**INTRODUCTION**

Herpes simplex virus type 2 (HSV-2) is a common sexually transmitted infection that may cause recurrent, painful genital lesions. Affecting over 400 million people worldwide, it is transmitted via viral shedding from the genital tract during clinical recurrences and more commonly during episodes of subclinical shedding.1

**RESULTS: Patient Demographics**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Median</th>
<th>1st Quartile</th>
<th>3rd Quartile</th>
<th>5th Percentile</th>
<th>95th Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>25.0</td>
<td>20.0</td>
<td>30.0</td>
<td>20.0</td>
<td>35.0</td>
</tr>
<tr>
<td>Female</td>
<td>26.0</td>
<td>21.0</td>
<td>31.0</td>
<td>20.0</td>
<td>35.0</td>
</tr>
</tbody>
</table>

**RESULTS: Safety**

<table>
<thead>
<tr>
<th>Safety Category</th>
<th>Drug Product</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site pain</td>
<td>84.1%</td>
<td>88.6%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>88.6%</td>
<td>91.1%</td>
</tr>
<tr>
<td>Headache</td>
<td>88.6%</td>
<td>95.5%</td>
</tr>
<tr>
<td>Muscle pain</td>
<td>84.1%</td>
<td>88.6%</td>
</tr>
<tr>
<td>Nausea</td>
<td>88.6%</td>
<td>91.1%</td>
</tr>
</tbody>
</table>

**Table 2: Viral Shedding Reduction per Group**

<table>
<thead>
<tr>
<th>Protein dose</th>
<th>% Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>30/75 µg</td>
<td>90.0%</td>
</tr>
<tr>
<td>30/50 µg</td>
<td>92.7%</td>
</tr>
<tr>
<td>30/25 µg</td>
<td>95.6%</td>
</tr>
</tbody>
</table>

**Table 3: Lesion Rate Reduction per Group**

<table>
<thead>
<tr>
<th>Protein dose</th>
<th>% Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>30/75 µg</td>
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<tr>
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<td>30/25 µg</td>
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</tr>
</tbody>
</table>

**DISCUSSION & CONCLUSIONS**

In this Phase 2 study, GEN-003, a therapeutic vaccine for genital herpes, demonstrated profound and durable effect on viral shedding and lesion rates, confirming results of a previous Phase 1 study. Safety was acceptable for a therapeutic vaccine. The placebo effect observed on lesion rates, had not been seen in the first study, and may reflect an expectation of benefit, 61 randomization scheme, and/or short follow-up for placebo recipients. Twelve month data will be available in early 2016.