950P Olaparib maintenance therapy in patients (pts) with platinum-sensitive relapsed (PSR) ovarian cancer (OC) and stable disease (SD) following platinum-based chemotherapy

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Background: The PARP inhibitor olaparib (Lynparza®) is approved as maintenance therapy in pts with PSR OC who are in complete or partial response to platinum-based chemotherapy. Currently, pts with SD are observed until disease progression; the efficacy of maintenance olaparib in these pts is unknown. In a Phase II study (NCT01081951), progression-free survival (PFS) was significantly prolonged in pts with PSR OC receiving olaparib plus platinum-based chemotherapy followed by maintenance olaparib vs those receiving platinum-based chemotherapy alone (Oza et al. Lancet Oncol 2015). This post hoc analysis evaluated outcomes in pts with SD on scans at the end of chemotherapy and the efficacy of maintenance olaparib vs observation.

Methods: In this open-label, multicentre trial, pts with PSR serous OC, primary peritoneal cancer or fallopian tube cancer were randomized to olaparib capsules 200 mg twice daily (bid) on days 1–10 of each 21-day cycle plus paclitaxel and carboplatin AUC 4 on day 1 (n = 81) followed by maintenance olaparib 400 mg bid (continuously), or paclitaxel and carboplatin AUC 6 on day 1 (n = 81) without maintenance olaparib. The latest scan from randomization up to 2 weeks after the final dose of carboplatin was used to assess the best objective RECIST v1.1 response at the end of chemotherapy (blinded independent central review).

Results: At the end of chemotherapy, 24 (29.6%) pts who had also received low-dose olaparib and 21 (25.9%) pts without olaparib had SD as their best response (timing of the scan ranged from 2.10 months before to 0.49 months after the last dose of carboplatin). Median PFS, calculated from the end of chemotherapy, was 8.74 months with maintenance olaparib at standard dose vs 5.40 months without maintenance olaparib (hazard ratio 0.50; 95% CI 0.25, 1.00). Delayed responses following the end of chemotherapy occurred in four pts receiving maintenance olaparib (16.7%; two complete and two partial responses) and three pts without maintenance olaparib (14.3%; all partial responses). The number of lines of prior chemotherapy did not appear predictive of PFS benefit.

Conclusions: Maintenance olaparib may prolong PFS in OC pts with SD following platinum-based therapy.

Clinical trial identification: NCT01081951.

Editorial acknowledgement: Editorial assistance was provided by Gillian Keating, Mudskipper Business Limited, funded by AstraZeneca.

Legal entity responsible for the study: AstraZeneca.

Funding: AstraZeneca.

Disclosure: A.M. Oza: Honoraria: Intas Pharma. D. Cibula: Fees for advisory boards: Roche, AstraZeneca. A. Oaknin: Fees for advisory boards: Roche, AstraZeneca, PharmaMar, Clovis Oncology, Tesaro; Support for travel/accommodation: Roche, AstraZeneca, PharmaMar. C. Poole: Honoraria for advisory boards: Pfizer, AstraZeneca, Genomic Health, Lilly; Honoraria for talks: Pfizer, AstraZeneca, Genomic Health; Consultancy fees: Creavo Medical Technologies. R.H.J. Mathijssen: Research funding: Astellas, Bayer, Boehringer Ingelheim, Cristal Therapeutics, Novartis, Pamgene, Pfizer, Roche, Sanofi; Consultation fees: Novartis, Servier; Travel support: Astellas, Pfizer. G.S. Sonke: Research funding: AstraZeneca, Merck, Novartis, Roche. N. Colombo: Honoraria: Genentech, AstraZeneca, PharmaMar; Fees for consulting/advisory boards: Genentech, PharmaMar, AstraZeneca, Clovis Oncology, Pfizer, MSD, Tesaro; Research funding: AstraZeneca. P. Vuylsteke: Fees for advisory boards: AstraZeneca, Roche, Eli Lilly. H. Hirte: Honoraria for advisory boards: AstraZeneca, Roche. J. Pfisterer, L.C. Hanker: Fees for advisory boards: Roche, AstraZeneca, Tesaro. M. Plante: Support for travel/accommodation: AstraZeneca. A. Fielding, V. Haddad, J. Chmielecki: Employee of AstraZeneca. M. Friedlander: Fees for advisory boards: AstraZeneca, MSD. All other authors have declared no conflicts of interest.