Objective

The primary objective is to assess preliminary radiographic objective responses in CRPC patients treated with seviteronel using the combined data from INO-VT-464-CL-001 and INO-VT-464-CL-004.

Study Design

- Radiographic and PSA data were collected from 51 patients enrolled in INO-VT-464-CL-001 (NCT02330100) or INO-VT-464-CL-004 (NCT02330101).
- These studies are evaluating the safety, tolerability and pharmacodynamic effects (tumor responses, PSA and testosterone decreases) of seviteronel given without steroid supplementation either bid with food (INO-VT-464-CL-001) or at night without food (INO-VT-464-CL-004).
- Patients were either TN or had progressed on abiraterone/prednisone (ZF) or enzalutamide (XF) or abiraterone/prednisone/ezetimibe/chemotherapy (at least 2 of the 3, SP).

Results

Table 1: Demographics of patients included in objective response analysis (n=23)

<table>
<thead>
<tr>
<th>Study</th>
<th>Dose Regimen</th>
<th>TN</th>
<th>ZF</th>
<th>XF</th>
<th>SP</th>
</tr>
</thead>
<tbody>
<tr>
<td>INO-VT-464-CC-001</td>
<td>900 mg bid (n=10)</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>INO-VT-464-CL-004</td>
<td>450 mg bid + DT (n=12)</td>
<td>2</td>
<td>2</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>INO-VT-464-CL-005</td>
<td>600 mg bid + DT (n=1)</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>INO-VT-464-CL-006</td>
<td>50 mg bid (n=4)</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

- 23 of 38 M patients with ≥1 target lesion had ≥1 post-baseline scan
- Of 15 patients who were included treated bid (Study 001), 10 had PD, 1 had SD and 2 had a PR.
- Of 8 patients who were treated qd (Study 004), 2 had PD, 2 had SD and 1 had a PR.
- No patients had a CR in either study.

Conclusions

- Medical history of glaucoma
- Prior surgical controls with bicalutamide and enzalutamide treatment
- De novo resistance to enzalutamide Oct 2013 to Dec 2013
- Discontinued seviteronel June 2014 due to visual fogginess (fic) no new CRPC therapy started
- PSA undetectable 19 mo after seviteronel discontinuation, no signs of clinical or radiographic progression

References