P045 Real-world outcomes with abiraterone in metastatic castration-resistant prostate cancer: The Prostate Cancer Registry

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Introduction & Objectives: In randomised controlled trials, abiraterone acetate plus prednisone or prednisolone ("AAP") prolonged survival in patients with chemotherapy-naive, metastatic castration-resistant prostate cancer (mCRPC) and those with mCRPC previously treated with docetaxel. This study evaluated real-world characteristics, efficacy outcomes and safety of patients with mCRPC receiving AAP as first- or second-line treatment, using final data from the international Prostate Cancer Registry (PCR).

Materials & Methods: The PCR (NCT02236637) is a large, prospective, observational, real-world study documenting the treatment of mCRPC in routine medical practice. Patients from 16 countries were enrolled between 2013 and 2016 consecutively, irrespective of their treatment, to avoid selection bias. Patients and disease characteristics were collected at baseline, and patients were followed for up to 3 years. Treatment exposure, overall survival and full safety were evaluated for patients receiving first- and second-line AAP (post-docetaxel only) and also in the subgroup of patients with cardiovascular (CV) comorbidities. Data is presented descriptively.

Results: Of 3003 patients in the Registry, 754 received AAP as first-line mCRPC treatment and 394 received AAP as second-line treatment. In total, 504 (67%) and 234 (59%) patients receiving first- and second-line AAP, respectively, had CV comorbidities. Median treatment duration for patients on first-line AAP was 11.2 months overall and 11.1 months for patients with CV comorbidities; for patients on second-line AAP, median treatment duration was 8.7 months overall and 9.0 months for patients with CV comorbidities. Median overall survival was similar between overall patient populations and those with CV disease: 27.1 and 27.4 months (first-line AAP), and 23.4 and 23.1 months (second-line AAP), respectively. Treatment emergent adverse events (TEAEs) were reported in 65% and 56% of patients receiving first- and second-line AAP, respectively, and were severe in 41% of cases in each group. Most common TEAE classes for first- and second-line treatment were general disorders (29%, 26%), musculoskeletal and connective tissue disorders (23%, 18%) and gastrointestinal disorders (18%, 14%), respectively. Most common serious adverse event classes were general disorders (11%, 10%) and infections and infestations (8%, 6%), respectively.

Conclusions: These real-world data confirm those from randomised trials and indicate that first- and second-line AAP is effective for treating mCRPC, with no new safety signals. Importantly, efficacy outcomes were similar between the overall populations and patients with baseline CV comorbidities, suggesting that AAP is effective in this latter group of patients.