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How Are ARIs Being Used to Intensify Therapy for High-Risk Localized Prostate Cancer After Local Therapy?

Announcer:
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Dr. McKay:
Hello, my name is Rana McKay, and I'm a GU Medical Oncologist at the University of California in San Diego. Today we're going to be discussing how ARIs are being used to intensify therapy for high-risk localized prostate cancer after local treatment.

The model for prostate cancer clinical states integrates our understanding of both the natural history and the treated history of prostate cancer. And this framework can really be utilized to help us understand what's the goal of any given therapy that any patient may receive, whether that be systemic therapy, local treatment with surgery, or radiation. And for patients presenting with localized disease, multimodal treatment strategies which integrate local and systemic therapies can really be utilized to help optimize cure for individuals with high-risk disease. So what we will do is present a series of clinical trials that are currently enrolling patients to help improve outcomes for individuals with high-risk prostate cancer.

The first of these studies is the ERADICATE trial. And the ERADICATE trial is an adjuvant trial that integrates the use of adjuvant hormonal therapy, post radical prostatectomy, for high-risk individuals that are at risk of recurrence following surgery. This trial integrates the Decipher score, and also the CAPRA score, and enrolls patients who have a CAPRA score greater than 3 and Decipher score of greater than 0.6. And patients are randomized 1:1 to receive treatment with either darolutamide and ADT for 12 months, or placebo and ADT for 12 months, with a primary endpoint of metastasis-free survival.

The ADAM trial is another postop study that's enrolling patients who have high-risk features by D'Amico criteria with a PSA of less than 0.2 post RP. And patients are randomized to receive apalutamide versus observation. The primary endpoint of this trial is PFS, and the trial is enrolling 260 patients.

The PRESTO trial has already been conducted, and we've already seen data from this study. This trial is a little bit different and is focused on the biochemically recurrent setting. The trial enrolled patients who had a prior radical prostatectomy with biochemically recurrent prostate cancer with a PSA of greater than 0.5 and a PSA of doubling time of less than or equal to 9 months, and patients were not allowed to have metastases based off of conventional imaging, and their last dose of ADT needed to be greater than 9 months prior to study enrollment. Patients were randomized 1:1:1 receive an LHRH analog, an LHRH analog with apalutamide, or an LHRH analog with apalutamide and abiraterone for 52 weeks. This was a positive trial that resulted in a statistically significant improvement in biochemical progression-free survival of the experimental arms compared to the control arm. The median was 24.9 months for ADT plus apalutamide, compared to 20.3 months for ADT alone, with a hazard ratio there is 0.52. Additionally, we did also see an improvement of biochemical progression-free survival in patients that had received triple therapy with API, with abiraterone, apalutamide, and ADT.

The EMBARK trial also enrolled patients in a similar population. This was a trial conducted in the biochemically recurrent setting.

Patients were eligible if they had a PSA of greater than 1, if they had a PSA doubling time of less than or equal to 9 months, and they were not allowed to have metastases on conventional imaging based off of central review. And patients on this study were stratified to receive enzalutamide plus leuprolide, placebo plus leuprolide, which was the primary analysis, and enzalutamide monotherapy. And the primary endpoint here was metastasis-free survival by independent review. This trial was also a positive trial, resulting in a statistically significant improvement of MFS in people on doublet therapy with enzalutamide and Lupron, compared to Lupron alone. Additionally, there was decreased rates of PSA progression with the combination. And the overall survival data are still maturing.

So in conclusion, there have been several studies that are currently ongoing that are investigating ARSIs following definitive local therapy for patients with prostate cancer, both in the adjuvant setting and also in the biochemically recurrent setting. Adjuvant darolutamide and apalutamide following RP is being investigated. Enzalutamide and apalutamide have certainly demonstrated promising results in two phase 3 trials in the BCR setting.

Thank you for listening.

Announcer:
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