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Ultra-low PSA as a real-world indicator of androgen receptor pathway inhibitors (ARPI) treatment response in metastatic prostate cancer

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Objective:
Real-world evidence is needed to complement clinical trial data on response to androgen receptor pathway inhibitors (ARPIs) in metastatic prostate cancer, particularly in underrepresented Eastern European populations. In this interim analysis, we evaluated whether achieving ultra-low prostate-specific antigen (PSA), defined as PSA <0.02 ng/mL within three months after ARPI initiation, was associated with treatment response in routine practice.

Methods:
This retrospective real-world cohort study included patients with metastatic hormone-sensitive and metastatic castration-resistant prostate cancer, treated with ARPI-based therapy in an Eastern European oncology center. Demographic, clinical, treatment, and longitudinal PSA data were collected from routine medical records, with further accrual and data collection ongoing. Ultra-low PSA was defined as PSA <0.02 ng/mL within three months after ARPI initiation. The association between ultra-low PSA achievement and best documented treatment response was assessed descriptively and by unadjusted logistic regression.

Results:
Among patients treated with an ARPI (n=44), treatment patterns reflected routine practice, including apalutamide (n=22), enzalutamide (n=16), abiraterone (n=2), and abiraterone + olaparib (n=4). PSA data were evaluable in 41 patients. Ultra-low PSA within the first three months was achieved in 14/41 patients in the PSA-evaluable population (34.1%), with proportions varying across treatment groups. By treatment, ultra-low PSA occurred in 42.1% of patients receiving apalutamide, 25.0% receiving enzalutamide, 50.0% receiving abiraterone, and 25.0% receiving abiraterone + olaparib. Among patients with evaluable PSA data and documented best response (n=29), response rates were higher in those achieving ultra-low PSA compared with those who did not: 81.8% versus 50.0%, respectively. This

corresponds to an unadjusted odds ratio of 4.50 (95% CI 0.75–26.93), supporting a positive association between ultra-low PSA achievement and treatment response.

Conclusions:
In this interim Eastern European real-world cohort, achievement of ultra-low PSA within three months after ARPI initiation was associated with higher likelihood of treatment response in patients with metastatic prostate cancer receiving ARPI-based therapy. These preliminary findings could support ultra-low PSA as a potential marker of ARPI response in routine practice. Further accrual, extended data collection, and longer follow-up are ongoing to validate these findings and clarify their association with progression-free and overall survival outcomes.