Real world prospective evaluation of clinical outcomes in patients with non-metastatic castrate resistant prostate cancer treated with darolutamide.

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Background: The RECORD Study is a real world data, prospective evaluation of clinical outcomes in patients with nmCRPC treated with Darolutamide. This study will increase the understanding of treatment response and management and in particular inform regarding use of next generation imaging in this setting.

Methods: Patient data from 9 UK centres was collected based on the recommendation of NICE for Darolutamide as an option for the treatment of non-metastatic castrate resistant prostate cancer (nmCRPC) from November 2020. Data cut-off was 15 September 2022. The study is ongoing.

Results: 87 patients were analysed with a median age of 78 (range 61-92). Median pre-treatment PSA and PSA doubling time (PSAdT) were 13 (range 1.99-110.6) mg/L and 5.05 (range 0.6 - 10) months. 42 patients (49.4%) had pre-treatment PSAdT of <6 months and 43 (50.6%) patients had PSAdT of ≥6 months (2 patients had no pre-treatment PSAdT data). 6 patients (6.90%) had next generation imaging prior to initiation of Darolutamide. Median duration of treatment on Darolutamide was 17 months for patients with pre-treatment PSAdT <6 months but median duration had not been reached for patients with pre-treatment PSAdT ≥6 months after 24 months of treatment, a significant difference p=0.018 (HR=0.385, 95% CI 0.17-0.88). 30 patients have come off treatment so far (34.5%); 21 (70%) for disease progression, 5 (16%) for a medical cause unrelated to the drug (e.g. COVID infection, reduced performance status secondary to pre-existing Parkinson's), 3 (10%) for unacceptable toxicity (rash, Grade3 fatigue, muscle aches, memory issues), and 1 patient died (unrelated).

Conclusions: In the RECORD study, predominantly the diagnosis of nmCRPC is based on conventional imaging. The majority of patients respond and tolerate Darolutamide well, comparable with the ARAMIS trial. There is a significant difference between time on Darolutamide for those with pre-treatment PSAdT of <6 months compared with ≥6 months. Further long-term toxicity, MFS and OS data will continue to be collected prospectively within the study.