For patients with gastric cancer (GC), including gastric adenocarcinoma (GA) or gastric esophageal junction cancer (GEJA), we report the study design of CARMEN-GC01 (NCT05071053; EudraCT: 2021-001976-26), which is a Phase 2, open-label, single-arm, multicenter, 2-part study to evaluate tusamitamab ravtansine (BYMHERA™) in pretreated patients with GC/GEJA. Key secondary objectives are to assess safety and tolerability, duration of response, progression-free survival, and overall survival. The combination of tusamitamab ravtansine plus ramucirumab may lead to improved 2L outcomes in patients with GC/GEJA and if appropriate, human epidermal growth factor receptor 2 (HER2) status.

### STUDY OVERVIEW

- **Primary Endpoint:** ORR
  - Part 1 is a safety run-in, which will be followed by Part 2 expansion

- **Secondary Objectives:**
  - Key secondary objectives are to assess safety and tolerability, duration of response, progression-free survival, disease control rate, pharmacokinetics, and immunogenicity

- **Figure 2:** Mechanism of action of tusamitamab ravtansine

### STUDY ENDPOINTS

#### Primary Endpoints
- Part 1: Incidence of study-drug-related dose-limiting toxicities
- Part 2: Objective response rate, defined as the proportion of participants who have confirmed complete response (CR) or partial response (PR) as best overall response per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1

#### Secondary Endpoints
- Incidence of treatment-emergent adverse events, serious adverse events, and laboratory abnormalities according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCCITCAE) version 5.0
- Duration of response (time from first documented evidence of CR or PR until progressive disease per RECIST version 1.1 or death from any cause)
- Progression-free survival (time from the date of first administration to the date of first documented disease progression or death due to any cause)
- Disease control rate, defined as the percentage of patients with confirmed CR, PR, or stable disease as best overall response per RECIST version 1.1
- Incidence of anti-therapeutic antibody against tusamitamab ravtansine
- Pharmacokinetic parameters of tusamitamab ravtansine and ramucirumab

### PATIENT ELIGIBILITY

- **Key Inclusion Criteria**
  - Patients 18 years old
  - Histologically or cytologically confirmed diagnosis of GC or GEJA
- **Key Exclusion Criteria**
  - Untreated brain metastases, leptomeningeal disease, or uncontrolled spinal cord compression
  - History of gross hemoptysis in prior 2 months
  - Significant concomitant illness

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### REFERENCES: