

Understanding A New Treatment Option for Advanced Bladder Cancer

Guest Speakers: Vadim Koshkin, MD
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Mr. Robert Ashton
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Dr. Vadim Koshkin:

So what are some of the important things to actually discuss with your doctor and with your healthcare team about this therapy? Well, it is important to be on the same page about what is the goal and expected outcome of this treatment, right? Different patients, I think, have very different goals, and it's important to understand that from the outset. For that reason, discussing your expectations with your physician, your healthcare team is, of course, critical as well. The expected duration of treatment and side effects, very important here and you know, we discussed some of that a little bit earlier.

Then I think it's important to define, or at least discuss, what does success look like with treatment like this? What are we aiming for? Again, this is very different for different patients and can be affected by a wide variety of things, right. An absolutely critical thing is to always discuss the extent of your side effects actually after already starting therapy with your doctor, because, again, I think that's an absolutely critical part of successful treatment, because it does affect how we give this regimen, how we adjust doses, and really, really, what we do. For a patient to exercise and express themselves and their voice in that situation is absolutely important.



What should you discuss with your doctor about this therapy?

- What is the goal and expected outcome of treatment?
- Discuss your expectations
- Expected duration and side effects
- What does success with this treatment look like?
- Always discuss the extent of your side effects with your doctor

Dr. Vadim Koshkin:

So, what is the future of this therapy? Well, increasingly I think we will see more and more patients with urothelial cancer receiving this treatment. Actually, even in the time since I made the slides, which is just earlier this week, this is already proving to be the case, because just a couple of days ago, we actually heard a press release from results of a clinical trial of this

combination for patients now with metastatic disease, but with muscle invasive bladder cancer so patients who are treated with this therapy, this combination treatment, followed by a surgery to remove the bladder, with the attempt to, of course, get rid of the cancer completely to cure it.

There is a clinical trial that investigated this combination treatment specifically in that patient population that we now know is positive, meaning it's better than the prior standard of care, which likely means that in the coming you know, months, two years, the FDA will likely approve this therapy. Again, we have to see the data first, but usually positive trial, big positive trial like that, leads to an FDA approval for a very different and a broader patient population, those with muscle invasive disease.

And so, I think you know, when we talk about this combination a couple of years from now, it'll be a much broader population of patients that is being treated with this. We will have a lot more with this therapy. We'll have more information about you know, side effects as well and their expected resolution as more and more patients are treated with this.

Dr. Vadim Koshkin:

So, to summarize, enfortumab vedotin-pembrolizumab, the combination we're discussing today, is a very effective treatment option for patients with advanced bladder cancer. It has led to significant strides in the care and treatment of patients with this disease, and you know, that has changed even, again, in the time since these slides were made earlier this week. It


significantly exceeds outcomes, this combination, relative to you know, what we were seeing with prior standard of care therapies like chemotherapy.

But, on the other hand, it is associated with a specific side effect profile that, you know we have to keep in mind, we have to monitor and manage very carefully to really allow more

What is the Future of this Therapy? 

- Increasing numbers of patients with urothelial cancer will be receiving this treatment
- Will have more information on expected duration of treatment, which patients can stop treatment earlier
- This regimen will likely be moving into earlier treatment setting, making it available for a broader patient population
 - Patients with muscle invasive bladder cancer
- More information about potential side effects and their expected resolution



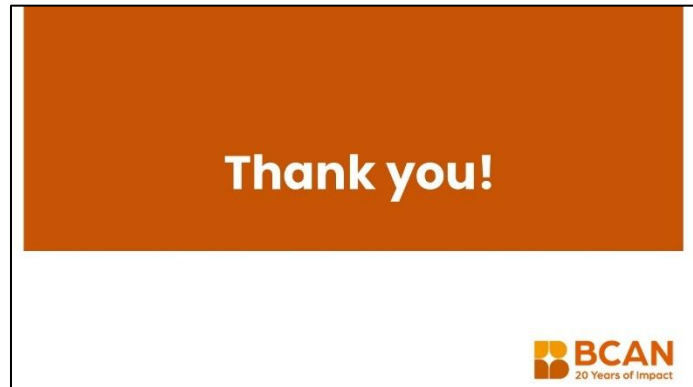
Summary 

- Enfortumab vedotin + Pembrolizumab combination is a novel, very effective treatment option for patients with advanced bladder cancer
- Far exceeds outcomes seen with previously available therapies (like chemotherapy), bringing new hope
- This combination is associated with a specific side effect profile which requires careful monitoring and management
- Patient communication with their treatment team is key

patients to achieve greater success on this treatment. With that, patient communication with their treatment team is absolutely key and absolutely critical. That's why, again, I think it is especially important to hear the patient voice in all this and really how this treatment, you know, affects your day-to-day and how it really can help many patients. That's why I'm really glad that we have a patient today to describe their experience with this as well.

Dr. Vadim Koshkin:

But in the meantime, I, again, thank you for your attention with this, and look forward to the questions in a discussion later.



Robert Ashton:

All right. Thank you so much, Patricia, and thank you for the introduction earlier. Just to add onto the introduction, Patricia mentioned that I have a part-time job of consulting. I also have a second part-time job, and that's my cancer treatment.

I do approach it as a job. I was diagnosed with stage two bladder cancer in the fall of 2016, and it has since progressed to stage four. I've gone through numerous treatments, from procedures and surgeries, immunotherapies, chemotherapies, radiation in various combinations and currently, I am on the enfortumab-pembrolizumab combination. I started enfortumab in November of 2022 and added pembrolizumab about one and a half years ago.

So far, I'm having a good response to it, to the treatment. It has manageable side effects for me at this time. It's mostly fatigue. I can't blame all the fatigue on this combination, though. I've been fatigued for some time with all the therapies I've been on. I do have a bit of neuropathy in my hands and my feet in the form of numbness, and I have a variable appetite. Some days I'm not hungry at all and some days I want to eat the house down.

The other thing I wanted to point out for this therapy is I do find it relative convenient to take. On those days, on day one of this 21-day cycle, when I receive both the enfortumab and the pembrolizumab, the infusion time is a total of one hour. It's 30 minutes of time for each drug, which adds to 60 minutes. If you've been through other treatments, for instance, cisplatin or some of the other platinum-based drugs, you know, they can take a lot longer and you may lay in the infusion center for some time. So that's one thing I really appreciate about this combination.

You know living with cancer since 2016 has taught me several things, and Patricia asked me to share some of these with you. First and foremost, I'm much more thankful than I ever was. I'm thankful for every day that I have, as well as the people in my life, both the old and new folks who I've met along the way. I'm thankful for the experiences I've had, as well as learnings that have changed and altered me and how I behave.

I try to live in the present and have no regrets. A little bit easier said than done, but I do focus on the now, not the past and not too far in the future. I live with what's called an open hand, which is letting go of those things that really don't matter and try to capture all the good things that come along. I do try to be more kind and patient, another thing that's a work in progress, but still achieving to be better.

Lastly, one of the things I think we've all probably learned about ourselves is that I'm stronger and braver than I ever thought I was, and so are you in the process, I know. While I realize I'll ultimately lose this war, I've been fortunate to win a lot of battles with the help of many people. I continue to learn about the disease and living with cancer.

Again, I want to thank Dr. Koshkin and the Bladder Cancer Advocacy Network for inviting me to be here today and sharing some of my experiences with everyone.

Patricia Rios:

Thank you, Robert, for accepting our invitation and being able to share your experience with others. You talked about some of the side effects that you experienced, fatigue being one of them. Could you tell us a little bit about how you manage that particular side effects or others?

Robert Ashton:

Sure. You know, everyone's cancer experience is different, and obviously I can only speak to mine, but the symptom that I have that affects me most on a daily basis is fatigue. As I said earlier, I can't blame this entirely on my current treatment with enfortumab and pembrolizumab. You know I've been on therapies for some time, and my fatigue goes back for some time as well.

But I typically try to fight this in two ways. First, I rest when I need to rest. I try to plan my days to ensure I have time built in to rest should I need it. And to be honest, I'm okay with going to bed by 9:00 PM if I need to.

Second, I try to exercise regularly. Most often the form of foot walking is I get both a physical and mental benefit from it. I had a, well, a very wise nurse once told me that exercise is the enemy of fatigue. She told me that if I can't walk for 20 minutes, to walk for 10. If I can't walk for 10 minutes, then walk for five. Her main message was just get up and move. And it's true. You know the hardest part is just getting started each day.

Patricia Rios:

Thank you for sharing that tip. That leads me to wonder, Dr. Koshkin, you shared many different side effects that result from this therapy. I'm curious to know, what are some of the, who else is part of, I guess, the team that helps manage patients, and also what are some of those surveillance or tests that are done as patients are on these treatments, besides the ones that you mentioned during the, your presentation?

Dr. Vadim Koshkin:

Yeah, that's a great question. I think it's absolutely important and critical to highlight the importance of the healthcare team right, which is so much more just than the physician. You know, Robert knows all these people on my team cause you know he they interact with them very closely. But it's you know the nurses who you know work closely with me and then work closely with patients and you know help patients manage side effects and then communicate those to me and communicate other things to me that patients express.

We have nurse practitioners as well who you know are able to see the patients and also prescribe medications and prescribe certain interventions in actually the same way that physicians can. There are you know actually non-medical ... Well, non-clinical personnel, I should say, so the schedulers who make sure that you know the infusion of a you know given treatment is timed correctly with you know the appointment and things like that.

I think their role in helping patients navigate all that is very important. Then we have a lot of colleagues from other teams that help manage, you know, side effects or some of the other complications as well. So Robert mentioned things like fatigue right, and I would add to that appetite loss and other symptoms you know that our symptom management colleagues actually help with a lot and that's, those are additional doctors and additional nurses and nurse practitioners who work with them, who focus on that aspect of cancer care, right, which goes in parallel with treatment, but is, you know, probably just as critical. It's actually making sure that the patients can feel better and, you know, deal with and tolerate some of these challenging treatments better as well.

Then, of course, if more significant or, well, I shouldn't even say more significant, but side effects that require other medical input happen. So things like, you know, inflammation in the lungs that I was alluding to earlier, then we often involve other physicians as well, so like pulmonologists that focus on the lungs or physicians that focus on the liver or GI tract. So it, in many instances ... Oh, dermatologists as well; that help with rashes that are a common side effect here. So in many cases like that, it ends up being quite an extensive team that a patient interacts with. We're talking about tens of people right and quite a lot.

Patricia Rios:

Thank you for explaining that and I know that's something that came up when Robert and I were discussing and he was praising his team at UCSF. I'm curious to know, in terms of the how widespread this treatment is available, is it available outside of non-academic centers, say, for example, community-based practices?

Dr. Vadim Koshkin:

Yeah, at this point is is. As most treatments in oncology, initially when it's part of clinical trials, it's only available, yeah, at academic places that run those trials. Although many community practices now actually run clinical trials as well, right? So you can seek out that therapy there. But once it's well FDA approved and more widely available, you can really get it anywhere.

I think there is some geographic variability with uptake of this particular regimen. I think certainly, well, in Northern California where I practice, I think it's been, you know, pretty widely used. I don't know if that's the case in all areas of the country, because actually, I mean, we've seen actually some data that yeah, in many places, it yeah hasn't actually probably been used as broadly as it should be given the really positive data we're seeing, right?. So in some places, you know, it still, you know, prior therapies like chemotherapy are being used when, you know, I don't know that there's a strong reason to do that.

But, overall, I mean, yeah, I think in the last year and a half, we've seen a lot of uptake with this. We have, you know, pretty good data now again suggesting how patients would this do in what I call the real-world settings, so outside of clinical trials, but in everyday practice.

