eAppendix

SUPPLEMENTARY METHODS

Key protocol amendments included eliminating the limit of 3 prior cytotoxic treatment regimens in the eligibility criteria, adding a new inclusion requirement for subjects to have platelet counts   
≥100,000 cells/mm3 to be eligible for treatment in inclusion criterion 7, allowing subjects with other histotypes not previously specified (endometrioid, mixed cell, or clear cell) to be enrolled, and the addition of gemcitabine as a treatment option in the TC arm. Additional amendments include allowing pleural fluid to be collected for tumor cell analyses (if such collection was more feasible than tumor biopsy or ascites collection), allowing subjects with previous platinum hypersensitivity to be enrolled if they successfully undergo an institutional desensitization protocol, allowing guadecitabine dose reduction from 30 mg/m2 to 24 mg/m2 in the event of guadecitabine-specific toxicity, and allowing dose reduction for carboplatin by one AUC dose level.

KEY TRIAL MILESTONES

The enrollment period was December 10, 2012 (first subject dosed) to May 12, 2014 (last subject first dose). The last dose occurred on November 27, 2015. The last subject observation included in the database was on April 15, 2016. The database was locked on July 07, 2016. No subjects were continuing to receive treatment at the time of database lock, and no subjects were continuing in follow-up. Fourteen subjects who were in follow-up were discontinued from the study at the time of database lock.