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Expert Perspectives From AUA 2025: Contextualizing the Evolving Landscape of Bladder Cancer

Announcer:
Welcome to CME on ReachMD. This activity, titled “Expert Perspectives From AUA 2025: Contextualizing the Evolving Landscape of Bladder Cancer” is provided by Prova Education.

Dr. Shore:
Well, at the AUA 2025 annual meeting, exciting new data were presented that have the potential to shift the treatment paradigm of bladder cancer. Are you ready for this next wave of practice changes?

This is CME on ReachMD. I’m Dr. Neal Shore.

Dr. Psutka:
And I'm Dr. Sarah Psutka. It's a pleasure to be here with you, Neal.

So there were some really interesting abstracts on new approaches in treating BCG-naïve, high-risk, non-muscle invasive bladder cancer at this last AUA.

Neal, can you review these studies for us?

Dr. Shore:
Yeah, there were a bunch. Right off the bat, I had the privilege to do the phase 3 presentation for CREST in the plenary. And essentially, this is a subcutaneous PD blocker, sasanlimab, in combination with BCG induction and maintenance. And that was arm A. There's arm C, which was the control arm, induction and maintenance BCG for 2 years. The combination arm, sasanlimab subq PD blocker, every month, again for about 2 years. There was arm B that was the subq sasanlimab every 4 weeks for 2 years, but only the induction. Bottom line, the event-free survival favored the combination arm, hazard ratio of 0.68.

So that, I think, is the first of 4 different phase 3 BCG-naïve, high-risk NMIBC patient populations that are looking to see, by adding a PD blocker, would that make a difference?

So, Sarah, how would you interpret the clinical relevance of these data in the BCG-naïve, high-risk population and incorporate these new regimens into practice, if indeed they become available?

Dr. Psutka:
Well, the premise here is that we know that patients with BCG-naïve disease who receive induction BCG, about 40% of those patients are destined to have recurrence or progression. So seeing a novel combination IO plus BCG regimen that decreases that event-free

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survival by over 30%—it was 32% reduction in event-free survival—I think is encouraging.

Dr. Shore:
Yeah, I agree with everything you mentioned. And some of our colleagues, regarding the CREST study, may say, "Well, can I manage the immune-related adverse events of a checkpoint inhibitor, a PD blocker?" And I would say the answer is yes, if you have the enthusiasm and the desire. So we always like to increase options and improve upon that 40% recurrence rate, as you mentioned, for our high-risk patients, particularly the patients with CIS and T1 disease.

So there are also some new data on novel approaches in treating the BCG-unresponsive, high-risk NMIBC patients.

Sarah, what do our listeners need to know about these studies?

Dr. Psutka:
So first there's the TAR-200 device. So this is a gemcitabine-eluting device that is placed in the bladder. And there were updated results presented from what was the SunRISe-1 trial. So this is a phase 2b study. The second cohort in that study looks at TAR-200 monotherapy.

Joe Jacobs specifically presented this, the results of the TAR-200 monotherapy arm, or cohort 2 from the SunRISE-1 trial. So these are patients with BCG-unresponsive carcinoma in situ, with or without papillary disease. There were 85 patients. And the punchline is that the CR rate, either centrally confirmed or investigator assessed, they were greater than 80%. That is the first time we've seen CR rates in this disease space greater than 80%, so centrally confirmed was 82.4%. And the median duration of response was over 2 years at 25.8 months.

In general, there were about 80% of patients or more who had some treatment-emergent adverse events, but the vast majority were low-grade urinary adverse events that we as urologists are very comfortable treating. Only 13% of patients had grade 3 or greater treatment-emergent adverse events, and there were no treatment-related deaths. So this is generally relatively well tolerated, mostly with urinary toxicity.

Cohort 4 of SunRISe-1 specifically looked at patients who had papillary disease only, without carcinoma in situ. And again, this is BCG-unresponsive, high-risk, non-muscle invasive bladder cancer. And this cohort had 52 patients in it. Felix Guerrero-Ramos presented these results, basically demonstrating that among those patients who had all of their disease resected and then went on to every-3-week placement of the TAR-200 device for the first 24 weeks and every-12-week placement until week 96, the 6-month disease-free survival rate was 85.3%, 9-month disease-free survival is 81%, and the toxicity profile is similar to what I mentioned in cohort 2.

Now, switching agents completely, the other study that was presented that I think is really important for our listeners to hear about is the updated results from the BOND-003 trial. And this was cohort C, so this, again, is patients with BCG-unresponsive non-muscle invasive bladder cancer who have carcinoma in situ. This is a single-arm phase 3 study, it was presented by Mark Tyson, that looked at the drug, cretostimogene grenadenorepvec. It is an oncolytic immunotherapy that basically is taken into tumor cells, replicates within tumor cells. It's lethal to the cells that it transfects, but when those cells then rupture, it also induces a tumor antigen-triggered antitumor immune response. But basically, in this study, there were 112 patients, with a median follow-up of about 22 months and the overall CR rate here was 75.5%. Importantly, the 12-month duration of response was 64%, and the 24-month duration of response was 58%. So you're seeing a median duration of response here that's over 2 years.

So, Neal, how do you interpret the clinical relevance of these data? And how would you think about incorporating these new regimens into practice if and when they become available?

Dr. Shore:
I think the data here for the drug-releasing system, the TAR-200, which has gemcitabine, which is essentially really dramatically improving the dwell time. So there's greater exposure to gemcitabine, rather than giving it its liquid form, traditionally, via the catheter. And the data, as you nicely summarize, excellent in both CIS and papillary.

And then cretostimogene, a different mechanism of action, works on RB1 defect.

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I think one of the nice things about the drug-releasing system, the TAR-200, is it's a sort of off-the-shelf product, and there's no freezing, there's no refrigeration required. It's catheterization. It's given and put in, taken out, on a kind of a 3-week basis.

But I think this is super exciting, great for the field.

Dr. Psutka:
Yeah, I couldn't agree more.

Dr. Shore:
For anyone just tuning in, you're listening to CME on ReachMD. I'm Neal Shore, and it's been a great pleasure to be joined today by Dr. Sarah Psutka. We're discussing the new data on NMIBC that were presented at this year's annual AUA 2025 meeting.

Dr. Psutka:
So there were also some ongoing trials that were highlighted at the AUA, specifically in BCG-unresponsive, high-risk, non-muscle invasive bladder cancer, that we're waiting anxiously to see the results of. Neal, what can you tell us about those?

Dr. Shore:
Yeah, I can summarize these, actually, pretty quickly. SunRISe-5, part of that SunRISe platform. As you said, the SunRISe-1 was in the BCG-unresponsive. There's a SunRISe-3, which is looking at the BCG-naïve. SunRISe-2 and SunRISe-4 is in muscle invasive disease. But SunRISe-5 is these patients who are BCG-exposed or BCG-unresponsive. And a direct comparison in a phase 3 trial against intravesical chemotherapy, choosing gemcitabine or mitomycin. And this exposed population, as well as the unresponsive, that's a very large population, and so I think that'll be particularly interesting as we learn more about that. And that data is going to be forthcoming.

The BOND-003, again, the cretostimogene formulation. Single-arm again, looking now, instead of the CIS population, the high-risk papillary only. So that's very important because there is some differences in response rates. I think you covered very nicely in the earlier segment regarding the mode of administration and the safety profile. But again, this will give us additional data that's going to be forthcoming, hopefully at next year's AUA.

Anything to add on that, Sarah?

Dr. Psutka:
Well, I think when you think about sort of where these novel agents first got evaluated, it was in the area of the highest need, which is that patient population who had BCG-unresponsive carcinoma in situ, with or without papillary disease.

But now I think the trials that are ongoing, the trials we just presented the results for, we're looking at that those patients who have papillary-only disease without CIS.

So again, yeah, I'm very excited to see what these trials will show in the coming years.

It's not surprising, in this era of precision medicine, that biomarker-directed therapies are also being studied in non-muscle invasive bladder cancer.

There were some highlights from the AUA specifically looking at taking this strategy into the non-muscle invasive space. Neal, can you share some of those highlights from the studies presented at the AUA in 2025?

Dr. Shore:
Yeah, there were several. One really interesting one for this high-risk group is combining an antibody-drug conjugate known as disitamab vedotin, a novel antibody-drug conjugate that targets HER2 protein.

But what our colleagues in China have done here is they've combined BCG intravesically with intravenous exposure to disitamab vedotin in this high-risk NMIBC population. Overall, it's a small group, but they actually had a pretty manageable safety profile. And I think this is a very cutting-edge way of looking at patients and trying to optimize, synergistically, the mechanism of action, the immunobiologic mechanism of intravesical BCG with an antibody-drug conjugate given intravenously. So I think it's provocative.

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There's the phase 3 TAR-210 intravesical erdafitinib. So different from the drug-releasing system that's the TAR-200 which is gemcitabine, the erdafitinib is an FGFR receptor blocker. And it's interesting too because it's sort of a zero-order kinetics, and so typically, when you put in this particular drug-releasing system, the 210 vs the gemcitabine 200, you can put it in, it can be exchanged every 12 weeks, as opposed to every 3 weeks, which certainly has some advantage there.

So in the phase 3 study, it's looking at this novel releasing system vs intravesical chemotherapy for patients who were BCG-exposed with high-risk NMIBC features but have to have, either by tissue or by urine, FGFR alterations. Of note, we see FGFR alterations in metastatic urothelial cancer, about 25% of those patients, but it's much higher in NMIBC. Not so high in CIS, but it's much higher in papillary and T1 depending upon the analysis of about 60%. So I think that's going to be a really provocative trial, and it's phase 3.

The MoonRISe-1 is also a phase 3 study looking at the TAR-210, the drug-releasing system of erdafitinib. And again, this will be vs intravesical chemotherapy for patients with these FGFR altered based upon tissue or urine-based analysis. And the concordance with the urine and the tissue is actually really pretty good. And this is going to be in the intermediate-risk NMIBC population, which has, heretofore, really not had a lot of clear pathway of regulatory approval.

But there are a lot of these patients. And in the era for some where there's a BCG shortage, I think this intermediate-risk population is important, and I'm glad it's being studied.

So comments or thoughts on these 3 important ongoing studies, Sarah?

Dr. Psutka:
Just to highlight what you said, we know that the FGFR mutations are prevalent in all bladder cancers, but they are especially prevalent in the non-muscle invasive bladder cancer patient population. And they are mostly prevalent in the low-grade tumor. So that's why, especially this MoonRISe-1 trial, I'm really interested in seeing the results of, because this patient population, this kind of, as you said, heretofore unexplored, really kind of orphan disease space, intermediate-risk, non-muscle invasive bladder cancer, this is very common bladder cancer.

Dr. Shore:
Yeah, and I think one of the great aspects is the accessibility of these drug-releasing systems. I also think trying to be more precision based, looking for FGFR alteration, and which is very easy to obtain now in urine or even a simple biopsy in the clinic. And I love the fact that the 210, like the 200, is an off-the-shelf product, which, for me, I always think, how do we get greater accessibility to our colleagues in rural parts of the world or not necessarily have great access to freezers and accessibility even to academic medical centers that may have all the bells and whistles, but patients still need to get some options. So I'm thrilled that these studies are ongoing.

Sarah, this has been great. But before we wrap up, can you share maybe 1 or 2 take-home messages for the audience?

Dr. Psutka:
I think 2 main take-home points. The first is that there are a number of new therapies that we're starting to see more mature data. One of the really exciting advances, I would say, is, of course, the ability now to start thinking about how we can deliver tolerable treatments to the bladder with a pretty standard and acceptable toxicity profile that are novel in terms of their approach for how they're treating the cancer, but also the ability to, for example, with the novel devices that allow us to sustain the contact between the treatment and the bladder wall, we're getting longer treatment dwell times and sustained exposure of the cancer to the new treatment. I think that's really exciting.

The biggest news, I think, is that we're starting to see a total rewriting of the horizon in terms of what we're going to be expecting to see in terms of CR rates, or complete response rates, which are outstripping our prior benchmarks, which were really around 40% or lower. We're now seeing patients sustaining 70% to 80% complete response rates, and they're durable responses with data out to 2 years. And I think that's a game changer for patients with high risk, especially the non-muscle invasive, BCG-unresponsive disease.

And then obviously, I think, to your point, Neal, that we're going to start to be really thinking about how do we include novel biomarker testing in our clinic practice to help to select those patients who might best respond to some of these drugs. And I think that that's going

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to be a kind of a critical change in our paradigm in the coming years in terms of incorporating precision medicine into the early phase of bladder cancer treatment.

Dr. Shore:
Well, that was a great summary. This has been a wonderful opportunity to dialogue with you, Sarah. So I want to thank the audience for listening, and certainly Dr. Sarah Psutka, who's brilliant and really has helped summarize so many of these really important studies that have read out and many more that will ultimately read out, and it's going to change, as she says, your options. And many of them will be proverbial paradigm changing, and I think that's great.

Dr. Psutka:
Thank you so much, Neal. This has been an absolute pleasure, and I really appreciate and congratulate you and all of the investigators on the trials that you presented at the AUA. And thanks very much for the opportunity to talk about all of these really exciting developments.

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