Torjman L, Ben Romdhane N, et al. First-line thalidomide-dexamethasone therapy in preparation for autologous stem cell transplantation in young patients (<61 years) with symptomatic multiple myeloma. *Bone Marrow Transplant*. Aug 2005;36(3):193-198.
2. Cavo M, Zamagni E, Tosi P, et al. Superiority of thalidomide and dexamethasone over vincristine-doxorubicin-dexamethasone (VAD) as primary therapy in preparation for autologous transplantation for multiple myeloma. *Blood*. Jul 1 2005;106(1):35-39.
3. Ludwig H, Drach J, Tothova E, et al. Thalidomide-dexamethasone versus melphalan-prednisolone as first line treatment in elderly patients with multiple myeloma: An interim analysis. *J Clin Oncol (Meeting Abstracts)*. June 1, 2005 2005;23(16_suppl):6537-.
4. Osman K, Comenzo R, Rajkumar SV. Deep venous thrombosis and thalidomide therapy for multiple myeloma. *N Engl J Med*. Jun 21 2001;344(25):1951-1952.
5. Rajkumar SV, Hayman S, Gertz MA, et al. Combination therapy with thalidomide plus dexamethasone for newly diagnosed myeloma. *J Clin Oncol*. Nov 1 2002;20(21):4319-4323.
6. Rajkumar S, Hussein M, Catalano J, et al. A multicenter, randomized, double-blind, placebo-controlled trial of thalidomide plus dexamethasone versus dexamethasone alone as initial therapy for newly diagnosed multiple myeloma. *J Clin Oncol*. 2006;24(18S):7517.
7. Klueppelberg U, Chen S, Aloba M, et al. Long-term treatment of newly-diagnosed multiple myeloma with low-dose thalidomide, dexamethasone and zoledronate (TDZ). *J Clin Oncol*. 2005;23(16S):6697.
8. Rajkumar SV, Blood E, Vesole D, Fonseca R, Greipp PR. Phase III clinical trial of thalidomide plus dexamethasone compared with dexamethasone alone in newly diagnosed multiple myeloma: a clinical trial coordinated by the Eastern Cooperative Oncology Group. *J Clin Oncol*. Jan 20 2006;24(3):431-436.
9. Dimopoulos MA, Anagnostopoulos A, Terpos E, et al. Primary treatment with pulsed melphalan, dexamethasone and thalidomide for elderly symptomatic patients with multiple myeloma. *Haematologica*. Feb 2006;91(2):252-254.
10. Schutt P, Ebeling P, Buttkeireit U, et al. Thalidomide in combination with vincristine, epirubicin and dexamethasone (VED) for previously untreated patients with multiple myeloma. *Eur J Haematol*. Jan 2005;74(1):40-46.

11. Zangari M, Siegel E, Barlogie B, et al. Thrombogenic activity of doxorubicin in myeloma patients receiving thalidomide: implications for therapy. *Blood*. Aug 15 2002;100(4):1168-1171.
12. Cavo M, Zamagni E, Tosi P, et al. Superiority of thalidomide and dexamethasone over vincristine-doxorubicindexamethasone (VAD) as primary therapy in preparation for autologous transplantation for multiple myeloma. *Blood*. July 1, 2005 2005;106(1):35-39.
13. Weber D, Rankin K, Gavino M, Delasalle K, Alexanian R. Thalidomide alone or with dexamethasone for previously untreated multiple myeloma. *J Clin Oncol*. Jan 1 2003;21(1):16-19.
14. Chanan-Khan AA, Miller KC, McCarthy P, et al. VAD-t (Vincristine, Adriamycin, Dexamethasone and Low-Dose Thalidomide) Is an Effective Initial Therapy with High Response Rates for Patients with Treatment Naive Multiple Myeloma (MM). *ASH Annual Meeting Abstracts*. November 16, 2004 2004;104(11):3463-.
15. Anagnostopoulos A, Weber D, Rankin K, Delasalle K, Alexanian R. Thalidomide and dexamethasone for resistant multiple myeloma. *Br J Haematol*. Jun 2003;121(5):768-771.
16. Dimopoulos MA, Zervas K, Kouvatsas G, et al. Thalidomide and dexamethasone combination for refractory multiple myeloma. *Ann Oncol*. Jul 2001;12(7):991-995.
17. Huang SY, Tang JL, Yao M, et al. Reduction of leukocyte count is associated with thalidomide response in treatment of multiple myeloma. *Ann Hematol*. Sep 2003;82(9):558-564.
18. Palumbo A, Bertola A, Falco P, et al. Efficacy of low-dose thalidomide and dexamethasone as first salvage regimen in multiple myeloma. *Hematol J*. 2004;5(4):318-324.
19. Tosi P, Zamagni E, Cellini C, et al. Thalidomide alone or in combination with dexamethasone in patients with advanced, relapsed or refractory multiple myeloma and renal failure. *Eur J Haematol*. Aug 2004;73(2):98-103.
20. Dimopoulos MA, Hamilos G, Zomas A, et al. Pulsed cyclophosphamide, thalidomide and dexamethasone: an oral regimen for previously treated patients with multiple myeloma. *Hematol J*. 2004;5(2):112-117.
21. Garcia-Sanz R, Gonzalez-Porras JR, Hernandez JM, et al. The oral combination of thalidomide, cyclophosphamide and dexamethasone (ThaCyDex) is effective in relapsed/refractory multiple myeloma. *Leukemia*. Apr 2004;18(4):856-863.
22. Kropff MH, Lang N, Bisping G, et al. Hyperfractionated cyclophosphamide in combination with pulsed dexamethasone and thalidomide (HyperCDT) in primary refractory or relapsed multiple myeloma. *Br J Haematol*. Aug 2003;122(4):607-616.
23. Urbauer E, Kaufmann H, Nosslinger T, Raderer M, Drach J. Thromboembolic events during treatment with thalidomide. *Blood*. Jun 1 2002;99(11):4247-4248.
24. Kyriakou C, Thomson K, D'Sa S, et al. Low-dose thalidomide in combination with oral weekly cyclophosphamide and pulsed dexamethasone is a well tolerated and effective regimen in patients with relapsed and refractory multiple myeloma. *Br J Haematol*. Jun 2005;129(6):763-770.
25. Badros AZ, Goloubeva O, Rapoport AP, et al. Phase II study of G3139, a Bcl-2 antisense oligonucleotide, in combination with dexamethasone and thalidomide in relapsed multiple myeloma patients. *J Clin Oncol*. Jun 20 2005;23(18):4089-4099.
26. Wang M, Weber DM, Delasalle K, Alexanian R. Thalidomide-dexamethasone as primary therapy for advanced multiple myeloma. *Am J Hematol*. Jul 2005;79(3):194-197.
27. Offidani M, Corvatta L, Marconi M, et al. Low-dose thalidomide with pegylated liposomal doxorubicin and high-dose dexamethasone for relapsed/refractory multiple myeloma: a prospective, multicenter, phase II study. *Haematologica*. Jan 2006;91(1):133-136.
28. Zangari M, Anaissie E, Barlogie B, et al. Increased risk of deep-vein thrombosis in patients with multiple myeloma receiving thalidomide and chemotherapy. *Blood*. Sep 1 2001;98(5):1614-1615.
29. Barlogie B, Tricot G, Anaissie E, et al. Thalidomide and hematopoietic-cell transplantation for multiple myeloma. *N Engl J Med*. 2006;354(10):1021-1030.

30. Zervas K, Dimopoulos MA, Hatzicharissi E, et al. Primary treatment of multiple myeloma with thalidomide, vincristine, liposomal doxorubicin and dexamethasone (T-VAD doxil): a phase II multicenter study. *Ann Oncol*. Jan 2004;15(1):134-138.
31. Hassoun H, Reich L, Klimek VM, et al. Doxorubicin and dexamethasone followed by thalidomide and dexamethasone is an effective well tolerated initial therapy for multiple myeloma. *Br J Haematol*. 2005;132:155-161.
32. Lee CK, Barlogie B, Munshi N, et al. DTPACE: an effective, novel combination chemotherapy with thalidomide for previously treated patients with myeloma. *J Clin Oncol*. Jul 15 2003;21(14):2732-2739.
33. Hussein MA. Modifications to therapy for multiple myeloma: pegylated liposomal Doxorubicin in combination with vincristine, reduced-dose dexamethasone, and thalidomide. *Oncologist*. 2003;8 Suppl 3:39-45.
34. Minnema MC, Bretkreutz I, Auwerda JJ, et al. Prevention of venous thromboembolism with low molecular-weight heparin in patients with multiple myeloma treated with thalidomide and chemotherapy. *Leukemia*. Dec 2004;18(12):2044-2046.
35. Rus C, Bazzan M, Palumbo A, Bringhen S, Boccadoro M. Thalidomide in front line treatment in multiple myeloma: serious risk of venous thromboembolism and evidence for thromboprophylaxis. *J Thromb Haemost*. Nov 2004;2(11):2063-2065.
36. Palumbo A, Bertola A, Musto P, et al. Oral melphalan, prednisone, and thalidomide for newly diagnosed patients with myeloma. *Cancer*. Oct 1 2005;104(7):1428-1433.
37. Palumbo A, Bertola A, Musto P, et al. Oral melphalan, prednisone and thalidomide for newly diagnosed myeloma patients. *J Clin Oncol (Meeting Abstracts)*. July 15, 2004 2004;22(14_suppl):6549-.
38. Palumbo A, Bringhen S, Caravita T, et al. Oral melphalan and prednisone chemotherapy plus thalidomide compared with melphalan and prednisone alone in elderly patients with multiple myeloma: randomised controlled trial. *Lancet*. Mar 11 2006;367(9513):825-831.
39. Rajkumar SV, Dispenzieri A, Fonseca R, et al. Thalidomide for previously untreated indolent or smoldering multiple myeloma. *Leukemia*. Aug 2001;15(8):1274-1276.
40. Rajkumar SV, Gertz MA, Lacy MQ, et al. Thalidomide as initial therapy for early-stage myeloma. *Leukemia*. Apr 2003;17(4):775-779.
41. Neben K, Moehler T, Benner A, et al. Dose-dependent effect of thalidomide on overall survival in relapsed multiple myeloma. *Clin Cancer Res*. 2002;8:3377-3382.
42. Singhal S, Mehta J, Desikan R, et al. Antitumor Activity of Thalidomide in Refractory Multiple Myeloma. *N Engl J Med*. November 18, 1999 1999;341(21):1565-1571.
43. Tosi P, Zamagni E, Cellini C, et al. Salvage therapy with thalidomide in patients with advanced relapsed/refractory multiple myeloma. *Haematologica*. Apr 2002;87(4):408-414.
44. Waage A, Gimsing P, Juliusson G, et al. Early response predicts thalidomide efficiency in patients with advanced multiple myeloma. *Br J Haematol*. Apr 2004;125(2):149-155.
45. Barlogie B, Desikan R, Eddlemon P, et al. Extended survival in advanced and refractory multiple myeloma after single-agent thalidomide: identification of prognostic factors in a phase 2 study of 169 patients. *Blood*. Jul 15 2001;98(2):492-494.
46. Wechalekar AD, Chen CI, Sutton D, Reece D, Voralia M, Stewart AK. Intermediate dose thalidomide (200 mg daily) has comparable efficacy and less toxicity than higher doses in relapsed multiple myeloma. *Leuk Lymphoma*. Jul 2003;44(7):1147-1149.
47. Yakoub-Agha I, Moreau P, Leyvraz S, et al. Thalidomide in patients with advanced multiple myeloma. *Hematol J*. 2000;1(3):186-189.
48. Juliusson G, Celsing F, Turesson I, Lenhoff S, Adriansson M, Malm C. Frequent good partial remissions from thalidomide including best response ever in patients with advanced refractory and relapsed myeloma. *Br J Haematol*. Apr 2000;109(1):89-96.
49. Hus M, Dmoszynska A, Soroka-Wojtaszko M, et al. Thalidomide treatment of resistant or relapsed multiple myeloma patients. *Haematologica*. Apr 2001;86(4):404-408.
50. Kumar S, Gertz MA, Dispenzieri A, et al. Response rate, durability of response, and survival after thalidomide therapy for relapsed multiple myeloma. *Mayo Clin Proc*. 2003;78(1):34-39.

51. Mileschkin L, Biagi JJ, Mitchell P, et al. Multicenter phase 2 trial of thalidomide in relapsed/refractory multiple myeloma: adverse prognostic impact of advanced age. *Blood*. Jul 1 2003;102(1):69-77.
52. Attal M, Harousseau JL, Leyvraz S, et al. Maintenance therapy with thalidomide improves survival in multiple myeloma patients. *Blood*. Jul 27 2006.
53. Zangari M, Barlogie B, Anaissie E, et al. Deep vein thrombosis in patients with multiple myeloma treated with thalidomide and chemotherapy: effects of prophylactic and therapeutic anticoagulation. *Br J Haematol*. Sep 2004;126(5):715-721.
54. Camba L, Peccatori J, Pescarollo A, Tresoldi M, Corradini P, Bregni M. Thalidomide and thrombosis in patients with multiple myeloma. *Haematologica*. Oct 2001;86(10):1108-1109.
55. Offidani M, Corvatta L, Marconi M, et al. Common and rare side-effects of low-dose thalidomide in multiple myeloma: focus on the dose-minimizing peripheral neuropathy. *Eur J Haematol*. Jun 2004;72(6):403-409.
56. Escudier B, Lassau N, Couanet D, et al. Phase II trial of thalidomide in renal-cell carcinoma. *Ann Oncol*. Jul 2002;13(7):1029-1035.
57. Daliani DD, Papandreou CN, Thall PF, et al. A pilot study of thalidomide in patients with progressive metastatic renal cell carcinoma. *Cancer*. Aug 15 2002;95(4):758-765.
58. Stebbing J, Benson C, Eisen T, et al. The treatment of advanced renal cell cancer with high-dose oral thalidomide. *Br J Cancer*. Sep 28 2001;85(7):953-958.
59. Dahut WL, Gulley JL, Arlen PM, et al. Randomized phase II trial of docetaxel plus thalidomide in androgen-independent prostate cancer. *J Clin Oncol*. Jul 1 2004;22(13):2532-2539.
60. Hwu W-J, Krown SE, Panageas KS, et al. Temozolomide Plus Thalidomide in Patients With Advanced Melanoma: Results of a Dose-Finding Trial. *J Clin Oncol*. June 1, 2002 2002;20(11):2610-2615.
61. Hwu W-J, Krown SE, Menell JH, et al. Phase II Study of Temozolomide Plus Thalidomide for the Treatment of Metastatic Melanoma. *J Clin Oncol*. September 1, 2003 2003;21(17):3351-3356.
62. Desai AA, Vogelzang NJ, Rini BI, Ansari R, Krauss S, Stadler WM. A high rate of venous thromboembolism in a multi-institutional phase II trial of weekly intravenous gemcitabine with continuous infusion fluorouracil and daily thalidomide in patients with metastatic renal cell carcinoma. *Cancer*. Oct 15 2002;95(8):1629-1636.
63. Nathan PD, Gore ME, Eisen TG. Unexpected toxicity of combination thalidomide and interferon alpha-2a treatment in metastatic renal cell carcinoma. *J Clin Oncol*. Mar 1 2002;20(5):1429-1430.
64. Hernberg M, Virkkunen P, Bono P, Ahtinen H, Maenpaa H, Joensuu H. Interferon alfa-2b three times daily and thalidomide in the treatment of metastatic renal cell carcinoma. *J Clin Oncol*. Oct 15 2003;21(20):3770-3776.
65. Steurer M, Sudmeier I, Stauder R, Gastl G. Thromboembolic events in patients with myelodysplastic syndrome receiving thalidomide in combination with darbepoietin-alpha. *Br J Haematol*. Apr 2003;121(1):101-103.
66. Kaufmann H, Raderer M, Wohrer S, et al. Antitumor activity of rituximab plus thalidomide in patients with relapsed/refractory mantle cell lymphoma. *Blood*. Oct 15 2004;104(8):2269-2271.
67. Kuruvilla J, Song K, Mollee P, et al. A phase II study of thalidomide and vinblastine for palliative patients with Hodgkin's lymphoma. *Hematology*. Feb 2006;11(1):25-29.
68. Dimopoulos MA, Tsatalas C, Zomas A, et al. Treatment of Waldenstrom's macroglobulinemia with single-agent thalidomide or with the combination of clarithromycin, thalidomide and dexamethasone. *Semin Oncol*. Apr 2003;30(2):265-269.
69. Coleman M, Leonard J, Lyons L, Szelenyi H, Niesvizky R. Treatment of Waldenstrom's macroglobulinemia with clarithromycin, low-dose thalidomide, and dexamethasone. *Semin Oncol*. Apr 2003;30(2):270-274.
70. Fine HA, Wen PY, Maher EA, et al. Phase II trial of thalidomide and carmustine for patients with recurrent high-grade gliomas. *J Clin Oncol*. Jun 15 2003;21(12):2299-2304.

71. McCollum AD, Wu B, Clark JW, et al. The combination of capecitabine and thalidomide in previously treated, refractory metastatic colorectal cancer. *Am J Clin Oncol*. Feb 2006;29(1):40-44.
72. Eisen T, Boshoff C, Mak I, et al. Continuous low dose Thalidomide: a phase II study in advanced melanoma, renal cell, ovarian and breast cancer. *Br J Cancer*. Feb 2000;82(4):812-817.
73. Chanan-Khan A, Miller KC, Takeshita K, et al. Results of a phase 1 clinical trial of thalidomide in combination with fludarabine as initial therapy for patients with treatment-requiring chronic lymphocytic leukemia (CLL). *Blood*. Nov 15 2005;106(10):3348-3352.
74. Rajkumar SV, Blood E. Lenalidomide and venous thrombosis in multiple myeloma. *N Engl J Med*. May 11 2006;354(19):2079-2080.
75. Zonder J, Barlogie B, Durie B, McCoy J, Crowley J, Hussein M. Thrombotic complications in patients with newly-diagnosed multiple myeloma treated with lenalidomide and dexamethasone - benefit of aspirin prophylaxis. *Blood*. 2006;107:403.
76. Rajkumar SV, Hayman SR, Lacy MQ, et al. Combination therapy with lenalidomide plus dexamethasone (Rev/Dex) for newly diagnosed myeloma. *Blood*. Dec 15 2005;106(13):4050-4053.
77. Niesvizky R, Pekle K, Gelbshtein U, et al. BiRD (Biaxin(R)/Revlimid(R)/Dexamethasone) Combination Therapy (Rx) Results in High Complete Remissions (CR) and Overall Responses in Myeloma (MM) with Poor Prognostic Features. *ASH Annual Meeting Abstracts*. November 16, 2005 2005;106(11):642.
78. Weber D, Chen C, Niesvizky R, et al. A Multicenter, Randomized, Parallel-Group, Double-Blend, Placebo-Controlled Study of Lenalidomide Plus Dexamethasone Versus Dexamethasone Alone in Previously Treated Subjects with Multiple Myeloma. *The 10th International Myeloma Workshop*. 2005:738.
79. Dimopoulos MA, Spencer A, Attal M, et al. Study of Lenalidomide Plus Dexamethasone Versus Dexamethasone Alone in Relapsed or Refractory Multiple Myeloma (MM): Results of a Phase 3 Study (MM-010). *Blood: ASH Annual Meeting Abstracts*. November 16, 2005 2005;106(11):6.
80. Hussein MA, Karam MA, Brand C, et al. Doxil (D), Vincristine (V), Reduced Frequency Dexamethasone (d) and Revlimid(R) (DVd-R) a Phase I/II Trial in Advanced Relapsed/Refractory Multiple Myeloma (RMM) Patients. *ASH Annual Meeting Abstracts*. November 16, 2004 2004;104(11):208.
81. Palumbo A, Falco P, Musto P, et al. Oral RevlimidR Plus Melphalan and Prednisone (R-MP) for Newly Diagnosed Multiple Myeloma. *ASH Annual Meeting Abstracts*. November 16, 2005 2005;106(11):785.
82. Richardson P, Jagannath S, Hussein M, et al. A multicenter, single-arm, open-label study to evaluate the safety and efficacy of single-agent lenalidomide in subjects with relapsed and refractory multiple myeloma. *Haematologica*. 2005;90(s1):154.
83. Richardson PG, Blood E, Mitsiades CS, et al. A randomized phase 2 study of lenalidomide therapy for patients with relapsed or relapsed and refractory multiple myeloma. *Blood*. Jul 18 2006.
84. Richardson P, Schlossman R, Munshi N, et al. A Phase 1 Trial of Lenalidomide (REVLIMID(R)) with Bortezomib (VELCADE(R)) in Relapsed and Refractory Multiple Myeloma. *ASH Annual Meeting Abstracts*. November 16, 2005 2005;106(11):365.
85. O. Onocologic Drugs Advisory Committee Meeting. FDA Briefing document for NDA 21-880;. Revlimid (CC-5013/lenalidomide). Rockville, MD: Rockville, MD: Food and Drug Administration, September 14, 2005.