Using Cerebrospinal Fluid Tumor Cell (CSF-TC) Assays to Track Disease Burden and Treatment Response in Patients with Leptomeningeal Metastasis

Methods

• Five (5) cases of LM were diagnosed and followed using the Biocpet™ CNSide™ platform

• For each specimen, approximately 6-8 mL of CSF was obtained and transported using the CNSide assay’s proprietary tubes

• Each specimen underwent CNSide TSC capture, immunochemistry (ICC), and (when applicable) fluorescence in situ hybridization (FISH)

Patient Demographics

<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Age</th>
<th>Diagnosis</th>
<th>Treatment</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>40</td>
<td>Breast (HER2+)</td>
<td>IT Herceptin Initiated</td>
<td>17 mos</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>70</td>
<td>Melanoma (PD-L1+)</td>
<td>IT Cytarabine, IT Temozolomide, IT Bevacizumab</td>
<td>12 mos</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>63</td>
<td>Esophageal</td>
<td>IT Topotecan</td>
<td>2 mos</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>59</td>
<td>Breast (ER+, PR+)</td>
<td>IT Cytarabine, IT Methotrexate</td>
<td>7 mos</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>74</td>
<td>Neuroendocrine Carcinoma</td>
<td>Capablectin, Temozolodside</td>
<td>5 mos</td>
</tr>
</tbody>
</table>

OS – Overall Survival, IT – Intrathecal

Conclusions

The CNSide assay shows significant advantages in monitoring treatment response and disease course in LM

• The CNSide assay identifies biomarkers in LM patients for which targeted therapeutic interventions can significantly improve neurological symptoms and survival

• Additional longitudinal trials to assess the utility of this platform for LM patients are warranted

Comparison of CNSide assay tumor cell capture rate vs. cytology in 64 samples

- In 34% (22/64) of samples, the CNSide assay was positive but cytology was negative
- In 14% (9/64) of samples, the CNSide assay and cytology were both negative
- In 2% (1/64) of samples, the CNSide assay was negative but cytology was positive
- In 50% (32/64) of samples, the CNSide assay and cytology were both positive

Percentage of HER2 amplified CSF-TC increases after start of therapy while total cell count declines

- HER2 amplification determined by FISH according to ASCO/CAP scoring criteria
- Euploid cases have called “HER2-low” were not counted as amplified