Transcript Details

This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/clinical-practice/oncology-hematology/sunrise-1-1-year-durability-and-patient-reported-outcomes-results/33075/

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SunRISe-1: 1-Year Durability and Patient-Reported Outcomes Results

Announcer:
Welcome to DataPulse from AUA 2025 on ReachMD. This activity, titled "SunRISe-1: 1-Year Durability and Patient-Reported Outcomes Results" is provided by Prova Education.

Dr. Shore:
Hi, everyone. Neal Shore here in Las Vegas AUA 2025. Want to tell you about a trial that's in progress that I presented today. I'm at one of the sites on the steering committee. This is for BCG-experienced or patients who are unresponsive, with high-risk NMIBC, and particularly, we're really just looking at patients with papillary or T1 disease. And what we're targeting are patients who have the FGFR3 alteration, and they can be enrolled whether they have a tissue-based alteration, or a urine-based alteration. And this is really improving the era of precision-based care.

We've known already that patients with FGFR alterations, we have an approved oral version of a drug called erdafitinib, approved back in 2017 for second-/third-line metastatic urothelial cancer patients. There's actually a higher prevalence of the alteration in NMIBC patients. So we're looking at these patients, randomizing them to receive the drug-releasing system known as the TAR-210, which has a zero-order kinetics release of erdafitinib. And so you insert and replace every 3 months or every 12 weeks, which is actually a really nice dosing schedule. And they'll be randomized against intravesical therapy, investigator's choice, gemcitabine or mitomycin. That's a very real-world decision point. So this is super exciting. It's a trial in progress. I love this kind of a study because it's very urology friendly. We can basically have these types of releasing systems which you can have off the shelf in your clinic.

And also the data previously on TAR-210 from earlier first-in-human studies and other earlier studies as part of the MoonRISe program, which is the TAR-210, erdafitinib; the TAR-200 is the gemcitabine program. There's 5 trials in that: SunRISe-1, 2, 3, 4, 5. Overall, very good tolerability. Patients may get some mild lower urinary tract-type symptoms and very much in the wheelhouse for urologists to insert and remove. So an exciting trial. Look forward to reporting it to you at a future time once we start to get the readout on the data.

I'm Neil Shore at AUA 2025 in Las Vegas. Thanks very much.

Announcer:
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