INTRODUCTION

- JNJ-902 is a bispecific antibody that engages TMEFF2-expressing tumor cells and CD3+ T cells causing exposure-dependent pro-inflammatory responses and target tumor cell lysis.
- JNJ-70218902 (JNJ-902), a TMEFF2 x CD3 Bispecific Antibody,

METHODS

- Study design schema (Figure 1)
- Key eligibility criteria
- Adults with measurable or evaluable mCRPC
- Adenocarcinoma with small-cell or neuroendocrine features allowed
- Have received prior treatment with at least 1 prior ADT or chemotherapy

OBJECTIVE

- We report initial results from a phase 1 dose escalation trial of JNJ-902 in patients with metastatic castration-resistant prostate cancer (mCRPC) (NCT04797277)

RESULTS

Patient Demographics

- JNJ-902 was administered subcutaneously (SC) at doses ranging from 0.3 to 6 mg once weekly (Q1W) and 2 to 6 mg once every 2 weeks (Q2W)
- As of April 28, 2022, 73 patients (pts) received at least 1 dose of JNJ-902 (Q1W dosing cohorts [n=36]; Q2W SC dosing cohorts [n=37])
- Baseline characteristics are shown in Table 1

Table 1. Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Median (range)</th>
<th>25th percentile</th>
<th>75th percentile</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>66 (45-84)</td>
<td>61.6</td>
<td>70.7</td>
<td>73</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td>72c</td>
</tr>
<tr>
<td>White</td>
<td>44 (60)</td>
<td>29 (40.5)</td>
<td>61 (84)</td>
<td>31 (43)</td>
</tr>
<tr>
<td>Black</td>
<td>15 (20)</td>
<td>11 (15)</td>
<td>26 (35)</td>
<td>23 (31)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (7)</td>
<td>3 (4)</td>
<td>7 (10)</td>
<td>7 (9)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>25.9 (19.1-37.3)</td>
<td>19.4</td>
<td>32.9</td>
<td>73</td>
</tr>
<tr>
<td>Physical performance status (ECOG)</td>
<td>0 (0-2)</td>
<td>0 (0)</td>
<td>2 (3)</td>
<td>73</td>
</tr>
<tr>
<td>Prior ADT history</td>
<td>1 (0-2)</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td>73</td>
</tr>
<tr>
<td>Number of AR-targeted, taxane, cytotoxic chemotherapy, and other therapy</td>
<td>7 (2-11)</td>
<td>3 (0-7)</td>
<td>10 (3)</td>
<td>73</td>
</tr>
</tbody>
</table>

Safety

- Overall, 7 (9.6%) of 73 pts reported at least 1 treatment-emergent adverse event (TEAE).
- Most frequently reported TEAEs were injection site reactions (70%), fatigue (45%), decreased appetite (44%), anemia (33%), back pain (25%), arthralgia (23%), and nausea (19%)
- Grade 3 or higher TEAEs (≥ 5% incidence) were anemia (18%), fatigue (11%), lymphopenia (7%), asthenia (6%), and hypertension (6%)
- Treatment discontinuation occurred in 1 pt experiencing at least 1 TEAE
- Of 73 pts, 68 (92%) of 73 pts had >1 cycle of treatment

Pharmacokinetics and Immunogenicity

- In 7 pts, JNJ-902 exhibited potent T cell-mediated cytotoxicity of tumor cells expressing TMEFF2 and CD3 on T cells causing exposure-dependent pro-inflammatory responses and target tumor cell lysis

Efficacy and Pharmacodynamics

- Of 73 pts, maximum prostate-specific antigen (PSA) reductions of at least 50% were reported for 8 pts (Q1W SC dosing cohorts [n=18]; Q2W SC dosing cohorts [n=5]) (Figure 2)
- An additional 7 pts achieved a maximum PSA reduction of at least 30% (Q1W SC dosing cohorts [n=5]; Q2W SC dosing cohorts [n=2]) (Supplementary Table 2)
- Conformed partial responses were observed in 5 pts

CONCLUSIONS

- JNJ-902 exhibited a tolerable safety profile at certain doses in mCRPC patients when PSA50 and RECIST responses were observed

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DISCLOSURES

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REFERENCES


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