
Eratema Dumbrava, MD* , Bartosz Chmielowski, MD, Oake Shephard, MD, Daniel Veenstra, MD, Geeta Jhaveri, MD, Ross Hebert, MD, Rashida Islam, MD, Zainab Yamani, MD, Erika Hamilton, MD, Catalina P. Papahadjopoulos, MD, Judy S. Wang, MD, Dr. Erin Oliver, PhD, Pierre Ferre, PhD, Hipol Barbin PhD, Gady Cojocaru, MD, Adolfo H. Arroyave MD, MPH, of Match Patel, MD

BACKGROUND
• COM701 is a novel first in class, pan-kinase inhibitor (PKI) that blocks the activity of a spectrum of TKIs as well as a spectrum of PD-1 inhibitors including nivolumab.
• The combination of COM701 and nivolumab has been shown to have preclinical efficacy.
• Preclinical studies indicate that the combination of COM701 + nivolumab results in the inhibition of anti-PD-1 antibodies and the prevention of resistance to current immune checkpoint inhibitors.

METHODS
• A phase I, open-label, dose-escalation study was conducted. A total of 17 patients were enrolled.

Key Primary Objective:
• Safety and tolerability of dual combination treatment in patients with metastatic breast cancer.

Secondary Objectives:
• PK of the dual combination treatment
• Pharmacodynamic activity of the combination

EVALUATION CRITERIA
• Key Inclusion Criteria:
  - Age ≥ 18 years
  - ECOG performance status ≤ 2
  - No prior treatment with any anti-PD-1, anti-CTLA-4 ICI

• Key Exclusion Criteria:
  - Active autoimmune disease requiring systemic treatment
  - Prior treatment with anti-PD-1, anti-CTLA-4 ICI

The primary study objective was to evaluate the safety and tolerability of the dual combination treatment in patients with metastatic breast cancer. The secondary objectives included the evaluation of PK and PD of the dual combination treatment.

Preliminary antitumor activity was observed in patients treated with the dual combination treatment. The combination of COM701 + nivolumab demonstrated promising antitumor activity in metastatic breast cancer patients, with an overall response rate of 24% (9/37 patients) and a disease control rate of 62% (23/37 patients). The most common treatment-related adverse events were grade 1-2 fatigue, diarrhea, and nausea.

CONCLUSIONS
• The combination of COM701 + nivolumab demonstrates promising antitumor activity in patients with metastatic breast cancer, with an overall response rate of 24% and a disease control rate of 62%.
• The combination is well tolerated, with grade 1-2 fatigue, diarrhea, and nausea being the most common treatment-related adverse events.
• Further studies are needed to confirm these preliminary findings and to evaluate the efficacy and safety of the combination in a larger patient population.