BACKGROUND

BEMPE signals preferentially through the IL-2R pathway

- BEMPE plus NIVO (NCT04207661) is a CD28/CTLA-4 checkpoint inhibitor combination designed to increase tumor-infiltrating lymphocytes (TILs), T-cell activity, and PD-1 expression.
- In melanoma, BEMPE has shown clinical activity and is approved for the treatment of metastatic melanoma.

SAFETY

Safety of BEMPEG plus NIVO was consistent with previous reports

- Grade 3/4 treatment-related AEs (>30% listed below)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Grade 3/4 AEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIVO alone</td>
<td>None</td>
</tr>
<tr>
<td>BEMPEG plus NIVO</td>
<td>15%</td>
</tr>
</tbody>
</table>

CONCLUSIONS

- In previously untreated patients with metastatic melanoma in PIVOT-02:
  - BEMPEG plus NIVO achieved deep and durable responses, with an ORR of 53%, a CR rate of 34%, and a mPFS of 30.9 months.
  - BEMPEG plus NIVO was well tolerated. TRAEs were predictable and consistent with previous reports.
  - Non-invasive, on-treatment exploratory biomarkers (CD8+ and PD-L1) demonstrated potential predictive value for response, before radiologic evidence was observed.

EXPLORATORY BIOMARKERS

Relationship between on-treatment (day 8) blood biomarkers in matched samples and response

- Correlation between blood biomarkers and response to BEMPEG plus NIVO was observed.

REFERENCES


ACNOWLEDGMENTS

- The study was supported by Nektar Therapeutics and Bristol-Myers Squibb.
- Authors contributed to the study as follows: <insert contribution details here>.