**INTRODUCTION AND SYNOPSIS**

- Rosacea is a chronic, inflammatory facial skin disease that affects 5% to more than 10% of the population and can adversely affect quality of life.\(^1,2\)
- Papulopustular rosacea is the second most common subtype.
- A low-dose formulation of minocycline hydrochloride (HCl), DFD-29, has shown significant therapeutic benefit versus placebo and doxycycline in treating papulopustular rosacea.\(^3\)

**OBJECTIVES**

- To assess the comparative bioavailability of DFD-29 (minocycline HCl modified-release capsules, 40 mg) vs Solodyn\(^\circledR\) (minocycline HCl, extended-release [ER] tablets, 105 mg)\(^4\)*
- To evaluate the impact of food on DFD-29 bioavailability
- To evaluate the safety and tolerability profile of DFD-29

**METHODS**

- This single-center, randomized, open-label, laboratory-blinded, 3-way, 6-sequence crossover study compared the pharmacokinetics of a single dose of:
  - DFD-29 fasting: DFD-29 40 mg after an overnight fast of ≥10.5 hours
  - DFD-29 fed: DFD-29 40 mg after an overnight fast of ≥10.5 hours and 30 minutes after the start of a high-fat, high-calorie breakfast
  - Minocycline ER: Minocycline HCL ER 105 mg after an overnight fast of ≥10.5 hours
- Blood samples were collected for PK assessments prior to and up to 72 hours after each drug dose, with a washout period of 7 calendar days between doses
- Safety was evaluated by monitoring adverse events (AEs), vital signs, and laboratory tests

**RESULTS**

- A total of 24 subjects were randomized and 23 subjects completed the study
- One subject in Group 5 prematurely discontinued due to COVID-19 per the physician’s discretion.
- Mean age of the subjects was 42.4 years (15.5 SD). Most subjects were male (20, 87.0%), white (18, 78.3%), and not Hispanic or Latino (18, 78.3%). Mean BMI was 25.0 kg/m\(^2\) (2.6 SD).

**CONCLUSIONS**

- Bioavailability was significantly lower after a single dose of DFD-29 40 mg under fasting and fed conditions vs minocycline HCl ER 105 mg following a single dose under fasting conditions.
- Food intake had no impact on DFD-29 C\(_{\text{max}}\) but may delay absorption and may slightly increase exposure.
- Overall, a single oral dose of DFD-29 40 mg and minocycline HCl ER 105 mg was generally safe and well tolerated.

**ABBREVIATIONS**

- AEs, adverse events; CI, confidence interval; CV, coefficient of variation; ER, extended-release; HCl, hydrochloride; SAE, severe adverse event; LS, least-square; SD, standard deviation; TEAEs, treatment-emergent adverse events.

**REFERENCES**


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*Vascular Pharmacists North America, LLC (VPSW, N. USA).

**Table 1. Study sequences**

<table>
<thead>
<tr>
<th>Group</th>
<th>Period 1</th>
<th>Period 2</th>
<th>Period 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (n = 4)</td>
<td>DFD-29 fasting</td>
<td>DFD-29 fed</td>
<td>Minocycline ER</td>
</tr>
<tr>
<td>Group 2 (n = 4)</td>
<td>DFD-29 fed</td>
<td>Minocycline ER</td>
<td>DFD-29 fasting</td>
</tr>
<tr>
<td>Group 3 (n = 4)</td>
<td>Minocycline ER</td>
<td>DFD-29 fasting</td>
<td>DFD-29 fed</td>
</tr>
<tr>
<td>Group 4 (n = 4)</td>
<td>DFD-29 fasting</td>
<td>Minocycline ER</td>
<td>DFD-29 fed</td>
</tr>
<tr>
<td>Group 5 (n = 4)</td>
<td>DFD-29 fed</td>
<td>DFD-29 fasting</td>
<td>Minocycline ER</td>
</tr>
<tr>
<td>Group 6 (n = 4)</td>
<td>Minocycline ER</td>
<td>DFD-29 fasting</td>
<td>DFD-29 fed</td>
</tr>
</tbody>
</table>

*VPSW, N. USA.*