Transcript Details
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Treating High-Risk Biochemically Recurrent Prostate Cancer: An Update from ASCO-GU

Announcer:
You're listening to *Project Oncology* on ReachMD. On this episode featuring Dr. Neal Shore, we'll discuss the EMBARK study, which focused on high-risk biochemically recurrent prostate cancer patients who suspended enzalutamide monotherapy treatment. Dr. Shore is the Medical Director for the Carolina Urologic Research Center in Myrtle Beach, South Carolina. He also presented a session on this exact topic at the 2024 ASCO Genitourinary Cancers Symposium. Let's hear from him now.

Dr. Shore:
The title for our oral podium presentation was "Outcomes of Men with High-Risk Biochemically Recurrent Prostate Cancer Who Suspended Enzalutamide Monotherapy Treatment in the Phase 3 EMBARK Study."

Let me just tell you a little bit about the EMBARK study in an overview. This was an 8-plus year trial in the making. We had over 1,000 patients globally. We looked at patients who had failed radical prostatectomy or radiation primary prostate treatment or both, and they had to have had a biochemical recurrence, PSA relapse, with a doubling time of less than or equal to 9 months. It was a 3-arm trial. One arm received open-label enzalutamide monotherapy on the approved dose 160 mg daily. That's a dose that's been approved across mHSPC, nmCRPC, and mCRPC. And then there was two arms that were blinded. One was a Q3 month leuprolide acetate with an oral placebo. The other was Q3 month leuprolide acetate with enzalutamide.

At the end of 36 weeks, if PSA is nadired in three arms to less than 0.2, there was a treatment holiday. Patients restarted therapy if in their radiation group, their PSA went above 5, or in the RP radical prostatectomy group, they went above 2. The primary endpoint of the entirety of the trial was metastasis-free survival, and it was evaluated by a blinded independent central radiological review. The trial was successful.

You know, we've known for a long time that for patients with high-risk localized prostate cancer, 20 to 50 percent of these patients will develop biochemical recurrence, so we have to figure out how do we treat these patients. And historically, for these high-risk BCR patients, we've had no Level I evidence, and we've historically used some early-generation, first-generation AR pathway inhibitors like bicalutamide or varying regimens of ADT intermittent continuous. This is the first phase 3 trial to develop Level I evidence looking at a 3-arm study of monotherapy T suppression, ADT, versus monotherapy enzalutamide versus combination enzalutamide with leuprolide. And what was also unique about our study is we had a treatment holiday at 36 weeks if they had a profound PSA nadir less than 0.2, and then patients resumed treatment.

When we talk about this treatment suspension, or some people like to call a holiday, at 37 weeks, which I think is very compelling to many patients and certainly to physicians because we tend to give patients a freedom from therapy, and they can oftentimes start to feel better whether they're on T suppression or AR inhibition.

A treatment suspension looking at the enza mono versus the leuprolide mono is 91 percent of the patients of the 355 on enzalutamide monotherapy received a treatment suspension as opposed to 72 percent of patients of the 332 in the leuprolide alone arm, so that was an interesting finding.

When we looked at the characteristics of those patients who got a treatment suspension, I think it was very interesting to see that their racial demographics, the doubling time the serum PSA was comparable. The number of patients or the percentage receiving RP alone or RT alone was also comparable as well as those who had both RP and RT.

Now, for the ones who didn't receive a treatment suspension, it was also fairly comparable. We do see that in the ones that didn't

receive a treatment suspension a little bit of a higher percentage—38 percent in the leuprolide monotherapy as opposed to 16 percent in the enzalutamide monotherapy.

Announcer:
That was Dr. Neal Shore talking about his presentation at the 2024 ASCO Genitourinary Cancers Symposium that focused on the EMBARK study. To access this and other episodes in our series, visit *Project Oncology* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!