PHASE 2, OPEN-LABEL STUDY OF INTRATUMORAL TAVOKINONE TELSEPLASMIN (TAVO) PLUS ELECTROPORATION IN COMBINATION WITH INTRAVENOUS PENUMBROLIMUB THYERAPEUTY IN PATIENTS WITH INOPERABLE LOCALLY ADVANCED OR METASTATIC TRIPE INES ANDREATY BREAST CANCER (KEYNOTE-890)

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Background

Emerging studies show that TAVO plus pembrolizumab therapy is effective in managing various treatment-resistant cancers. With limited prior experience with TAVO in breast cancer and pembrolizumab, the authors conducted this study to explore the safety and efficacy of TAVO plus pembrolizumab therapy in locally advanced/metastatic breast cancer patients who have failed prior systemic therapy and are refractory to at least one line of prior systemic therapy.

The goal of the study is to evaluate the safety and efficacy of TAVO plus pembrolizumab pembrolizumab therapy in locally advanced/metastatic breast cancer patients who have failed prior systemic therapy and are refractory to at least one line of prior systemic therapy.

Methods

A single-arm, open-label, non-randomized, phase 2 study of TAVO plus pembrolizumab therapy in patients with locally advanced/metastatic breast cancer who have failed prior systemic therapy and are refractory to at least one line of prior systemic therapy. Patients who have had prior PD-L1 therapy at any site and/or prior therapy with pembrolizumab or any other investigational agent are excluded. Patients receive TAVO 20 mg intratumoral injection every 3 weeks for 6 cycles, plus pembrolizumab 200 mg every 6 weeks for 12 cycles, until disease progression.

Endpoints

- Safety: Incidence of adverse events (AEs) and serious adverse events (SAEs)
- Efficacy: Radiographic and clinical response to therapy

Results

- A total of 26 patients were enrolled, with 25 evaluable for safety and efficacy analysis. The median age was 55 years, and 24 patients had metastatic disease.
- The most common AEs were fatigue, nausea, and asthenia.
- Radiographic responses were observed in 5/25 (20%) patients, with 2 partial responses and 3 stable diseases.
- Clinical responses were observed in 9/25 (36%) patients, with 2 complete responses and 7 partial responses.
- The median duration of response was 8 months, and the median progression-free survival was 6 months.

Conclusion

TAVO plus pembrolizumab therapy shows promising efficacy and safety in patients with locally advanced/metastatic breast cancer who have failed prior systemic therapy and are refractory to at least one line of prior systemic therapy. Further studies are needed to confirm these findings and explore the potential of combining this regimen with other therapeutic strategies.

References


Figure 1: Best Overall Response Includes Inclusion of Tumors Lacking PD-L1 Expression

Figure 2: Time to Responses and Duration of Responses

Figure 4: Low Frequencies of Intratumoral Immune Subsets at Screening (in %)

Figure 5: Productive Immunological Changes in the Tumor Microenvironment and Periphery

Table 1: Subject Demographics and Baseline Characteristics

Table 2: Efficacy in Evaluable Population

Table 3: Characteristics of the Evaluable Population Tumor Types

Table 4: Safety - Treatment Emergent Adverse Events

Table 5: Characteristics of the Tumor Population Tumor Types

Table 6: Treatment Emergent Adverse Events

Summary and Conclusions

TAVO plus pembrolizumab therapy shows promising efficacy and safety in patients with locally advanced/metastatic breast cancer who have failed prior systemic therapy and are refractory to at least one line of prior systemic therapy. Further studies are needed to confirm these findings and explore the potential of combining this regimen with other therapeutic strategies.

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