**Background**

Margetuximab is an Fc-engineered, anti-human epidermal growth factor receptor 2 (HER2) monoclonal antibody.

**Objectives**

- The primary objectives for Cohort A are to evaluate the safety and tolerability of margetuximab + retifanlimab
- The first patient was dosed on October 15, 2019
- In Cohort A, the efficacy of the margetuximab/retifanlimab combination is evaluated in approximately 100 patients

**Methods**

**Study Design**

- The description of study (NCT04082364) is a Phase 2 study conducted in two cohorts in treatment-naive patients with metastatically advanced HER2+ cancer
- **Cohort A**: 84 in 24:1 randomization arm with a time 2:1 design evaluating efficacy only of margetuximab/retifanlimab combination
- **Cohort B**: inclusion of patients positive for both HER2 IHC3+ and PD-L1+ (IHC3+), determined by a central laboratory before enrollment

**Results**

**Patients**

- The first patient was dosed on October 15, 2019
- All data presented as of August 10, 2021
- The recommended phase II dose in Cohort A was margetuximab 10 mg/kg and retifanlimab 80 mg every 3 weeks

**Efficacy**

- The best overall response by independent assessment for the first 40 response-evaluable non–MSI-H patients was 60%

**Safety**

- Treatment-emergent AEs of Grade ≥3 occurred in 41.9% (18/43) of patients; 7.0% (3/43) of patients experienced AEs leading to death

**Conclusion**

- Findings from Cohort A Part 1 suggest this CTX-free combination may be a potential option for patients with metastatic HER2+ advanced cancer

**References**

1. Margetuximab study, the majority of patients (87%) had tumor shrinkage of first scan.
2. The recommended phase II dose in Cohort A was margetuximab 10 mg/kg and retifanlimab 80 mg every 3 weeks
3. The first patient was dosed on October 15, 2019

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**Disclosures**

The authors declare that they have no conflict of interest.

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