Stephanie Chisolm:

It could all be information that the doctors would want to know. So let me get to some of the questions from the group. Based on Dr. Dickstein's experience, are there specific treatments you think are most promising for patients that are non-responsive to BCG? Are there things coming out, things in clinical trials you're saying, wow, these are going to make a big difference?

Dr Dickstein:

Yeah. So first one drug that just came out of a fairly recent clinical trial, it's called Adstiladrin. And the results were pretty exciting. So that actually is FDA approved and we're just waiting to operationalize it and get it going for our patients. So that's pretty exciting. And it was a result of-

Stephanie Chisolm:

That will be the end of the summer, beginning of fall, right?

Dr Dickstein:

That's right. So it's pretty exciting because it came from a lot of clinical trial work. And then probably the two of the ones that I'm pretty excited about are the CG oncology trials using a novel gene viral virus. And then the quilt trial is Immunity Bio using an enhancement of the immune system. Those are two of the most exciting trials, at least I think at the moment. But this is just my hedging because we'll have to see what the data shows.

Stephanie Chisolm:

Right. And until everything gets done and until enough patients get into a trial, they don't always have all that information, that data on which to make a decision to move it to the next phase of a clinical trial.

Stanley Wenocur:

And while you're in the trial, they may not tell you how it's going because they don't want to bias the trial.

Dr Dickstein:

Absolutely. And they usually don't.

Stanley Wenocur:

They don't.

Stephanie Chisolm:

Yeah. So here's a question for you, Dr. Dickstein. In your opinion regarding urine based biomarker trials, how much of an improvement would they provide over standard cytology? Would they provide the fidelity and confidence level to eventually take the place of cystoscopy?

Dr Dickstein:

Right. So that's a great question. And when we talk about these biomarkers, we have to talk about sensitivity and specificity and some of the statistics involved. So sensitivity is the ability to not miss a diagnosis. And the specificity is a positive result, really means that it's positive and not a false alarm. And so you have to look at the balance between those two. There's no perfect biomarker. There never will be a perfect biomarker, but we know that cytology is not very perfect. Cytology is also very user dependent. It has to be read by an expert versus a numerical output. So yeah, the hope is that one day, I'll put it this way, I'm not sure that we're ever going to get rid of cystoscopy, but we certainly hope to augment cystoscopy. So either decrease the amount of cystoscopies that we have to do or the frequency that we have to do. And so I think that is really the hope and goal.

Stephanie Chisolm:

I think that's the hope and goal of a lot of patients. If you don't have to have a cystoscopy, many patients are going to be way happier. If they could just provide a urine sample, that's easy. Everybody has to do that.

Dr Dickstein:

Absolutely.

Stephanie Chisolm:

All right. For a clinical trial, who pays for this? If the cost of the medication, does insurance cover your participation in a clinical trial? In general, I know everyone is unique, but in general.

Dr Dickstein:

So it depends on how the trial's designed and written. The vast majority, the patient has zero expense to it. Most of them, when it's a novel drug, the drug is typically covered by the sponsor of the trial, meaning the pharmaceutical company. But sometimes when they're combining a therapy that's already standard of care with a novel therapy, the standard of care therapy might be covered by the insurance company. And then again, the novel therapy being covered by the sponsor. But in general, patients don't really have any added expense from participating in a clinical trial.

Stanley Wenocur:

But if it doesn't work and you're on your own, then you do have an added expense.

Dr Dickstein:

That's true. That's the gamble that you take is, and obviously we hope that the trial does work. But in the event that doesn't, then we're back to options of what's on the table.

Stephanie Chisolm:

Okay. Dr. Dickstein, do you know of any clinical trials designed specifically to look at treatment efficacy in women with non-muscle invasive disease?

Dr Dickstein:

Yeah. Another good question. Right now, all of the trials are not exclusive to women. They include both men and women. So I don't know of any specifically designed only for women, but again, all of the trials are gender neutral at the moment.

Stephanie Chisolm:

Okay, great. And then since you mentioned Adstiladrin, do you know if that's only for use in patients with CIS or?

Dr Dickstein:

Yeah, so it's interesting. A lot of the trials are being studied in patients with CIS only or CIS plus papillary disease and not papillary disease only. And that is mostly because of the way that the FDA is approving the medications. So despite the way it's studied on a clinical trial, many times in the real world, people are still administering it for patients who are not necessarily the ones that were seen on the trial. Now, I'm not necessarily advocating for that, but a lot of patients are getting the drug off-label or not the way it was studied on the trial. And it depends on what your insurance covers and if there's any issues from that perspective. So in general, it was studied on CIS patients. But in real world experience, we will probably soon see whether or not there's efficacy in patients with papillary disease as well.

Stanley Wenocur:

What is CIS? What does that stand for?

Dr Dickstein:

So yeah, so patients that don't know the lingo, when we talk about the architecture of tumors, papillary tumors are tumors that we can visibly see. They have that cauliflower like appearance, CIS is carcinoma in situ. It refers to the stage of disease. It means it's just within the lining of the cells, and so you can't necessarily see it. Sometimes it looks like a red patch or an angry looking area, but sometimes it doesn't look like anything. And so that's a more difficult thing to treat because it's not necessarily visible to the naked eye. And so sometimes patients can have one architecture or the other, or they can even have a combination of the two.

Stephanie Chisolm:

Great. Well, I think that's it for our questions. Dr. Dickstein and Stanley, thank you so much for your insight and your information. It's been wonderful. And I do want to, again, thank our sponsors. Hold on, let me just share my screen. The EMD Serono Pfizer partnership, Merck, UroGen, and Bristol Myers Squibb for making the Treatment Talks possible this year. I appreciate it. You will all be getting an evaluation to let us know how the program went and some suggestions for future programs. And I thank you all for joining us. Thanks so much. I really appreciate it, Stanley and Dr. Dickstein,

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