HF10 is a bioselected replication-competent oncolytic virus derived from HSV-1. In preclinical studies, combining ipilimumab (CTLA-4 antibody) with HF10 has shown a higher rate of complete tumor regression compared to ipilimumab monotherapy.

**Introduction**

**Abstract #166420**

IIIC, or IV metastatic malignant melanoma. Phase II trial of HF10 and ipilimumab combination treatment was designed to assess the efficacy and safety of patients with Stage IIIB, IIIC, or IV metastatic malignant melanoma.

**Phase II Study Design**

**Study Objectives**

- Evaluate the efficacy, safety, and tolerability of HF10 at 1x10^7 TCID50/mL in combination with 3mg/kg ipilimumab (ipi) in patients with Stage IIIB, Stage IIIC, or Stage IV unresectable or metastatic malignant melanoma.

**Discontinuation:**

- Best overall response rate (BORR) at Week 24
- Progression-free survival (PFS)
- Overall survival (OS)
- Safety and tolerability
- Disease control rate (DCR)
- Two-year survival
- Four-year survival
- Five-year survival

**Key Inclusion Criteria**

- Stage IIIB, IIIC, or IV Stage (unresectable/metastatic)
- Patients with a confirmed diagnosis of metastatic malignant melanoma
- Adequate renal and hepatic function
- Life expectancy ≥ 24 weeks
- No known bleeding diathesis or coagulopathy

**Trial Treatment:**

- Treatment-Emergent Adverse Events (TEAEs)
- Investigator-assessed Adverse Events (AEs)
- Treatment-related AEs

**Phase II Overall Results**

**Table 1: Safety Summary**

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Number of Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Response (irCR + irPR)</td>
<td>48 (100%)</td>
</tr>
<tr>
<td>Safety and tolerability</td>
<td>48 (100%)</td>
</tr>
<tr>
<td>Overall survival</td>
<td>48 (100%)</td>
</tr>
</tbody>
</table>

**Table 2: Responses in the Efficacy Evaluable Population**

<table>
<thead>
<tr>
<th>Evaluable Population</th>
<th>24 weeks</th>
<th>48 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Response (irCR + irPR)</td>
<td>18 (40.0%)</td>
<td>12 (25.0%)</td>
</tr>
<tr>
<td>Disease control rate (DCR)</td>
<td>36 (75.0%)</td>
<td>30 (62.5%)</td>
</tr>
<tr>
<td>Complete response (CR)</td>
<td>8 (16.7%)</td>
<td>6 (12.5%)</td>
</tr>
<tr>
<td>Progression-free survival (PFS)</td>
<td>36 (75.0%)</td>
<td>30 (62.5%)</td>
</tr>
<tr>
<td>Overall survival (OS)</td>
<td>48 (100%)</td>
<td>48 (100%)</td>
</tr>
</tbody>
</table>

**DISCUSSION/CONCLUSIONS**

Treatment with HF10 plus ipilimumab was well-tolerated. Of 46 patients enrolled and treated: 50% were, median age 57 years (range 28-75), disease stage III-B 43%, IIC and III-A 43% and IV 24%. Most HF10-related AEs were Grade 2 similar to HF10 monotherapy. No DLTs were reported. 37% had grade ≥ 3 AEs, the majority due to ipilimumab-related AEs. All grade ≥ 3 AEs were grade ≥ 3 CRs. The majority of grade ≥ 3 AEs were grade ≥ 3 CRs. The majority of grade ≥ 3 AEs were grade ≥ 3 CRs. The majority of grade ≥ 3 AEs were grade ≥ 3 CRs. The majority of grade ≥ 3 AEs were grade ≥ 3 CRs.

**Acknowledgements**

- Patients, their families and caregivers
- Q. Schmidhammer – Nagoya University
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