BACKGROUND

- KN026 is a novel bispecific antibody that simultaneously binds to two distinct HER2 epitopes. KN046 is a novel bispecific antibody that binds to two distinct HER2 epitopes, the same domains as trastuzumab (CD80/CD86).

- Both preclinical and clinical studies have showed synergistic effect with the combination of an anti-HER2 antibody and an immune checkpoint blockade.

- This phase II study was to assess the efficacy and safety of KN026 (30mg/kg, Q3W, C1D1 & C1D8 loading) in combination with KN046 (5mg/kg, Q3W) treatment in patients with HER2-positive (IHC 3+ or HER2 gene amplification) solid tumors. Here we reported the efficacy and safety in patients with HER2-positive gastric/gastroesophageal junction cancer (GC/GEJ) without prior systemic treatment (NCT04521179).

STUDY DESIGN

- KN026 (30mg/kg, Q3W, C1D1 & C1D8) or KN046 (5mg/kg, Q3W).

RESULTS

- As of 30 Jan 2022, a total of 31 HER2 positive locally advanced unresectable or metastatic GC/GEJ patients without prior systemic treatment were enrolled, and 26 patients still received study treatment. The median age was 64 years old with 14 patients (45.2%) aged ≥65 years. 26 patients (83.9%) were HER2 IHC 3+ and 5 patients (16.1%) were HER2 IHC 2+ with HER2 gene amplification, and 25 patients (80.6%) were ECOG 0. Most patients (61.3%) had liver metastasis.

- As of 30 Jan 2022, 27 patients were evaluable for efficacy with 12 confirmed PRs, 9 unconfirmed PRs, 4 SDs and 2 PDs. The ORR was 77.8% (95% CI: 57.7, 91.4), and the DCR was 92.6% (95% CI: 75.7, 99.1).

CONCLUSIONS

- KN026 combined with KN046 treatment had demonstrated outstanding efficacy and manageable safety in HER2 positive GC/GEJ patients without prior systemic treatment. It is interesting to further test the efficacy and safety in randomized studies or larger sample studies.