Randomization will be stratified by region (Asia vs non-Asia), number of metastatic sites (≥3 vs <3), and prior gastroectomy (yes vs no). Zolbetuximab will be administered at a loading dose of 800 mg/m² IV on Cycle 1 Day 1 followed by 600 mg/m² IV every 3 weeks. Central testing of tumor tissue will determine CDL1N18.2 and HER2 status (if unknown); patients will be considered CDL1N18.2-positive (CDL1N18.2/PD-L1 high) if >75% of tumor cells demonstrate moderate-to-strong membranous immunohistochemical staining.

The primary endpoint is progression-free survival assessed by independent review committee. Secondary endpoints are overall survival, objective response rate, and duration of response, as well as the safety/tolerability, pharmacokinetics, and immunogenicity of zolbetuximab. As of June 30, 2020, 148 sites have been initiated.

**Clinical trial identification:** NCT03653507.

**Legal entity responsible for the study:** Astellas Pharma, Inc.

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continue per protocol. Treatment with pembrolizumab/placebo will continue for up to 35 patients, or until disease progression; overall survival (OS) time or until death due to other causes. Key secondary endpoints: objective response rate; duration of response; safety/tolerability, pharmacokinetics, and immunogenicity of zolbe. As of June 30, 2020, 190 sites have been initiated.

Clinical trial identification: NCT03675377.

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