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Insights From Global Key Opinion Leaders on Optimizing Patient Care in Gynecologic Malignances

Announcer:
Welcome to CME on ReachMD. This episode is part of our MinuteCE curriculum.

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Dr. Campos:
This is CME on ReachMD, and I'm Dr. Susana Campos.

Dr. Colombo:
And I'm Dr. Nicoletta Colombo.

Dr. Campos:
Management strategies for gynecological malignancies vary among different geographical regions due to guideline variances.

Dr. Colombo, what insights can you share from a European perspective? And namely, what are some of the regulatory and guideline nuances you use to optimize patient care?

Dr. Colombo:
Yeah, there are clear differences between US and Europe in terms of regulatory approval of drugs and particularly reimbursement, I think. In terms of regulatory approval, it is extremely rare, almost impossible, that EMA could grant accelerated approval based on a phase 2 study. EMA generally requires solid phase 3 data to grant an approval. So this, of course, may lead to some delay on the availability of some drugs in Europe, which instead may have received accelerated approval in the USA.

There are, however, also situations where the drug is approved in Europe and not in the USA. For example, niraparib is still available in Europe as maintenance in all patients with platinum-sensitive ovarian cancer, but it is not in the USA. Pembrolizumab/lenvatinib in Europe is approved for all patients with endometrial cancer, while in the USA it's only approved for the proficient mismatch repair population.

Reimbursement is another issue, and it is so much different from country to country.

And finally, I have to say that in the guidelines, we are not strictly adherent to the EMA approval if there are strong scientific evidences in favor of a specific treatment. However, even if one drug is in the guideline, this does not mean the patient can receive it if not EMA-approved and particularly nationally reimbursed.

So, Dr. Campos, what are your thoughts on the US regulatory and guidelines nuances you use to optimize patient care?

Dr. Campos:
I appreciate the differences that you've just kind of outlined between the European communities and the US. When there is a drug that is actually FDA-approved, it doesn't automatically make it into the NCCN Guidelines until there's a committee meeting reflecting the data

and the like. But oftentimes, what we do is we review the data. And we're cognizant of the data, we're cognizant of the FDA approval, we're cognizant of people's experiences with this particular agent, and we try to be mindful in terms of how we should apply this to patients with any gynecological malignancy.

And an example of this would be trastuzumab DXd. This is FDA-approved for HER2 3+. However, when the NCCN Guidelines committee met, we reviewed the data on the DESTINY-PanTumor02 trial. And when we reviewed that, it was clear that even the HER2/neu 2+ had activity. And given that this was a palliative setting, we wanted to make this available to patients based on the data that was published. So this is just an example how we potentially deviated from that of the FDA approval. Obviously, we included the FDA approval, but we deviated to some extent.

In terms of reimbursement, the NCCN Guidelines are very, very key for reimbursement in the United States. If there is a regimen that's listed on the NCCN Guidelines and it's either Category 1 or it's a Category 2A, this is reimbursed by the insurance company.

Dr. Colombo:
So to sum up, I think we can say that the European guidelines are generally based on level 1 evidences, which mainly come from large randomized trials and not necessarily reflect EMA approval. In fact, I think despite globalization and strong collaboration among clinicians across the ocean in conducting clinical trials, the outcome of the scientific evidences receive a different uptake by the local authorities.

Dr. Campos:
In the United States, I do think there's a good concordance between that of FDA approval and the NCCN Guidelines, but there continues to be some nuances, as we mentioned before, in terms of the data, the agreeability of a panel, and then the applicability to patients.

Well, that's all we have time for today. Thank you for a great discussion, Dr. Colombo, and thank you for our audience for listening.

Announcer:
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