Efficacy of Oral DFD-29, a Low-Dose Minocycline Formulation, in Patients in Germany and in the US: An Analysis of Two Phase 3 Trials

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SYNOPSIS

- A modified low-dose formulation of minocycline hydrochloride 40 mg (DFD-29) has been approved for treating inflammatory lesions in patients with rosacea in the United States (US)

OBJECTIVE

- This pooled analysis of two phase 3 trials evaluated the efficacy of DFD-29 in patients in Germany and the US

METHODS

- Two double-blind, placebo-controlled, phase 3 clinical trials among adults aged ≥18 years with moderate-to-severe rosacea were conducted in the US and Germany
- Participants were randomly assigned in a 3:3:2 ratio to oral DFD-29 (40 mg), doxycycline 40 mg, or placebo once daily for 16 weeks
- Key efficacy endpoints included the proportion of participants demonstrating Investigator's Global Assessment (IGA) treatment success (clear/almost clear skin) and reductions in total inflammatory lesion counts in the DFD-29 group compared to the placebo and doxycycline groups
- Sub-group analyses of the pooled results were conducted to evaluate the efficacy of DFD-29 in participants enrolled in the US and in Germany

RESULTS

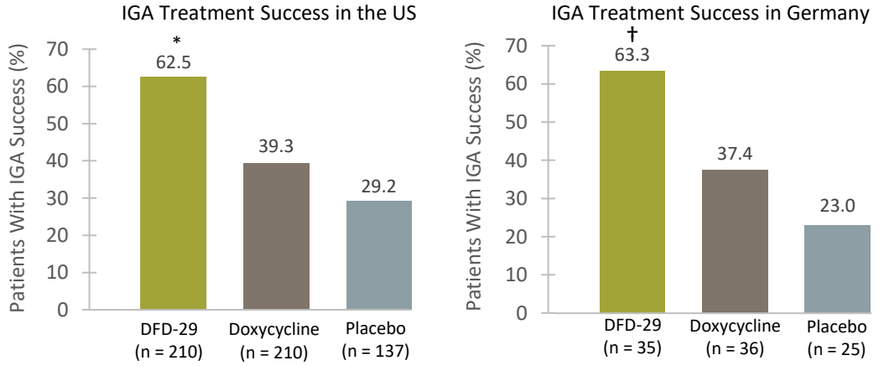
- A total of 653 participants were randomized, including 557 participants in the US and 96 participants in Germany
- In the pooled analysis of both trials, demographics and baseline characteristics were similar between treatment groups (**Table 1**)
- In the US, significantly more patients achieved IGA treatment success with DFD-29 vs placebo and doxycycline (**Figure 1**)
- In Germany, IGA success rates with DFD-29 were significantly higher vs placebo (*P*=0.006) and numerically but not statistically significantly higher vs doxycycline (*P*=0.064)

RESULTS (cont'd)

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, n (%)				
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), n (%)	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)
Country, n (%)				
US	210 (85.7)	210 (85.4)	137 (84.6)	557 (85.3)
Germany	35 (14.3)	36 (14.6)	25 (15.4)	96 (14.7)
IGA, n (%)				
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 1. Proportion of patients with IGA success (clear/almost clear skin) at Week 16

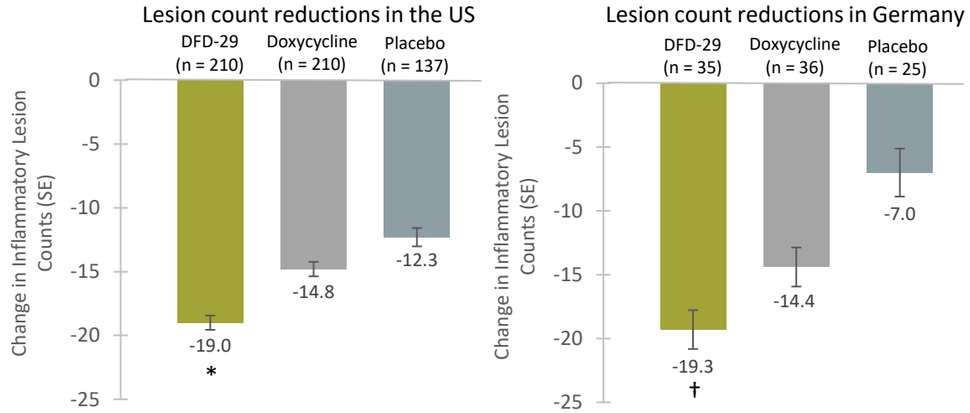


**P*<0.001 vs both placebo and doxycycline.

†*P*=0.006 vs placebo and *P*=0.064 vs doxycycline.

- DFD-29 showed significantly superior efficacy in LSM reductions in total inflammatory lesion counts vs both placebo and doxycycline in both the US and Germany

Figure 3. Reduction in inflammatory lesion counts at Week 16



**P*<0.001 vs both placebo and doxycycline.

†*P*<0.001 vs placebo and *P*=0.025 vs 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)

CONCLUSIONS

- DFD-29 showed superior efficacy to both placebo and doxycycline 40 mg in treating the inflammatory lesions of rosacea
- There were no clinically meaningful differences in DFD-29 efficacy versus placebo and doxycycline between geographic regions

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.

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