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Emerging immunotherapy combination strategies in genitourinary malignancies

Announcer:
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Dr. Srinivas:
Hello. This is CME on ReachMD, and I'm Sandy Srinivas. In this brief lecture, I would like to take you through some evidence behind emerging immunotherapy strategies and combinations across all of the GU oncology trials.

So I'm going to divide this into talking about kidney cancer first. And what we do know is, from the adjuvant side, we have pembrolizumab that's FDA approved based on KEYNOTE-564. Building on that, we have two additional trials that we are looking forward to the results in the future. The first one is the RAMPART trial, which is going to be looking at durvalumab for 1 year post nephrectomy or an arm that includes two doses of tremelimumab along with durvalumab. Large trial looking at DFS and OS as an endpoint. And another trial that I'm excited about is LITESPARK-022, this builds upon pembrolizumab that we have approved today, and is going to be adding belzutifan, our new HIF-2 inhibitor, along with pembrolizumab. This is again a 1,600-patient trial looking at DFS as an endpoint post nephrectomy.

Moving on to first-line clear cell RCC we now have four different IO combinations for patients with metastatic RCC. What can we do better? I'm really looking forward to the PDIGREE trial which takes all our patients with metastatic disease, giving them ipi/nivo. And those patients who have a stable disease or no progression that gets randomized to either nivolumab maintenance or get nivolumab plus cabozantinib. Then the last study that I want to highlight in kidney is a LITESPARK-012 study, which is going to be looking at the triplet of lenvatinib, pembrolizumab, plus belzutifan. So a lot of good things in kidney cancer that's ahead.

Moving on to bladder cancer. In the adjuvant space for muscle invasive bladder cancer now we have both nivolumab, plus recently we saw pembrolizumab from the AMBASSADOR study. The trial that's been run through the Cooperative Group is a trial called MODERN which is really an interesting study which will be based on ctDNA. Those patients who are ctDNA positive get randomized to either nivolumab or nivolumab plus relatlimab. And those who are ctDNA negative will get either nivolumab or surveillance.

Moving on to the neoadjuvant space which has become really busy, we recently saw the NIAGARA study, which looked at immunotherapy with durvalumab plus chemotherapy preoperative and then followed by adjuvant durvalumab being a positive study. There are trials similar to NIAGARA looking at either pembrolizumab as well as nivolumab, but also a trial with KEYNOTE B15/EV-304 looking at the combination of enfortumab with pembrolizumab versus chemotherapy. So a lot of interesting studies in this perioperative space, both for patients who are cisplatin eligible. Plus the VOLGA trial which specifically focuses on patients who are cisplatin ineligible, using a combination of durvalumab, tremelimumab, and enfortumab vedotin. So really excited about some of the emerging immunotherapy combinations in bladder cancer.

Finally, I want to focus on the remaining time talking about prostate cancer. Here we have very limited phase 3 studies. As we are

aware, sipuleucel-T was the first approved vaccine in metastatic CRPC. We have had many single-agent checkpoint inhibitor trials that have been negative to date. I want to highlight a few phase 3 studies. The IMbassador-250 was a phase 3 trial combining immunotherapy with atezolizumab with enzalutamide versus enzalutamide in metastatic CRPC, which was negative. So the only positive trial that I have to report combining an IO with a VEGF TKI was the CONTACT-02 trial. This was a large trial with 500 patients, the trial met its endpoint of having improved metastatic progression-free survival. The overall survival trial data is still immature, and we await those results.

I have to share my excitement in many early phase 1 studies which are bringing immunotherapy into our prostate cancer patients, which include studies targeting either PSMA or STEAP, and CAR T studies as well targeting both PSMA as well as PSCA.

So I think the future is really bright for combining immunotherapy in our GU malignancies, and I hope you found this episode helpful.

Announcer:
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