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## The Future of High-Risk Localized Prostate Cancer Treatment

### Announcer:

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### Dr. McKay:

Hello everyone. Welcome. My name is Rana McKay. I'm a GU medical oncologist at UC San Diego. And I have the lovely pleasure of being here with Dr. Fred Saad today, discussing highlights from ASCO, and really what this session is going to focus on is the future of high-risk localized prostate cancer treatment.

So just to kind of give a little bit of backdrop, patients with high-risk localized disease really represent an unmet need. You know, these patients have an increased risk of developing metastases related to prostate cancer, and even mortality related to prostate cancer. And really we need to identify interventions that are actually going to improve outcomes for these patients with therapy escalation of either systemic therapy or multimodal localized treatment. Fred, what is your experience with these high-risk localized patients, and sort of where the field is?

### Dr. Saad:

Yeah, clearly like you said this is an unmet need, and we're starting to get into the right direction, obviously ADT is the standard. And now more recently with STAMPEDE, that had an arm using ADT plus or minus abiraterone, that showed we were able to significantly improve progression-free survival, metastases free survival, and importantly, overall survival in the very high-risk group. So I'm looking forward to seeing what you thought were highlights at ASCO.

### Dr. McKay:

Yeah. You know, I completely agree with you that the STAMPEDE data had been practice-changing, where now we're integrating abiraterone use for patients with localized high-risk disease. And those patients were really high risk that were included on that trial. You know, worthwhile highlighting is several trials in progress from ASCO that are ongoing that will likely change the way we think about treatment for patients with localized high-risk disease. And one of the first trials that'll highlight is that ERADICATE trial led by Alicia Morgans. This is a phase three double-blinded study of adjuvant therapy following radical prostatectomy. And it's one of the only adjuvant, pure adjuvant studies that's currently ongoing, patients are randomized to receive darolutamide versus placebo. And what's unique here is that genomic stratification based on Decipher. So this trial is currently occurring through the cooperative groups. And one of the next studies to highlight is the DASL-HiCaP study. This trial is actually being run through the ANZUP cooperative group. This trial is basically a randomized phase three double-blind placebo control trial, where we're adding darolutamide, plus androgen deprivation therapy for patients receiving definitive or salvage radiation.

So it is a little bit more of a mixed population here, cause it's not just localized. It's not just people with initially diagnosed disease. Salvage radiation is allowed, and patients that recur post RP are allowed to be enrolled onto this study. But again, asking that same question of sort of intensification of hormonal therapy for patients with localized disease. And the last trial that I think is also worthwhile highlighting is the ATLAS study, which is looking basically at the addition of apalutamide to ADT for patients with high list localized or

locally advanced prostate cancer undergoing RT. And this is a phase three doubleblind placebo control trial that's also currently occurring. What are your thoughts Fred, about these three studies and how they're going to help shape the future of high-risk treatment?

**Dr. Saad:**

Yeah, so clearly these are all really important studies because what we need to do, and I try to simplify things when I talk to patients and other physicians is, patients that are actually destined to become metastatic, or especially destined to die of prostate cancer. I think we're realizing that we need to intensify as early as possible. So this is really an opportunity to take patients that are destined to die and are probably incurable with the standard of care we use today and have to intensify. And this is just pushing the field earlier, cause in low-risk metastatic disease, we do a really good job. And so this is just pushing it a little bit earlier because we would admit these very high risk patients are probably micrometastatic. So we really need to address how we identify those patients, is the next challenge. We clearly don't want to be over-treating but we definitely don't want to be under-treating patients who are destined to recur and die because you know, if we delay treatment we just don't do as well as hitting them hard up front. Like I've heard you say.

**Dr. McKay:**

Yeah, no, absolutely. I think that localized therapy intensification is key for cure. I think some of the challenges that many of the localized trials are going to face is with the advent of PSMA imaging and how that has the potential to you know, color the primary endpoints of particularly like metastasis free survival. You know, I think that's going to be kind of a challenge to these studies. So how is PSMA PET imaging that may be done post completion of therapy, or even at baseline when conventional imaging is negative? Like, how are we going to account for what somebody may do based on the results of that scan?

**Dr. Saad:**

Yeah. So like you say it might end up being a challenge because we might consider them metastatic when they're not really metastatic, but it might actually help us for those gray areas, where they look like they're non-metastatic, but on PSMA they have micrometastatic disease. And these patients really probably are the ones that are in the most need of intensification, and maybe the ones that have PSMA completely negative, we might not. So, I'd really like to see the field moving forward where we integrate biomarkers that include imaging, in terms of deciding. And like you said, what's interesting, with the ERADICATE studies, they're actually trying to integrate biomarkers like Decipher to help decide who might need intensification, and on the flip side, we have to figure out who doesn't need severe intensification because obviously there's cost and morbidity in everything we do.

**Dr. McKay**

Yeah. So thank you so much, Fred, for those insightful comments and thank you everybody for listening us today. Highlights from GU ASCO focused on the future of high-risk localized prostate cancer and where the field is going with currently ongoing trials for this disease space.

**Announcer:**

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