A Phase 1b Study of IMU-131 HER2/neu Peptide Vaccine plus Chemotherapy in Patients with HER2/neu Overexpressing Metastatic or Advanced Adenocarcinoma of the Stomach or Gastroesophageal Junction

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Aims: The primary objective of the study was to determine the safety and tolerability of IMU-131 combined with chemotherapy in patients with HER2/neu overexpressing gastric or gastroesophageal adenocarcinoma.

Methods: IMU-131 is a recombinant HER2/neu antigenic protein that contains a single linear epitope derived from the extracellular domain of HER2/neu. IMU-131 was given in combination with chemotherapy (5FU/CIv) in 14 Asian and Eastern European patients with HER2/neu positive metastatic or advanced gastric cancer. IMU-131 was administered weekly on Days 14-21 and chemotherapy was administered weekly on Days 1-6.

Results: A total of 11 patients were enrolled, with 8 of 11 patients receiving all 3 doses of IMU-131. The remaining 3 patients discontinued IMU-131 due to disease progression. The most common TEAEs were fatigue, myalgia, and nausea.

Conclusion: IMU-131 in combination with chemotherapy is well-tolerated and warrants further study in patients with HER2/neu positive gastric or gastroesophageal adenocarcinoma.

References: