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Are There Other Novel Approaches or Targeted Therapies for Early Relapse?

Announcer:
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Dr. Biran:
Hi there, this is Noa Biran. I am a Myeloma Physician in Hackensack, New Jersey. Today, I will be discussing the topic of Other Novel Approaches or Targeted Therapies for Early Relapse Myeloma.

So principles of therapy in relapsed refractory myeloma, as we have so many drugs and therapies to choose from, we need to consider four very important factors when choosing a therapy. What is the timing of the relapse? Sometimes we need to treat within days because we don't want to have end-organ damage. What is the response to prior therapy? Is the disease sensitive or refractory to IMiDs or proteasome inhibitors, for example? We also look at the biology of the relapse. It is important to re-evaluate bone marrows, because we want to look at high-risk status has that changed, has the disease acquired new mutations? And now we have the ability to look at next generation sequencing and evaluate for perhaps targetable mutations. And lastly, we want to look at the patient. What is the patient's performance status? What are the comorbidities? What side effects do we want to avoid in these patients? And how can the patient come to and from our treatment center for therapies? And if not, maybe we ought to choose oral therapies which might be easier.

One of the therapies we have to choose from in the relapsed refractory setting is the XP01 inhibitor, selinexor. The BOSTON trial evaluated the combination of selinexor, bortezomib, and dex in patients with early relapsed myeloma. You can see that in patients with high-risk disease, including deletion 17p, t(14;16), t(4;14), or amplification of chromosome-1, there were very similar number of patients in both the seli/bortezomib/dex arm and the bortezomib/dex arm. And you can see that most of these patients had prior proteasome inhibitor and IMiDs. So a very heavily pretreated and high-risk population.

Despite that, you see improvement in median progression-free survival with the triplet combination compared to the doublet. And you can see that the median PFS was 13.9 months, compared to 9.4 months with a hazard ratio of 0.7 in the entire patient cohort.

The TOURMALINE-MM1 study evaluated the oral proteasome inhibitor, ixazomib in combination with lenalidomide and dex, compared to len and dex alone. You can see that patients with relapsed refractory myeloma had 1 to 3 prior therapies and adequate organ function were randomized in a 1:1 fashion until progression of disease. And in this patient population, 21 and 17% had high-risk cytogenetics but almost all were previously exposed to bortezomib, and almost all had a prior transplant. There was a slightly lower amount of patients with prior lenalidomide in this patient population, 12% in both arms. The median PFS with the combination of ixazomib/len/dex was 20.6 months, compared to 14.7 months, with a hazard ratio of 0.742. So we can see that with an all-oral regimen, we still see a benefit compared to a doublet, and this is appropriate therapy for almost all types of patients.

You can see that addition of ixazomib to len and dex significantly prolonged PFS. The safety profile was relatively tolerable. In particular, we look at peripheral neuropathy because this is a toxicity that is seen very often and with higher grades with use of bortezomib-based therapy. So we see grade 3 and 4 peripheral neuropathy of about 2% in the patients who received ixazomib.

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To summarize, the combination of selinexor with bortezomib and dex in patients with multiple myeloma resulted in median PFS of 13.9, compared to 9.4 months. And we also saw benefit with the oral proteasome inhibitor, ixazomib, in combination with len/dex compared to the doublet. Both of these regimens are all-oral regimens with novel mechanism of action and may be appropriate in certain patients who are relapsing with multiple myeloma.

Thank you so much for joining me today.

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