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Recent Progress in the Treatment of Metastatic Hormone Sensitive Prostate Cancer (mHSPC)

Announcer:
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Dr. George:
Hi, folks. This is Dr. Dan George, Professor of Medicine and Surgery and Director of GU Oncology at the Duke Cancer Institute. And it's my pleasure to introduce my friend and colleague, Dr. Fred Saad. Fred, you want to introduce yourself?

Dr. Saad:
Yeah. Thanks, Dan. So Fred Saad, Head of Urology, and Director of GU Oncology at the University of Montreal Hospital Center. So happy to be here with you.

Dr. George:
Thanks, Fred. Happy to have you too. And we're here with MedEd On the Go to talk about what was maybe seen and unseen at ASCO 2023, this year, really a full meeting back and full force, 42,000 people present for the meeting and a lot of really interesting posters and discussions. Fred, there's some updates on darolutamide, particularly as changed to ARASENS and in some of the ongoing trials. Do you want to update us on what you saw?

Dr. Saad:
Sure, well, ARASENS, as everybody knows, is a randomized trial looking at whether the doublet at the time the optimal was docetaxel plus ADT. And in ARASENS, wanted to test whether docetaxel, ADT plus a novel hormonal therapy, and in this case was darolutamide, that was tested. And that triplet therapy actually led to much longer time to castration-resistant disease, and much better overall survival than what was considered optimal care at the time we started the study of docetaxel and ADT.

And since then, we've been looking at many other subsequent evaluations such as whether or not low volume and high volume, low-risk and high-risk benefit from this triplet over the doublet of ADT and docetaxel. And every time we do a subanalysis, we're finding really always a benefit to being more aggressive, meaning a triplet therapy. And I think most of us would consider ADT and a novel hormonal to be standard of care today. But what's the added value of the docetaxel? And we're seeing consistently that that triplet approach is coming out beneficial in pretty much across the board. And in this analysis, that's looking at, you know, time to pain progression and symptomatic progression, seems to benefit across the board, and is not limited to only a single group of patients, like we might have thought. And so, the idea of excluding docetaxel in all patients, except the very worst, is probably not the best approach.

Dr. George:
Interesting. You know, it is an interesting endpoint, time to pain progression. Because, one, not every patient develops pain, right? But those that do have a much worse prognosis. So it's really looking at the subset of aggressive disease, defining it by their future outcomes, rather than their past baseline characteristics. And in this group of patients, you know, destined to develop, you know, pain, it's, much longer in those that are getting this upfront chemotherapy, and an AR inhibitor, particularly darolutamide. So, and you said

that was true across the subgroups?

Dr. Saad:
Yeah, absolutely. You know, and sometimes we get mistaken, we can underestimate the aggressivity of the disease by PSA, or even by volume of disease. And that's where we get, you know, we both probably got burned by patients with low PSA and we're being reassured, but actually a disease is progressing by non-PSA producing more aggressive clones, that might actually be helped by the addition of another therapeutic approach or another mechanism of action like chemotherapy.

So I think, in doubt, at least patients have to be part of that decision-making of whether or not that 6 extra cycles of docetaxel shouldn't be taken up front.

Dr. George:
Fantastic, fantastic. And then there was a trial and progress, the ARASEC study, that was really looking at, you know, at - really a single-arm study, looking at ADT and darolutamide in this metastatic hormone sensitive disease. Tell us about that study and some of the other treatment studies that are going on in this space internationally.

Dr. Saad:
Yeah, and that train has basically left, right? You know, I think ADT plus some form of novel hormonal therapy is here to stay. And I think that's what's most appreciated, both by us that we treat the patients and by the patients themselves. Now the question that keeps coming up is darolutamide right now is approved in combination with docetaxel, but it's very attractive to think of darolutamide as an option in combination with ADT. So we need to do those trials. They're hard trials to do, and in the States, it's almost impossible to do because you have access to all of these novel hormonals, and who wants to be randomized against a placebo today in the States where you have access. And so ARASEC is a single-arm study, so all patients get it. And it's compared to a cohort that's very similar to see the outcome.

But we're actually doing the randomized trial. And that's already completed recruitment around the world where we don't have easy access. And so that's the ARANOTE study. So this is going to be a supportive study in the States to ARANOTE that's completed recruitment, randomized very much like TITAN or ARCHES, ADT plus darolutamide versus ADT plus placebo, with an RPFs endpoint. And hopefully, we'll be able to report those results pretty soon.

But I think ARASEC is very important for the American population where that randomization could not happen.

Dr. George:
Absolutely, absolutely. And it's a kind of a creative way to kind of backfill the data that we're missing, with this agent that we've seen with other agents in this class of AR inhibitors, and fully expect this to, you know, to be positive and to show that kind of treatment effect. But, you know, as you said, hard to do here in the States. So we'll, you know, excitedly await that result, and hopefully be able to fill out our NCCN guidelines and recommendations based on those two studies as well.

Well, great stuff at ASCO, as always. Thanks so much, Fred, for joining me on this one.

Dr. Saad:
Great, thanks.

Announcer:
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