

DFD-29, a low dose oral minocycline, shows significant improvement in quality of life in subjects with papulopustular rosacea

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Introduction

- Rosacea is a chronic facial skin disease that can have an adverse effect on quality of life.
- DFD-29 a low dose oral minocycline is being evaluated as an anti-inflammatory treatment option for papulopustular rosacea.

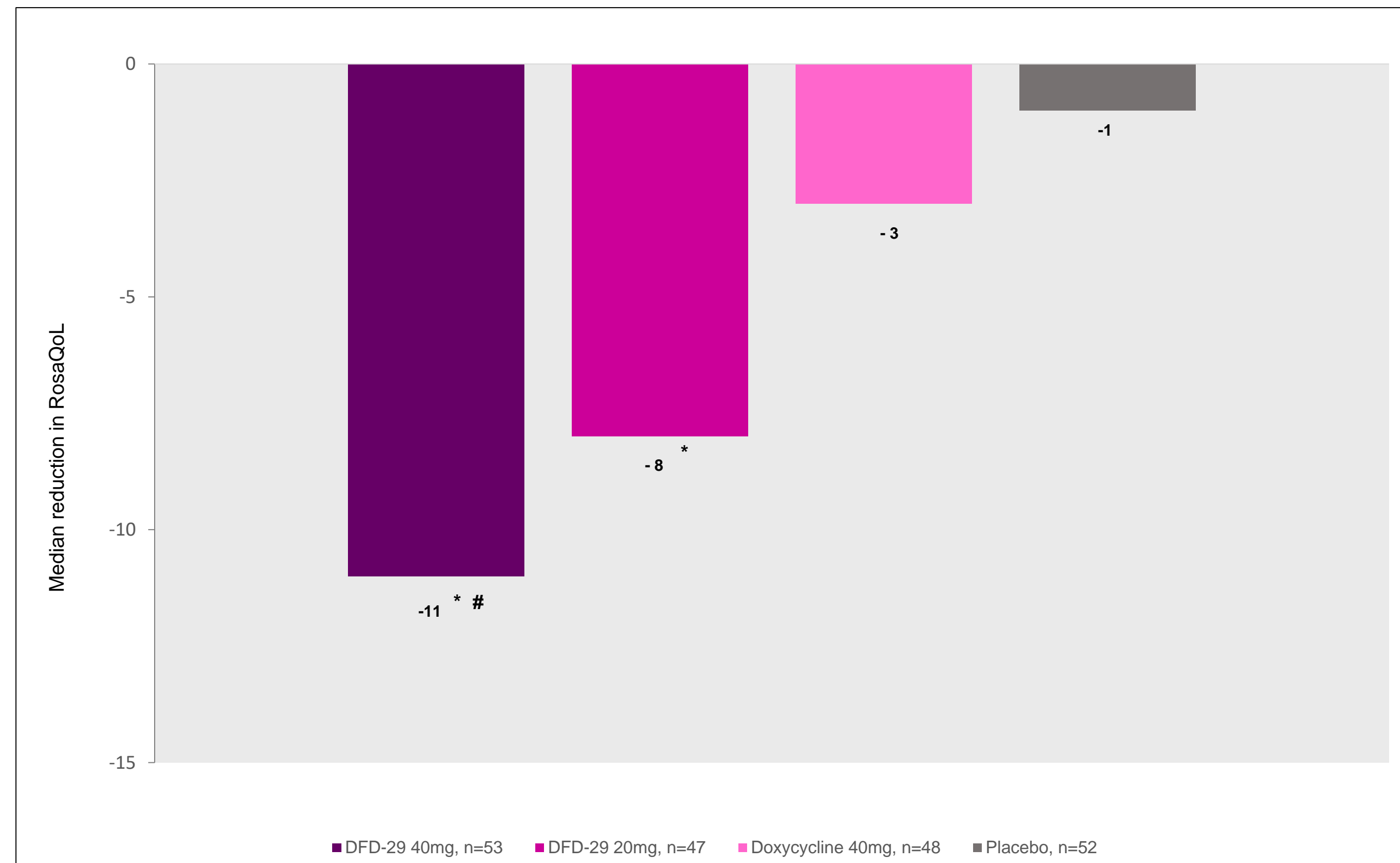
Methods

- This phase 2, randomized, double-blind trial enrolled adults with mild, moderate or severe papulopustular rosacea.
- Subjects were randomized to receive DFD-29 (minocycline HCl) 40 mg extended release (ER) capsules, DFD-29, 20 mg ER capsules, Oraycea® (doxycycline HCl) 40 mg capsules or placebo, one capsule a day for 16 weeks.
- A key endpoint in the study was to assess change in the Quality of Life (QoL) using RosaQoL (a rosacea specific QoL tool) from baseline to week 16. RosaQoL has 21 general questions each rated on a 5-grade scale, and 6 global questions. A reduction in the total RosaQoL score indicates an improved QoL.
- In an earlier phase 1 study, the dermal Interstitial Space Fluid (dISF) levels of doxycycline (Oraycea) and minocycline (DFD-29) were measured, using Open-Flow Microperfusion (OFM) in healthy human subjects.

Results

- The Full Analysis Set (FAS) included 200 subjects. Of these, 53 subjects were in the DFD-29 (40 mg) group, 47 in DFD-29 (20 mg), 48 in doxycycline (40 mg) and 52 in the placebo group. At week 16 the median reduction in total RosaQoL was 11 points in DFD-29 (40 mg), 8 points in DFD-29 (20 mg), 3 points in doxycycline (40 mg) and 1 point in the placebo group (Fig.1).
- Highly statistically significant treatment differences ($p < 0.0001$) were demonstrated for DFD-29 (40 mg) versus placebo and doxycycline (40 mg), as well as for DFD-29 (20 mg) versus Placebo.
- The OFM study demonstrated that DFD-29 (40 mg) and oral doxycycline 40 mg, provide similar dermal interstitial space fluid (dISF) levels of minocycline and doxycycline, respectively.

Figure 1. RosaQoL reduction at week 16



*Statistical significance reported vs placebo, # Statistical significance reported vs Doxycycline

Conclusions

- Improvement in the quality of life is a significant unmet need in rosacea. DFD-29 has the potential to meet this unmet need, and be an important therapeutic tool in the physician's armamentarium.