STUDY DESIGN
The study was a single arm phase I study with the purpose of evaluating the safety and efficacy of combined GATipotuzumab (TO) and Tomuzotuximab (EP) in combination with standard chemotherapy, or targeted agents in advanced/metastatic solid tumors, in patients with refractory disease.

RESULTS
All 30 patients experienced 108 TEAEs overall. 94% of the reported TEAEs were non-serious, 5% were serious, and 1% were life-threatening. Only 1 TEAE was considered related to the combination (lung cancer, Grade 5 toxicity).

Overall, the safety profile of the combination was consistent with that of the individual agents. Moreover, some toxicities were observed which were not previously reported for either agent alone.

Some toxicities that were previously reported for Tomuzotuximab alone were not seen with the combination. For example, thrombocytopenia was not observed with the combination while neutropenia was more common with the combination than with either agent alone.

No new or unexpected toxicities were observed with the combination and the toxicity profile was consistent with that observed with each agent alone.

In conclusion, this study confirmed the safety and efficacy of the combination of GATipotuzumab and Tomuzotuximab in advanced/metastatic solid tumors.

Conclusions
The combination therapy of GATipotuzumab and Tomuzotuximab was well tolerated and showed promising antitumor activity in a variety of refractory solid tumors.

Future studies are needed to further evaluate the safety and efficacy of this combination in different tumor types and to determine the optimal dosing and schedule for clinical use.

#2542 Safety and tolerability results of the GATTO study, a phase Ib study combining the anti-TA-MUC1 antibody Gatipotuzumab with the anti-EGFR antibody Panitumumab in patients with refractory solid tumors

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Background
The phase I GATTO study explored the feasibility, tolerability and preliminary activity of combining Gatipotuzumab (TO), a novel humanized monoclonal antibody against the tumor-associated antigen of MUC1 (TA-MUC1) on anti-EGFR antibody Panitumumab. Preliminary evidence suggests a complex interaction between TA-MUC1 and EGFR on the cell surface of tumor cells, and suggests that combination treatments could result in improved antitumor activity.

Methods
The study included 30 patients in a parallel phase I (20 patients with EP and 10 patients with TOM) to which no standard treatment was available. The first 18 patients were enrolled in a safety run in phase I then the number of dose-limiting toxicities (DLTs) was evaluated in order to determine the dose to be escalated. Patients received IP at doses ranging from 100 mg q2W to 1200 mg q2W in combination with the phase I planned dose in patients with colorectal carcinoma, and suggested strategies involved extended cytotoxic activity with the dual target.

Results
- All 30 patients experienced 256 TEAEs. In the extension phase, 100 mg q2W of EP was considered tolerable and was recommended for further studies.
- Nine TEAEs in 5 patients were reported as serious, none related to treatment.
- The vast majority of reported TEAEs were mild to moderate (83.9%).
- The most commonly reported serious TEAE was neutropenia (7/30 patients).
- No new or unexpected toxicities were observed with the combination and the toxicity profile was consistent with that observed with each agent alone.

Conclusions
The combination therapy of GATipotuzumab and Tomuzotuximab was well tolerated and showed promising antitumor activity in a variety of refractory solid tumors. Further studies are needed to further evaluate the safety and efficacy of this combination in different tumor types and to determine the optimal dosing and schedule for clinical use.