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Clinical Evidence on Emerging Antigen-Directed Strategies in ES-SCLC

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Dr. Leal:
Hello, this is CE with GLC, and I'm Dr. Ticiana Leal. Today, I'll review clinical evidence on emerging antigen-directed strategies in the treatment of extensive-stage small cell lung cancer.

First, I'd like to highlight the phase 1/2 trial CA001-030, which is a trial of BMS-986012 plus nivolumab in relapsed/refractory small cell lung cancer.

Fucosyl-GM1 is a glycosphingolipid expressed predominantly on lung cancers and limited on normal tissue. BMS-986012 is a non-fucosylated human IgG1 antibody that binds selectively to Fuc-GM1.

What we saw is the combination had a promising efficacy with an overall response rate of 38%. We saw a median duration of response of 26.4 months, median PFS of 2.1 months, and importantly, promising median overall survival of 18.7 months.

Overall in this study, we saw that the combination had a manageable safety profile, with low-grade pruritus as the most common treatment-related adverse event. This supporting further evaluation of this combination in the frontline setting.

The next study I'd like to highlight is the randomized phase 2 trial of CA001-050, which was a trial of frontline nivolumab plus chemotherapy plus/minus BMS in extensive-stage small cell lung cancer.

This study included patients with treatment-naive extensive-stage small cell lung cancer, and they were randomized 1:1 to induction with BMS plus nivolumab plus chemotherapy, followed by maintenance of the combination of BMS plus nivolumab versus nivolumab plus chemotherapy, followed by nivolumab maintenance.

This study was reported out at ESMO 2024, demonstrating here similar PFS between the 2 arms, with a median PFS of 5.2 months with the combination of nivo plus chemo versus 5.8 months with the combination of BMS plus nivolumab.

With the overall survival endpoint, what we saw was a numerical improvement of the overall survival going from 11.4 months with nivo plus chemo versus 15.6 months with BMS plus nivolumab plus chemotherapy, showing a very promising median overall survival, including at the 12-month overall survival rate of 67% with the experimental combination versus 48% with nivolumab plus chemotherapy.

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And although this did not meet statistical significance, given the promising median overall survival in the frontline setting and overall the tolerability of BMS plus nivolumab plus chemotherapy, this is moving forward and is currently being investigated in a randomized phase 3 trial.

Next, I'd like to highlight other strategies that are moving to the frontline in the investigational space. This is the phase 1b DeLLphi-303 trial, which had several frontline cohorts. I'll highlight here the frontline cohort including patients with platinum etoposide plus an anti-PD-L1, and then combining this with tarlatamab.

Tarlatamab is a T-cell engager that targets DLL3 and is now being investigated in this study. And what we saw in the frontline cohort of first-line chemotherapy plus immunotherapy plus tarlatamab is that this combination showed a safety profile that was consistent with what you'd expect from tarlatamab plus the experience that we've had with chemoimmunotherapy.

With regards to the overall efficacy endpoints in this first-line cohort, what we saw was promising activity with regards of the combination of tarlatamab plus chemotherapy and immunotherapy, which included both atezolizumab and durvalumab, with a 12-month overall survival rate of 80.6%.

I'd also like to highlight the experience with I-DXd. I-DXd is a B7-H3 antibody-drug conjugate with a topo I inhibitor payload.

Here, what you're seeing is now the efficacy of IDeate-Lung01 with I-DXd in previously treated patients. As you can see here, overall very promising activity of I-DXd, with a confirmed overall response rate of 48%.

The most common treatment-related adverse events noted here were grade 1 and 2 in nature, as noted here in this slide, in 10% or greater of patients, was nausea and myelosuppression.

Thanks very much for listening. I hope this brief overview will be useful in your practice.

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