982P Phase II study of the safety and efficacy of oral capecitabine in patients with platinum-pretreated advanced or recurrent cervical carcinoma

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Background: Cervical cancer is underrepresented in the gynecological clinical research. The objective of this observational study was to evaluate the activity and the safety of capecitabine in patients with platinum-pretreated recurrent cervical carcinoma.

Methods: In this phase II study we enrolled patients with advanced or recurrent cervical carcinoma pretreated with platinum-based therapy. All patients signed an informed consent and were treated at the Gynecological Units of the IRCCS National Cancer Institute of Milan (Italy). All patients received a starting dose of oral capecitabine 1250 mg/m^2 twice a day continuously from day 1 to day 14 every 21 days, dose reduction to 1000 mg/m^2 twice a day was permitted due to adverse events (AE). We used Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 to evaluate response to therapy and Common Terminology Criteria for Adverse Events (CTCAE) version 4.0 to evaluate adverse events. We performed descriptive analysis and Kaplan Meier test using SPSS 20.0.

Results: From December 2013 to January 2017, we enrolled 20 patients with advanced or recurrence cervical carcinoma, already exposed to platinum, to received oral capecitabine. All patients receive a combination of carboplatin plus paclitaxel as first-line therapy for advanced/recurrent disease. Median age at the first capecitabine administration was 56.9 years (range from 27 to 82 years). After three cycles of oral capecitabine the clinical benefit rate (CBR) was 60.0% (5.0% of CR, 30.0% of PR and 25.0% of SD). No grade 3 or worse adverse events were reported. CBR was 88.8% in adenocarcinomas

versus 36.4% in squamous cell carcinomas (P = 0.067). The most frequent grade 1 or 2 adverse events were fatigue (50%), hand-foot syndrome (38.9%) and diarrhea (22.2%).

Conclusions: Our study suggests that oral capecitabine should be considered an active and safe treatment in patients with platinum-pretreated advanced or recurrent cervical carcinoma. A greater activity has been documented in patients with adenocarcinomas compared with squamous cell carcinomas.

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