ELSEVIER

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LATE BREAKING ABSTRACTS

.

Phase 3 Randomized Study of Daratumumab (DARA) + Bortezomib, Lenalidomide, and Dexamethasone (VRd) Versus Vrd Alone in Patients (Pts) with Newly Diagnosed Multiple Myeloma (NDMM) Who Are Eligible for Autologous Stem Cell Transplantation (ASCT): Primary Results of the Perseus Trial

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Introduction: DARA plus bortezomib, thalidomide, and dexamethasone (D-VTd) quadruplet therapy has shown clinical benefit versus VTd alone and is approved for transplant-eligible pts with NDMM. VRd induction followed by autologous stem cell transplant (ASCT), VRd consolidation, and lenalidomide (R) maintenance is also considered a standard of care for transplant-eligible NDMM. In the phase 2 GRIFFIN study, intravenous DARA combined with VRd (D-VRd) induction/consolidation followed by D-R maintenance improved depth of response and progression-free survival (PFS) versus VRd induction/consolidation and R maintenance in transplant-eligible pts with NDMM after >4 years of follow-up. The phase 3 PERSEUS study is evaluating subcutaneous DARA (DARA SC) in combination with VRd induction/consolidation followed by D-R maintenance versus VRd induction/consolidation and R maintenance in transplant-eligible NDMM. Here we report the primary analysis of PERSEUS.
Methods: Pts with NDMM who were aged 18-70 years and eligible for high-dose therapy and ASCT were randomized 1:1 to D-VRd or VRd, stratified by International Staging System (ISS) stage and cytogenetic risk. All pts received up to six 28-day cycles (4 pre-ASCT induction, 2 post-ASCT consolidation) of VRd (V: 1.3 mg/m^2 SC on Days [D] 1, 4, 8, 11; R: 25 mg PO on D 1-21; d 40 mg PO/IV on D 1-4, 9-12) followed by R maintenance therapy (10 mg PO on D 1-28 until progressive disease [PD]). Pts in the D-VRd arm also received DARA SC (DARA 1,800 mg co-formulated with recombinant human hyaluronidase PH20 [rHuPH20; 2,000 U/mL; ENHANZE® drug delivery technology, Halozyme, Inc.]) weekly in Cycles 1-2, every 2 weeks in Cycles 3-6, and every 4 weeks during maintenance until PD. The primary endpoint is PFS; key secondary endpoints include overall complete response or better (≥CR) rate, overall minimal residual disease (MRD)-negativity rate (10^{-5} threshold; clonoSEQ®), and overall survival. Response and disease progression were assessed using a computerized algorithm based on IMWG response criteria. Overall MRD-negativity rate was defined as the proportion of pts who achieved MRD negativity and ≥CR at any time.
Results: 709 pts were randomized (D-VRd, n=355; VRd, n=354). Median (range) age was 60 (31-70) years; 14.8% had ISS stage III disease, and 21.7% had high cytogenetic risk (t[4;14], t[14;16], or del[17p]). At clinical cutoff, 314 pts in the D-VRd arm and 299 pts in the VRd arm had completed all 4 induction and 2 consolidation cycles, 309 and 294 pts had undergone ASCT, and 322 and 300 pts entered maintenance. At a median follow-up of 47.5 months, PFS was significantly improved with D-VRd versus VRd (HR, 0.42; 95% CI, 0.30-0.59; P <0.0001 [crossing the prespecified stopping boundary of 0.0126]; **Figure**). Median PFS was not reached in either arm; estimated 48-month PFS rates were 84.3% for D-VRd versus 67.7% for VRd. Prespecified subgroup analyses showed a consistent PFS improvement with D-VRd versus VRd across clinically relevant subgroups, including pts with ISS stage III disease and pts with high cytogenetic risk. Overall rates of ≥CR (87.9% vs 70.1%; P <0.0001) and MRD negativity (75.2% vs 47.5%; P <0.0001) were significantly higher with D-VRd versus VRd. Overall survival was immature, with 78 deaths on study (D-VRd, 34 [9.6%]; VRd, 44 [12.4%]). Overall, 7 deaths due to COVID-19 occurred (D-VRd, 4; VRd, 3). The most frequent (≥10%) grade 3/4 treatment-emergent adverse events (TEAEs) for the D-VRd/VRd arms were neutropenia (62.1%/51.0%), thrombocytopenia (29.1%/17.3%), diarrhea (10.5%/7.8%), pneumonia (10.5%/6.1%), and febrile neutropenia (9.4%/10.1%). For D-VRd and VRd, serious TEAEs occurred in 57.0% versus 49.3% of pts, and TEAEs leading to treatment discontinuation occurred in 8.8% versus 21.3% of pts.
Conclusions: DARA SC combined with VRd in transplant-eligible pts with NDMM significantly improved PFS and increased depth of response (≥CR and MRD negativity), with consistent PFS benefit across clinically relevant subgroups. The safety profile was consistent with the known safety profiles for DARA SC and VRd. These data, together with results from the phase 2 GRIFFIN study, demonstrate the consistent and clinically meaningful benefit of quadruplet DARA plus VRd followed by D-R maintenance versus triplet VRd followed by R maintenance and support the combination of DARA plus VRd followed by D-R maintenance as a new standard of care for transplant-eligible NDMM.

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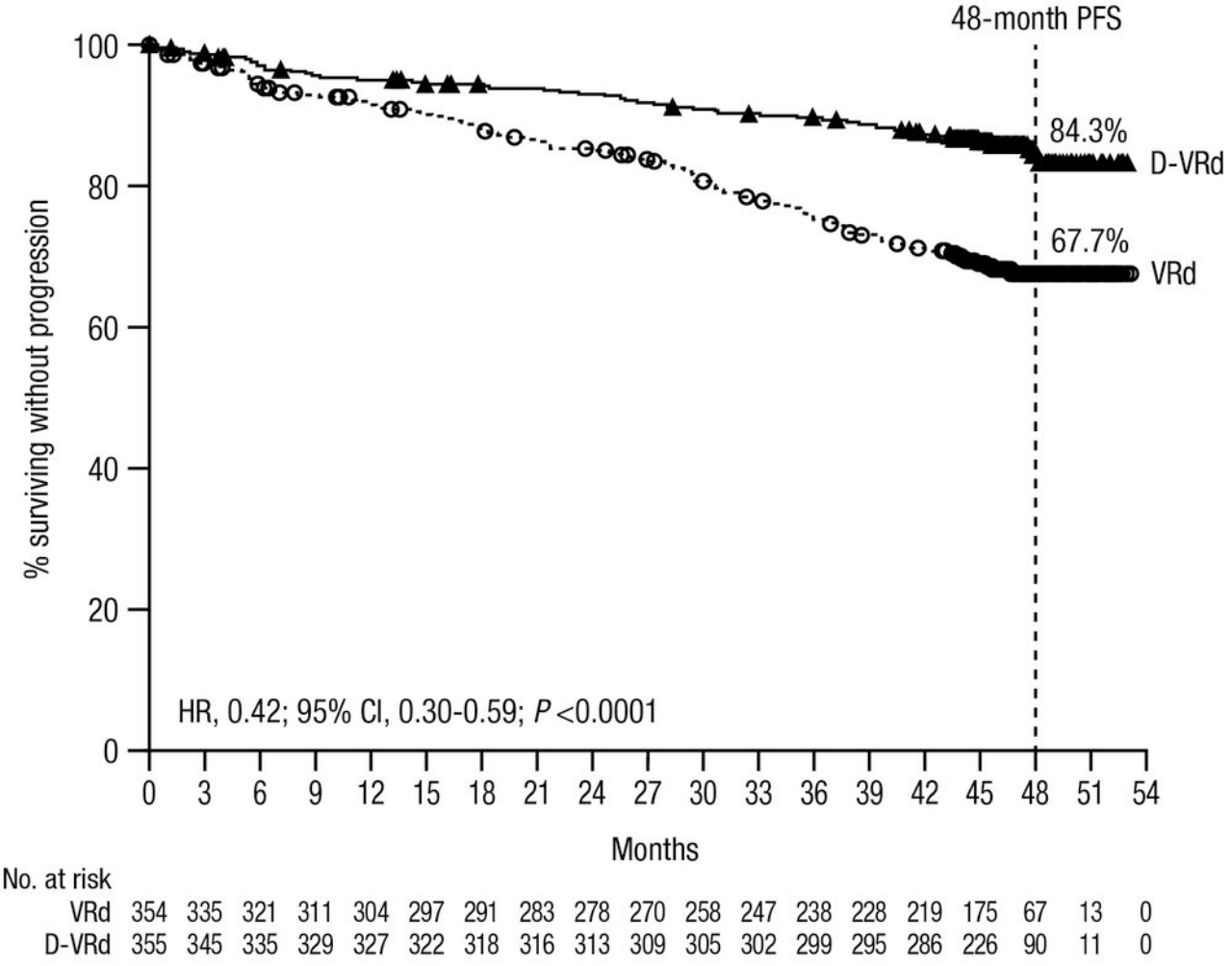
OffLabel Disclosure: Daratumumab is currently approved in combination with bortezomib, thalidomide, and dexamethasone for the treatment of patients with transplant-eligible newly diagnosed multiple myeloma, but it is not yet approved in combination with bortezomib, lenalidomide, and dexamethasone for the treatment of patients with transplant-eligible newly diagnosed multiple myeloma.

Figure. PFS with D-VRd versus VRd in transplant-eligible NDMM.



PFS, progression-free survival; D-VRd, daratumumab plus bortezomib/lenalidomide/dexamethasone; VRd, bortezomib/lenalidomide/dexamethasone; HR, hazard ratio; CI, confidence interval.

Figure 1

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