Efficacy and safety of daratumumab plus bortezomib and dexamethasone in newly diagnosed Mayo 2004 stage IIIA or IIIB light-chain amyloidosis: a prospective phase II study

Authors

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Supplemental material

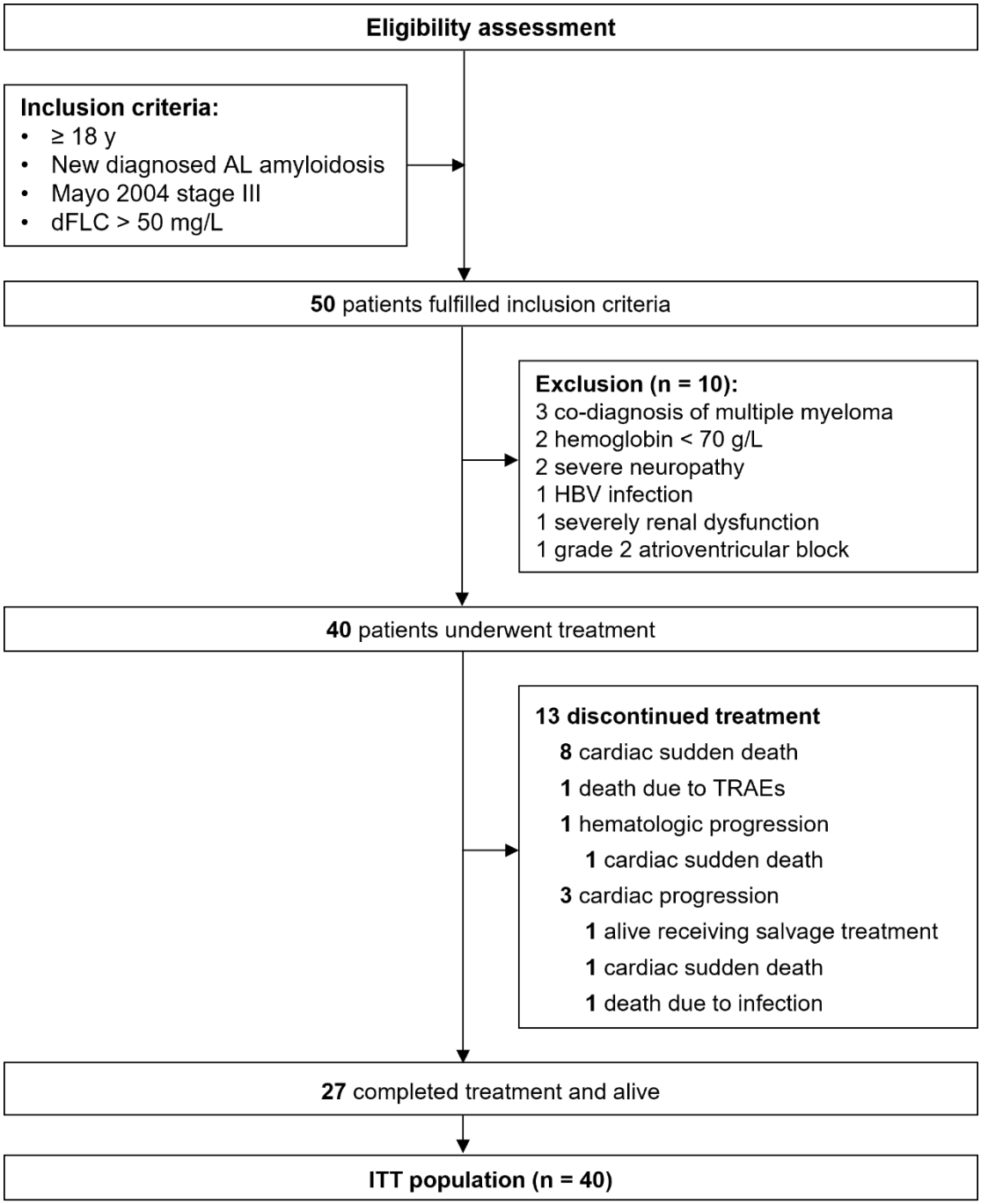
Supplemental Table 1. Summary of cardiac, renal and hepatic response assessments.

All the patients	Best response N (%)	3 months N (%)	6 months N (%)	12 months N (%)
Cardiac response (n = 40)				
CR	3 (7.5)	1 (2.5)	1 (2.5)	3 (7.5)
VGPR	15 (37.5)	2 (5.0)	10 (25.0)	13 (32.5)
PR	9 (22.5)	12 (30.0)	8 (20.0)	10 (25.0)
ORR	27 (67.5)	15 (37.5)	19 (47.5)	26 (65.0)
Renal response (n = 12)	5 (41.7)	4 (33.3)	2 (16.7)	2 (16.7)
Hepatic response (n = 10)	2 (20.0)	0 (0.0)	0 (0.0)	2 (20.0)
Mayo stage IIIA				
Cardiac response (n = 20)				
CR	2 (10.0)	1 (5.0)	1 (5.0)	2 (10.0)
VGPR	6 (30.0)	1 (5.0)	2 (10.0)	4 (20.0)
PR	5 (25.0)	4 (20.0)	6 (30.0)	7 (35.0)
ORR	13 (65.0)	6 (30.0)	9 (45.0)	13 (65.0)
Renal response (n = 6)	1 (16.7)	1 (16.7)	0 (0.0)	0 (0.0)
Hepatic response (n = 7)	1 (14.3)	0 (0.0)	0 (0.0)	1 (14.3)
Mayo stage IIIB				
Cardiac response (n = 20)				
CR	1 (5.0)	0 (0.0)	0 (0.0)	1 (5.0)
VGPR	9 (45.0)	1 (5.0)	8 (40.0)	9 (45.0)
PR	4 (20.0)	8 (40.0)	2 (10.0)	3 (15.0)
ORR	14 (70.0)	9 (45.0)	10 (50.0)	13 (65.0)
Renal response (n = 6)	4 (66.7)	3 (50.0)	2 (33.3)	2 (33.3)
Hepatic response (n = 3)	1 (33.3)	0 (0.0)	0 (0.0)	1 (33.3)

Abbreviations: CR, complete response; ORR, overall response rate; PR, partial response; VGPR, very good partial response

Supplemental Table 2. Summary of treatment-related adverse events in all the patients (n = 40).

Treatment-related adverse events	All the patients		Mayo stage IIIA		Mayo stage IIIB	
	Any grade	Grade ≥3	Any grade	Grade ≥3	Any grade	Grade ≥3
	Number of patients (%)					
Hematologic						
Anemia	15 (37.5)	1 (2.5)	8 (40.0)	0 (0.0)	7 (35.0)	1 (5.0)
Thrombocytopenia	6 (15.0)	0 (0.0)	2 (10.0)	0 (0.0)	4 (20.0)	0 (0.0)
Leukocytopenia	5 (12.5)	0 (0.0)	2 (10.0)	0 (0.0)	3 (15.0)	0 (0.0)
Nonhematologic						
Upper respiratory infection	14 (35.0)	0 (0.0)	6 (30.0)	0 (0.0)	8 (40.0)	0 (0.0)
Diarrhea	10 (25.0)	5 (12.5)	5 (25.0)	2 (10.0)	5 (25.0)	3 (15.0)
Infusion reaction	9 (22.5)	1 (2.5)	5 (25.0)	0 (0.0)	4 (20.0)	1 (5.0)
Nausea	8 (20.0)	2 (5.0)	5 (25.0)	1 (5.0)	3 (15.0)	1 (5.0)
Increased transaminase	8 (20.0)	0 (0.0)	4 (20.0)	0 (0.0)	4 (20.0)	0 (0.0)
Increased bilirubin	6 (15.0)	0 (0.0)	1 (5.0)	0 (0.0)	5 (25.0)	0 (0.0)
Fatigue	5 (12.5)	1 (2.5)	3 (15.0)	1 (5.0)	2 (10.0)	0 (0.0)
Pulmonary infection	3 (7.5)	3 (7.5)	1 (5.0)	1 (5.0)	2 (10.0)	2 (10.0)
Emesis	3 (7.5)	2 (5.0)	1 (5.0)	1 (5.0)	2 (10.0)	1 (5.0)
Constipation	3 (7.5)	0 (0.0)	3 (15.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intestinal obstruction	2 (5.0)	2 (5.0)	1 (5.0)	1 (5.0)	1 (5.0)	1 (5.0)
Herpes zoster	2 (5.0)	1 (2.5)	2 (10.0)	1 (5.0)	0 (0.0)	0 (0.0)
Peripheral neuropathy	2 (5.0)	1 (2.5)	2 (10.0)	1 (5.0)	0 (0.0)	0 (0.0)
Gastrointestinal bleeding	2 (5.0)	1 (2.5)	1 (5.0)	1 (5.0)	1 (5.0)	0 (0.0)
Gastrointestinal infection	1 (2.5)	1 (2.5)	1 (5.0)	1 (5.0)	0 (0.0)	0 (0.0)
Urinary system infection	1 (2.5)	1 (2.5)	0 (0.0)	0 (0.0)	1 (5.0)	1 (5.0)
Ischemic stroke	1 (2.5)	1 (2.5)	1 (5.0)	1 (5.0)	0 (0.0)	0 (0.0)
Cholecystitis	1 (2.5)	1 (2.5)	0 (0.0)	0 (0.0)	1 (5.0)	1 (5.0)
Pancreatitis	1 (2.5)	1 (2.5)	0 (0.0)	0 (0.0)	1 (5.0)	1 (5.0)
Pneumothorax	1 (2.5)	1 (2.5)	0 (0.0)	0 (0.0)	1 (5.0)	1 (5.0)
Oral ulcer	1 (2.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)
Insomnia	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)
Anorexia	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.0)	0 (0.0)
Dizziness	1 (2.5)	0 (0.0)	1 (5.0)	0 (0.0)	0 (0.0)	0 (0.0)



Supplemental Figure 1. Trial profile.

Abbreviations: AL, light-chain; dFLC, difference between involved and uninvolved free light chain; ITT, intention-to-treat; TRAEs, treatment-related adverse events