PHASE 1 Trial Showing Immune Response and Safety of Dendritic Cell Vaccine in Newly Diagnosed GBM and Recurrent GBM Patients

POSTER # 2615

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Disclosures

No disclosures.
Introduction

- Antigens isolated from GBM CSCs induce potent and long-lasting immune response.
- GBM rat models that were vaccinated (with DCs exposed to different tumor antigen) showed increased survival.
38 malignant glioma (11 nGBM, 27 rGBM) underwent resection then nGBM patients had S.O.C. chemoradiation.

1 week later, started vaccines weekly for 4 weeks, then every other month until disease progression or vaccine depletion.

2 weeks after last vaccine, blood samples were taken to evaluate for vaccine response using IFN-γ ELISpot assay.
Group A: Newly Diagnosed GBM

01 Surgery
- Craniotomy
  - Dr. John Yu

02 RT/TMZ
- 6 weeks
  - Group B did not receive

03 Vaccine #1
- 1 week after S.O.C.
- 1 vaccine per week

04 MRI #1
- Vaccine #4

05 Cycle 1 TMZ
- Start q4week cycles
  - 1 week after 4th vac

06 Vaccine #5
- 3 weeks after Cycle 1
- Every 8 weeks

07 MRI #2
- Every 8 weeks MRI
  - 4 weeks after 5th vac

08 Continue Maintenance until PD or vaccine depletion

Visit #
- 1
  - Screen & Enroll
  - Apheresis
- 2
- 3
  - Standard of Care
- 4
  - Vaccine Induction Phase
- 5
  - Vaccine Maintenance Phase
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
Group B: Recurrent GBM

01 Surgery
Craniotomy
Dr. John Yu

02 Vaccine #1
1 week after S.O.C.
1 vaccine per week

03 Screen & Enroll
Apheresis

04 MRI #1
Vaccine #2
Vaccine #3

05 Cycle 1 TMZ
Start q4 week cycles
1 week after 4th vac

06 Vaccine #5
3 weeks after Cycle 1
Every 8 weeks

07 MRI #2
Every 8 weeks MRI
4 weeks after 5th vac

04 Visit #
Screen & Enroll
Apheresis

05 Vaccine Induction Phase

06 Vaccine Maintenance Phase

07 Continue Maintenance until PD or vaccine depletion
## Results

### Table 1: Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>Newly Diagnosed Glioblastoma</th>
<th>Recurrent Glioblastoma</th>
</tr>
</thead>
<tbody>
<tr>
<td># Subjects enrolled</td>
<td>11</td>
<td>27</td>
</tr>
<tr>
<td>Median age at enrollment</td>
<td>59</td>
<td>56</td>
</tr>
<tr>
<td>KPS at enrollment</td>
<td>80</td>
<td>80</td>
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</tbody>
</table>

### Table 2: Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Newly Diagnosed Glioblastoma</th>
<th>Recurrent Glioblastoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median Time to Progression</td>
<td>8.9 months (2.8, 14.5)</td>
<td>3.5 months (2.1, 6.0)</td>
</tr>
<tr>
<td>Median Overall Survival</td>
<td>21.7 months (11.3, 23.4)</td>
<td>12.0 months (8.4, 13.9)</td>
</tr>
</tbody>
</table>
Results

• Treatment was well-tolerated with no related grade 3/4 toxicities.
• Interferon-gamma ELISpot analysis in 25 patients revealed that 3 of 8 nGBM and 6 of 17 rGBM patients demonstrated a denovo immune response.
Summary Points

• This trial demonstrated that a subset of patients had a strong immune response against CSC antigens which may target the root of the propagating cell population for GBM.
• Treatment was safe and well-tolerated.
• TTP and OS compared favorably to historical controls.
• Ongoing efforts include characterizing and expanding the subset of patients who most benefit from vaccine therapy.