Omadacycline demonstrated lower microbiological success despite high clinical success versus nitrofurantoin in women with cystitis.

### Methods

Females aged 18–85 years with a diagnosis of uncomplicated cystitis with pyuria were randomized to receive one of four dose regimens of OMC, or nitrofurantoin (NIT), for 7 days (Table 1), in this Bayesian adaptive phase 2 study.

#### Table 1. Treatment groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Dose Regimen</th>
<th>Study Days</th>
<th>Participated</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>Omadacycline 300/450 q24h, fed</td>
<td>Study Days 2–7</td>
<td>94/100 (94%)</td>
<td>94/100 (94%)</td>
</tr>
<tr>
<td>Group 2</td>
<td>Omadacycline 450/450 q12h, fed</td>
<td>Study Days 2–7</td>
<td>94/100 (94%)</td>
<td>94/100 (94%)</td>
</tr>
<tr>
<td>Group 3</td>
<td>Nitrofurantoin 100/100 q12h, fed</td>
<td>Study Days 2–7</td>
<td>94/100 (94%)</td>
<td>94/100 (94%)</td>
</tr>
<tr>
<td>Group 4</td>
<td>Omadacycline 300/600 q24h, fed</td>
<td>Study Days 2–7</td>
<td>94/100 (94%)</td>
<td>94/100 (94%)</td>
</tr>
</tbody>
</table>

Notes: 1. Groups 1 and 2 were fed for all treatments. 2. Groups 3 and 4 were fed for all but the highest daily dose (800 mg). 3. OMC was ascertained via a single-blind ITT (sITT) analysis, oMC was ascertained via a single-blind ITT (sITT) analysis.

Efficacy was assessed as noninferiority of investigator’s assessment of clinical response (ACR) at PTE (Day 16) to the intent-to-treat (ITT) population, per the regulatory approval guidance of the US Food and Drug Administration (FDA).

- **ACR**: ACR at D3 (day of last treatment).
- **Microbiological response at D3 and PTE**: In the microbiological-ITT (mITT) population, all randomized patients who had a study-qualifying pre-treatment baseline urine culture.

### Results

#### Conclusions

Clinical success rates were high in the OMC and NIT groups, although no OMC group met criteria of noninferiority to NIT.

Microbiological responses with all doses of OMC were lower than the NIT group.

Results were potentially influenced by the higher baseline MICs observed in this study compared with the previous phase 1b study.

OFC was well tolerated, with a safety profile consistent with its current labeling.

### Statistical analysis

Noninferiority of OMC to NIT was demonstrated if the lower limit of the two-sided exact 95% confidence interval (CI) for the difference in ACR at PTE was within −10%.

### References

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