A phase 1b/2 open label study of IMU-131 HER2/Neu peptide vaccine plus cisplatin and either 5-fluorouracil or capecitabine chemotherapy in patients with HER2/Neu overexpressing metastatic or advanced adenocarcinoma of the stomach or gastroesophageal junction

Ursula Wierermand,1 Anthony J Good,2 Erika Garner-Spitzer,1 Yue Chao,1 Jure Bulat4, Arlene Dechangkhunluk,1 Wicht Arbornwira,4 Chayut Chaoetum2, Cha-Jui Yen,6 Thomas Cheung Yau,4 Marina Maglakelidze13, Sereyong Tanasanymon3,14, Jedzada Manechavakagorn2,15, Aumkhae Sokprasert13,15, LiYuan Bai,14, Wen-Chi Chou15, Teraerat Ungtrakul,16, Leslie Chong,2, Nick Ede2

1. Medical University Vienna, Vienna, Austria 2. Imugene, Sydney, Australia 3. Department of Oncology, Taipei Veterans General Hospital, Taipei, Taiwan 4. ARENSIA Exploratory Medicine Research Unit, Institute of Oncology, Chisinau, The Republic of Moldova 5. University of Alberta, Edmonton, AB, Canada 6. National Cancer Institute, Bangkok, Thailand 7. Maharaj Nakorn Chiang Mai Hospital, Muang Chiang Mai District, Thailand 8. National Cheng Kung University Hospital, Tainan, Taiwan 9. Department of Medicine, The University of Hong Kong, Queen Mary Hospital, Hong Kong, Hong Kong 10. ARENSIA Exploratory Medicine LLC, Telhis, Georgia 11. King Chulalongkorn Memorial Hospital, Bangkok, Thailand 12. Rajivithi Hospital, Bangkok, Thailand 13. Sri Nagarid Hospital, Khon Kaen, Thailand 14. China Medical University Hospital, Taichung, Taiwan 15. Linkou Chang Gung Memorial Hospital, Taoyuan, Taiwan 16. Faculty of Medicine and Public Health, HRH Princess Chulabhorn College of Medical Science, Bangkok, Thailand

ABSTRACT

Background: Gastric cancer is the 5th most frequently diagnosed cancer and the 3rd leading cause of cancer deaths. HER2/neu is overexpressed in 15% to 25% of patients with gastric cancer and associated with a poor prognosis. Monoclonal antibodies against HER2/neu have shown to be effective but alternative treatments are needed due to cost and global availability issues. IMU-131 is a B-cell peptide vaccine composed of 3 B-cell epitopes derived from the extracellular domain of HER2/neu. Polyclonal antibodies against IMU-131 peptides binding 3 separate regions of HER2/neu have been shown to elicit antitumor activity in vitro and a phase I study demonstrated safety and immunogenicity in Her-2 +/+ metastatic breast cancer patients. Fusion of the single peptides into a hybrid peptide conjugated to CRM197 in conjunction with the adjuvant Montanide (P467-CRM-Montanide) improved formulation and stability of the vaccine. With the present Phase 1b/2 trial performed in patients with HER2/neu overexpressing gastric or gastroesophageal junction (GEJ) adenocarcinoma, it is hypothesized that administration of IMU-131 in addition to chemotherapy is safe and immunogenic, and will prolong survival and may delay tumor progression and/or reduce tumor burden.

Methods: This study is an international open-label multicenter study performed in 16 Asian and Eastern European sites with up to 18 patients enrolled in Phase 1b. This dose escalation study is designed to assess safety, tolerability, immunogenicity and recommended phase 2 dose of IMU-131. Each patient will receive 3 injections of IMU-131, at a single dose level on Days 0, 14, and 35, accompanied by cisplatin and 5-fluorouracil or capecitabine every 21 days. The RP2D will be evaluated in the dose expansion Phase 2 study with 68 patients being enrolled.

Results: The study is ongoing with the completion of the phase 1b portion in 4Q18. Conclusions: No conclusions can be drawn at this time.

REFERENCES