Triple-negative breast cancer (TNBC) lacks expression of epidermal growth factor 2 protein and accounts for 15%-20% of metastatic breast cancers. TNBC has an aggressive course and is associated with poor prognosis, especially when metastatic.1-7

Monoclonal antibodies targeting the programmed cell death 1 (PD-1)/programmed death ligand 1 (PD-L1) pathway have shown some clinical activity as monotherapy or in combination with chemotherapy in patients with TNBC, response to PD-1/PD-L1 has been observed primarily in those who are treatment naïve.8,9

Immune-related adverse events, including inflammatory pneumonitis, colitis, and transaminitis, are known toxicities of PD-1/PD-L1 axis-blocking antibodies and are commonly treated with steroids.10,11

CX-072 is an investigational Probody Therapeutics-directed therapy against PD-L1 and has demonstrated antitumor activity by tumor-associated protease activity.12

CX-072 and PD-L1

STUDY DESIGN

CX-072 is an investigational Probody Therapeutics-directed therapy against PD-L1 and has demonstrated antitumor activity by tumor-associated protease activity.12

CX-072 is a first-in-human, open-label, dose-escalation, multicenter, phase 1/2a study of CX-072 (Figure 2). Phase 1 was designed to evaluate the safety and determine the maximum tolerated dose and/or maximum achieved dose of CX-072 as monotherapy. Phase 2a is the dose expansion of CX-072 monotherapy at 10 mg/kg every 2 weeks in a specific tumor type, including TNBC with skin metastases.

CX-072 and PD-L1

END POINTS

Primary End Points
- Objective response rate according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1)
- Duration of response
- Progression-free survival
- Incidence of antitody-related events
- Pharmacokinetic profile of CX-072

Secondary End Points
- Objective response rate according to immune-related RECIST
- Immuno-modulatory activity of CX-072 in on-treatment biopsy samples
- Potential predictive markers of CX-072 activity

SPECIFIC ASSESSMENTS

- Imaging for tumor response assessment will be performed every 8 weeks for the first 12 months, then every 12 weeks thereafter
- Archival tissue must be provided at baseline, and patients must consent to additional biopsies to aid in translational analyses
- Imaging for tumor response assessment will be performed every 8 weeks for the first 12 months, then every 12 weeks thereafter
- Potential predictive markers of CX-072 activity

STUDY PROGRESS

Sites in the United States and Europe are open for the enrollment of patients with TNBC and skin metastases to be treated with CX-072 monotherapy

This study is registered with ClinicalTrials.gov, number NCT03013491

For more information, please visit https://clinicaltrials.gov/ct2/show/NCT03013491 or contact clinicaltrials@cytomx.com

REFERENCES


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