IMU.ACS.001

PHASE 1B STUDY
OF IMU-131,
A HER2 TARGETING
B-CELL VACCINE
IMU-131 IS A THERAPEUTIC B-CELL PEPTIDE VACCINE COMPOSED OF 3 EPITOPES FROM THE EXTRACELLULAR DOMAIN OF HER2/NEU CONJUGATED TO CRM197, EMULSIFIED WITH MONTANIDE

Peptides “mimic” the epitope

IMU-131 IMMUNOTHERAPY

IMU-131 ANTIBODY SECRETION

Via helper T-cells

TUMOR CELL

HER-2/NEU

Epitope = Antibody Binding Site

IMU-131 attacks the same target as the cancer drug Herceptin®
IMU.ACS.001 PHASE 1B: DESIGN & RESULTS

**Trial**
- HER2 Gastric or GEJ cancer
- Phase 1b
- Open label
- Dose escalation
- 14 sites in Asia and Eastern Europe

**Patients**
- Advanced stage IIIb or IV
- 7 HER2+++ , 3 HER2++ (FISH positive), 4 HER2++ expressing tumors
- Age 57yo (21 - 79)
- ECOG 1(7) and 0(7)
- 9 Asian, 5 Caucasian
- 5 female, 9 male

**Study**
- 14 patients in 3 cohorts (10µg (3), 30µg (6) and 50µg (5))
- Dosed on D0, D14, D35
- IMU-131 in combination with chemo: cisplatin and 5FU or capecitabine

**Endpoints**
- Recommended Phase 2 Dose of IMU-131
- Safety and Toxicity
- Immunogenicity (anti-peptide (P467) and anti-HER-2 antibody titres)

**Study Results**
- No safety or toxicity issues
- All patients had increased antibody response
- 1 Complete Response
- 5 Partial Response
- 4 Stable Disease
- 1 Progressive Disease
- 50 µg selected as Ph2 dose
• 10 patients had 18 SAEs
• No SAEs related to IMU-131
• 1 mild injection site reaction
• No significant LVEF changes

• The 50 µg dose produced the most consistent anti-peptide (P467) and anti-HER-2 specific antibodies compared to 10 and 30 µg doses
• The preliminary immunology and clinical response data are promising.
• Safety data indicate that IMU-131 is well-tolerated with no significant local or systemic reactions.
• There were no dose-limiting toxicities observed, no significant injection site reactions and no IMU-131 related SAEs.
• Preliminary response data demonstrates 50 µg of IMU-131 was associated with tumor size reduction.
• The 50 µg dose of IMU-131 is being used in a phase 2 study.