

Efficacy of Oral DFD-29, a Low-Dose Minocycline Formulation, in Patients With Rosacea: A Pooled Analysis of Two Phase 3 Trials

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BACKGROUND

- A modified low-dose formulation of minocycline hydrochloride 40 mg (DFD-29) is now available in the United States as Emrosi™ (minocycline hydrochloride [HCl]) for treating the inflammatory lesions of rosacea
- In this pooled analysis, we evaluate the efficacy of DFD-29 compared to Oracea® (doxycycline 40 mg) and placebo in the two phase 3 trials

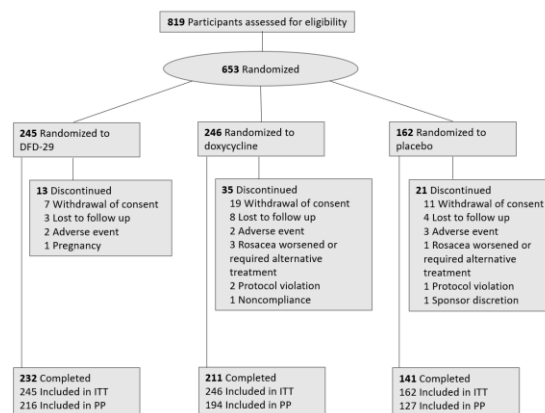
METHODS

- Two double-blind, placebo-controlled, phase 3 clinical trials (MVOR-1 [NCT05296629] and MVOR-2 [NCT05343455]) among adults aged ≥18 years with moderate-to-severe rosacea were conducted in the US and Germany¹
- Participants were randomized in a 3:3:2 ratio to oral DFD-29 (minocycline HCl capsules) 40 mg, doxycycline 40 mg, or placebo once daily for 16 weeks
- The coprimary efficacy endpoints were
 - The proportion of participants demonstrating Investigator's Global Assessment (IGA) treatment success with DFD-29 vs placebo
 - Reductions in total inflammatory lesion counts with DFD-29 vs placebo
- Comparisons between DFD-29 and doxycycline were secondary endpoints

RESULTS

- A total of 653 participants were randomized (323 in MVOR-1 and 330 in MVOR-2), as shown in **Figure 1**

Figure 1. Patient disposition



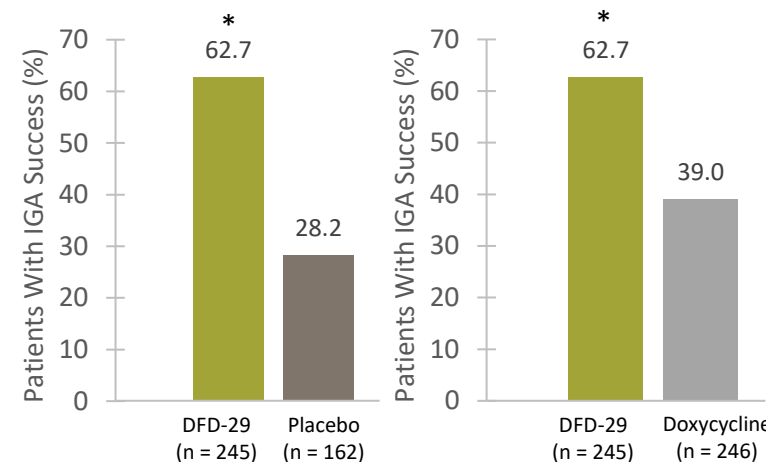
RESULTS (cont'd)

- In the pooled analysis of both trials, demographics and baseline characteristics were similar between groups (**Table 1**)

Table 1. Demographics and baseline characteristics, n (%)

	DFD-29 (n = 245)	Doxycycline (n = 246)	Placebo (n = 162)	Total (N = 653)
Mean age, y (SD)	48.7 (13.5)	50.2 (14.5)	49.3 (14.0)	49.4 (14.0)
Female, n (%)	195 (79.6)	174 (70.7)	127 (78.4)	496 (76.0)
Race				
African American/Black	6 (2.4)	5 (2.0)	1 (0.6)	12 (1.8)
Asian	7 (2.9)	9 (3.7)	7 (4.3)	23 (3.5)
White	229 (93.5)	229 (93.1)	151 (93.2)	609 (93.3)
Other	2 (0.8)	2 (0.8)	1 (0.6)	5 (0.8)
Ethnicity				
Hispanic or Latino	92 (37.6)	99 (40.2)	58 (35.8)	249 (38.1)
Mean weight, kg (SD)	86.0 (20.8)	87.6 (22.0)	85.2 (22.8)	86.4 (21.7)
IGA				
Moderate	211 (86.1)	221 (89.8)	145 (89.5)	577 (88.4)
Severe	34 (13.9)	25 (10.2)	17 (10.5)	76 (11.6)
Mean inflammatory lesion count (SD)	25.2 (9.2)	24.4 (8.9)	25.0 (8.4)	24.9 (8.9)

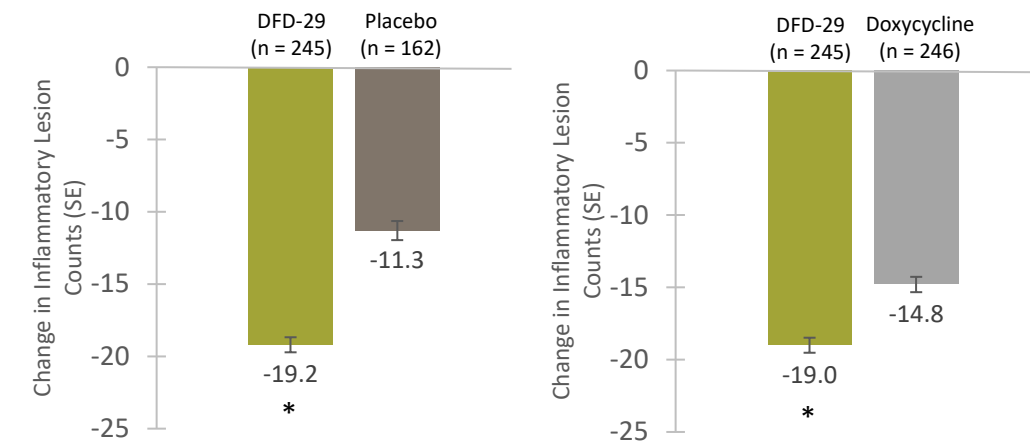
Figure 2. Proportion of patients with IGA treatment success at Week 16



*P<0.001 vs both placebo and doxycycline.

- DFD-29 demonstrated superior efficacy in IGA success rates (**Figure 2**) and inflammatory lesion counts (**Figure 3**) vs both placebo and doxycycline (P<0.001 for all comparisons)

Figure 3. Reduction in inflammatory lesion counts at Week 16



*P<0.001 vs both placebo and doxycycline.

- DFD-29 was generally well tolerated, with no notable between-group differences in the frequency or severity of reported AEs (**Table 2**)

Table 2. Treatment-emergent adverse events, n (%)

	DFD-29 (n = 243)	Doxycycline (n = 237)	Placebo (n = 158)	Total (N = 638)
≥1 TEAE	83 (34.2)	65 (27.4)	57 (36.1)	205 (32.1)
Any treatment-related TEAE	14 (5.8)	16 (6.8)	11 (7.0)	41 (6.4)
Any serious AE	2 (0.8)	0	1 (0.6)	3 (0.5)
AEs leading to treatment discontinuation	3 (1.2)	3 (1.3)	4 (2.5)	10 (1.6)
Most common TEAEs				
COVID-19	11 (4.5)	11 (4.6)	9 (5.7)	31 (4.9)
Nasopharyngitis	17 (7.0)	12 (5.1)	16 (10.1)	45 (7.1)
Headache	5 (2.1)	8 (3.4)	4 (2.5)	17 (2.7)
Diarrhea	5 (2.1)	5 (2.1)	6 (3.8)	16 (2.5)
Nausea	0 (0)	5 (2.1)	2 (1.3)	7 (1.1)

CONCLUSION

- This pooled analysis confirmed the superior efficacy of DFD-29 in the treatment of inflammatory lesions of rosacea versus both placebo and doxycycline 40 mg and demonstrated its favorable risk-benefit profile

ABBREVIATIONS: AEs, adverse events; IGA, Investigator's Global Assessment; SD, standard deviation; TEAE, treatment-emergent adverse event.

REFERENCE: 1. Bhatia N, et al. *JAMA Dermatol.* 2025;161(5):499-507.