Immunotherapy of Peritoneal Carcinomatosis with the Antibody Catumaxomab in Colon, Gastric, or Pancreatic Cancer: An Open-Label, Multicenter, Phase I/II Trial

Abstract:
Background: Peritoneal carcinomatosis (PC) is common in gastrointestinal (GI) cancer and there is no effective standard treatment. We investigated the tolerability and maximum tolerated dose (MTD) of the trifunctional antibody catumaxomab in patients with PC.

Methods: In this open-label, phase I/II clinical trial, patients with epithelial cell adhesion molecule (EpCAM)-positive PC from GI cancer received 4 sequential intraperitoneal catumaxomab infusions: day 0: 10 µg; day 3: 10 or 20 µg; day 7: 30, 50, or 100 µg; and day 10: 50, 100, or 200 µg. Dose escalation was guided by dose-limiting toxicities.

Results: The MTD was 10, 20, 50, and 200 µg on days 0, 3, 7, and 10, respectively. Catumaxomab had an acceptable safety profile: Most common treatment-related adverse events (at the MTD) were fever, vomiting, and abdominal pain. At final examination, 11/17 evaluable patients (65%) were progression free: 1 patient had a complete and 3 a partial response.

Median overall survival from the time of diagnosis of PC was 502 days.

Conclusions: Intraperitoneal catumaxomab is a promising option for the treatment of PC from GI cancer.

Keywords: Epithelial cell adhesion molecule (EpCAM); Catumaxomab; Antibody,