

Efficacy and Safety of Daratumumab Plus VCd in Newly Diagnosed Amyloid Light-chain Amyloidosis with Cardiac Involvement: A Pooled Analysis of Asian Patients from AMY2009 and AMY3001

Jin Lu¹, Ming-hui Zhao², Yu Wu³, Xiaonong Chen⁴, Zhen Cai⁵, Fude Zhou², Kenshi Suzuki⁶, Kihyun Kim⁷, Chihiro Shimazaki⁸, Jin Seok Kim⁹, Takayuki Ikezoe¹⁰, Chang-Ki Min¹¹, Shinsuke Iida¹², Nagaaki Katoh¹³, Tomoaki Fujisaki¹⁴, Ho-Jin Shin¹⁵, NamPhuong Tran¹⁶, Matteo Loi¹⁷, Yishen Yang¹⁸, Jianmin Zhuo¹⁹, Xue Gai²⁰, Kwang wei Wu²¹, Bijie Xun²⁰, Yulin Gong²⁰

¹Peking University People's Hospital, Peking University Institute of Hematology, National Clinical Research Centre for Hematologic Disease, Collaborative Innovation Center of Hematology, Beijing, China; ²Peking University First Hospital, Beijing, China; ³West China Hospital, Sichuan University, Chengdu, China; ⁴Ruijin Hospital Affiliated to Shanghai Jiao Tong University, Shanghai, China; ⁵The First Affiliated Hospital of Zhejiang University, Hangzhou, China; ⁶Department of Hematology, Japanese Red Cross Medical Center, Tokyo, Japan; ⁷Department of Medicine, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; ⁸Kyoto Kuramaguchi Medical Center, Kyoto, Japan; ⁹Yonsei University College of Medicine Severance Hospital, Seoul, Korea; ¹⁰Fukushima Medical University Hospital, Japan; ¹¹Seoul St Mary's Hospital, Seoul, Korea; ¹²Nagoya City University Institute of Medical and Pharmaceutical Sciences, Aichi, Japan; ¹³Shinshu University, Matsumoto, Nagano, Japan; ¹⁴Matsuyama Red Cross Hospital, Matsuyama, Japan; ¹⁵Pusan National University Hospital, Busan, South Korea; ¹⁶Johnson&Johnson, Los Angeles, CA, USA; ¹⁷Johnson&Johnson, Netherlands; ¹⁸IQVIA, Shanghai, China; ¹⁹Johnson&Johnson, Shanghai, China; ²⁰Johnson&Johnson, Beijing, China; ²¹Johnson & Johnson, Singapore, Singapore

Key Takeaway

D-VCd delivered rapid, deep response and durable clinical benefit alongside a manageable safety profile in Asian patients with cardiac AL amyloidosis, consistent with the findings from the individual AMY2009 and AMY3001 studies. These findings support D-VCd as an effective frontline standard of care for patients with cardiac-involved ND-AL amyloidosis.

Conclusions

D-VCd yielded rapid and deep hematologic responses in Asian patients with cardiac-involved ND-AL amyloidosis, with a HemCR rate of 61.0% and a median time to response of 58 days.

D-VCd achieved robust organ improvements at Month 6, showing cardiac and renal response rates of 48.8% and 34.1%, respectively.

The median overall survival was not reached and no new safety signals were identified.

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Supplementary material

<https://www.congresshub.com/Oncology/IMS2026/Daratumumab/Lu>

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Introduction

- Amyloid light-chain (AL) amyloidosis is a rare but life-threatening plasma cell disorder in which misfolded immunoglobulin light chains deposit in vital organs¹.
- Cardiac involvement is the leading cause of mortality and occurs in approximately 70% of newly diagnosed (ND) patients²⁻⁴.
 - In China, the most commonly involved organs is heart (83.6%)⁵. Most patients were classified as IIIa/IIIb (74.7%) and III/IV (73.2%) according to the Mayo 2004 and Mayo 2012 staging systems⁶.
 - Compared with foreign cohorts, patients in China generally have advanced cardiac stage, suggesting delayed diagnosis and insufficient evaluations^{6,7}.
- Daratumumab plus bortezomib, cyclophosphamide, and dexamethasone (D-VCd) is the only approved frontline regimen for newly diagnosed AL (ND-AL) amyloidosis^{1,8}. However, no dedicated data exist on its use in cardiac-involved Asian patients.
- Here, we report a post-hoc pooled analysis of D-VCd in cardiac-involved Asian population.

Results

Baseline Characteristics
The pooled Asian cohort (N=41) had a median age of 61 years (range, 37–82), with 65.9% male. Mayo cardiac stage II and IIIa were nearly equally represented (48.8% and 51.2%, respectively). The majority had multiple organ involvement (median 2.1 organs), and 68.3% had renal involvement at baseline. (**Table 1**)

Table 1: Baseline Characteristics		
	Asian subgroup n =41	China subgroup n =26
Median (range) age, years	61.0 (37-82)	58.0 (37-76)
Male sex, n (%)	27 (65.9)	18 (69.2)
Median (range) duration of follow-up, months	11.5 (0-21)	11.4 (0-13)
ECOG performance status, n (%)		
0	15 (36.6)	5 (19.2)
1	21 (51.2)	16 (61.5)
2	5 (12.2)	5 (19.2)
Type of measurable disease, n (%)	n =40	n =25
Serum FLC only	21 (52.5)	12 (48.0)
Number of organs involved, mean (SD)	2.1 (0.87)	2.2 (0.94)
Organ involvement, n (%)		
Gastrointestinal tract	5 (12.2)	2 (7.7)
Heart	41 (100)	26 (100)
Kidney	28 (68.3)	19 (73.1)
Liver	5 (12.2)	5 (19.2)
Soft tissue	8 (19.5)	5 (19.2)
Cardiac stage ^a , n (%)		
II	20 (48.8)	13 (50.0)
IIIa	21 (51.2)	13 (50.0)
NYHA functional class, n (%)		
I	19 (46.3)	9 (34.6)
II	19 (46.3)	14 (53.8)
IIIa	3 (7.3)	3 (11.5)
Renal function status, creatinine clearance < 60 mL/min, n (%)	19 (46.3)	12 (46.2)
Chronic kidney disease stage ^b , n (%)		
I	15 (36.6)	10 (38.5)
II	11 (26.8)	5 (19.2)
IIIa	10 (24.4)	8 (30.8)
IV	4 (9.8)	2 (7.7)
V (End stage renal disease)	1 (2.4)	1 (3.8)
Renal stage ^c , n (%)		
I	18 (43.9)	9 (34.6)
II	19 (46.3)	14 (53.8)
III	4 (9.8)	3 (11.5)

^aCardiac stage was classified in accordance with the European modification of the staging system of the Mayo Clinic.
^bRelative to the start of the first study treatment administration
^cRenal stage is derived based on the combination of eGFR (estimated glomerular filtration rate) and proteinuria
ECOG PS, Eastern Cooperative Oncology Group performance status; FLC, free light chains; NYHA, New York Heart Association

- Efficacy outcomes: Overall HemCR**
- In the Asian subgroup, the overall HemCR rate was 61.0% (95% CI, 44.5–75.8), with 53.7% (95% CI, 37.4–69.3) achieving HemCR by Month 6. In the China subgroup, the corresponding rates were 65.4% (95% CI, 44.3–82.8) and 61.5% (95% CI, 40.6–79.8), respectively. (**Figure 2 & 3**)
 - Among 25 hemCR patients, the median time to HemCR was 58 days (range, 28–240) in the Asian subgroup, and 60 days (range, 28–240) out of 17 HemCR Chinese patients.

- Organ response rate**
- The cardiac response rate at Month 6 in the Asian subgroup was 48.8% (95% CI, 32.9–64.9) vs. 53.8% (95% CI, 33.4–73.4) in the China subgroup. (**Figure 3**)
 - The renal response rate at Month 6 in the Asian subgroup was 34.1% (95% CI, 20.1–50.6) vs. 46.2% (95% CI, 26.6–66.6) in the China subgroup. (**Figure 3**)

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Methods

- Study design and patients**
- The pooled analysis included cardiac-involved Asian patients from China, Japan, and Korea with ND-AL amyloidosis (European modification of the Mayo Clinic Cardiac Staging System II–IIIa) treated with D-VCd. The study design was illustrated in Figure 1.

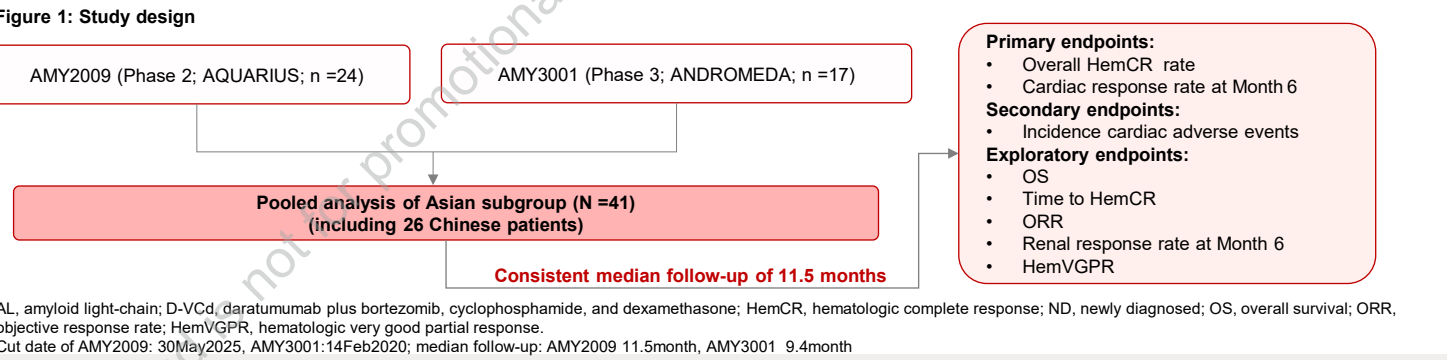


Figure 2: Overall HemCR Rate

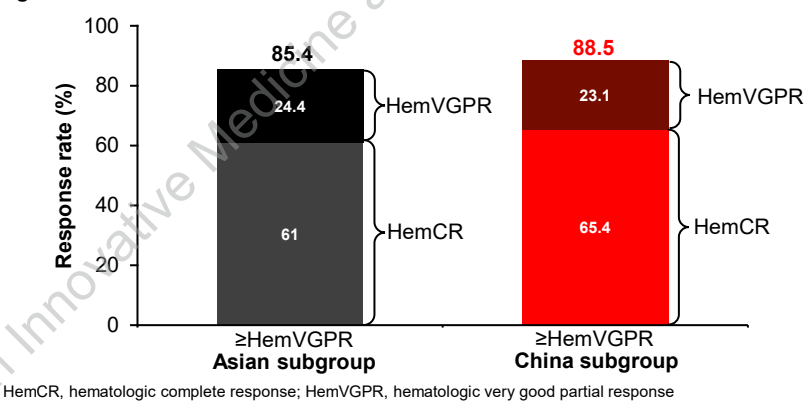


Figure 3: Hematologic response and organ response at Month 6

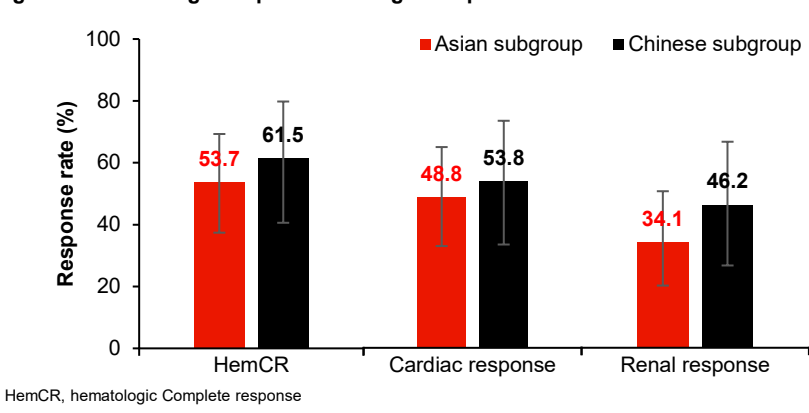
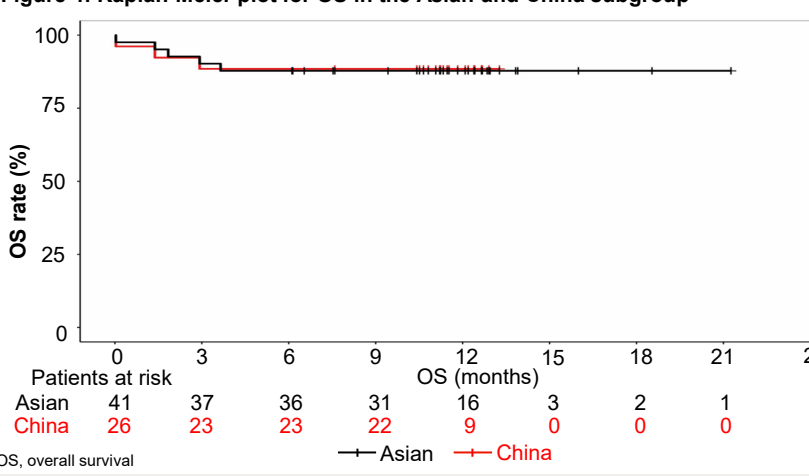


Figure 4: Kaplan-Meier plot for OS in the Asian and China subgroup



Survival outcomes

- The 12-month OS rate was 87.8% (95% CI, 78.3–98.4) in the Asian subgroup vs. 88.5% (95% CI, 77.0–100.0) in the China subgroup. (**Figure 4**)
- Median OS was not reached.

Safety

- All patients experienced ≥1 TEAE; serious and Grade ≥3 TEAEs occurred in 55.0% and 80.0%, respectively. (**Table 2**)
- TEAEs leading to death were reported in 3 patients (7.5%); 5 deaths (12.2%) occurred overall, with no patient discontinued treatment due to TEAEs.
- Cardiac TEAEs were observed in 30.0%, most commonly cardiac failure (20.0%).
- The safety profile of D-VCd in Asian patients was generally consistent with the overall safety population.^{3,4}

Table 2: Summary of TEAE and cardiac TEAE

	Asian subgroup n =40	China subgroup n =25
TEAE		
Patients with a TEAE, n (%)	40 (100.0)	25 (100.0)
Related TEAE, n (%)	36 (90.0)	25 (100.0)
Grade ≥3 TEAE, n (%)	32 (80.0)	23 (92.0)
Serious TEAE, n (%)	22 (55.0)	16 (64.0)
Related serious TEAE	14 (35.0)	9 (36.0)
TEAE leading to treatment discontinuation, n (%)	0	0
TEAE leading to death, n (%)	3 (7.5)	1 (4.0)
Related TEAE leading to death	2 (5.0)	1 (4.0)
Cardiac TEAE*		
Patients with a cardiac TEAE, n (%)	12 (30.0)	10 (40.0)
Related cardiac TEAE	6 (15.0)	4 (16.0)
Cardiac TEAE of any grade, n (%)		
Cardiac failure	8 (20.0)	6 (24.0)
Restrictive cardiomyopathy	3 (7.5)	3 (12.0)
Atrial fibrillation	1 (2.5)	1 (4.0)
Myocardial injury	1 (2.5)	1 (4.0)
Palpitations	1 (2.5)	1 (4.0)
Right ventricular dysfunction	1 (2.5)	1 (4.0)
Sinus tachycardia	1 (2.5)	1 (4.0)
Ventricular extrasystoles	1 (2.5)	1 (4.0)
Grade ≥3 cardiac TEAE, n (%)	7 (17.5)	5 (20.0)
Serious cardiac TEAE, n (%)	7 (17.5)	5 (20.0)
Related serious cardiac TEAE	5 (12.5)	3 (12.0)
Cardiac TEAE leading to death, n (%)	2 (5.0)	1 (4.0)
Related TEAE leading to death	2 (5.0)	1 (4.0)

*Including cardiac failure, atrial fibrillation, sinus tachycardia, restrictive cardiomyopathy, palpitations, right ventricular dysfunction, cardiac arrest, myocardial infarction, myocardial injury, tricuspid valve incompetence, ventricular extrasystoles
TEAE, treatment-emergent adverse events

Systemic-AL Amyloidosis

