Making Education Easy June 4-8, 2021

In this review:

Abbreviations used in this review

AE = adverse event; **CR** = complete response; **DOR** = duration of response; **EFS** = event-free survival; **HDI** = high-dose interferon; **irAE** = immune-related adverse event; **LDH** = lactate dehydrogenase; **len** = lenvatinib; **mDOR** = median duration of response; **MPR** = major pathologic response; **ORR** = objective response rate; **OS** = overall survival; **pCR** = pathologic complete response; **PD** = progressive disease; **pembro** = pembrolizumab; **PFS** = progression-free survival; **pNR** = pathologic non-response; **pPR** = pathologic partial response; **PR** = partial response; **pt** = patient; **RFS** = relapse-free-survival; **TBP** = treatment beyond progression; **TIL** = tumour infiltrating lymphocyte.

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Welcome to this review of the 2021 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting with a focus on melanoma.

The meeting included a diverse program from a multidisciplinary perspective and showcased what is possible when the cancer care community comes together to advance cancer research, treatment and patient care.

Dr Rachel Roberts-Thomson has selected presentations from the ASCO meeting and reviewed the research independently. The presentations include melanoma research in the metastatic, neo-adjuvant and adjuvant setting. All abstracts from the virtual meeting are available on-line at: https://conferences.asco.org/am/abstracts-posters

We hope you enjoy this Conference Review, and we invite you to send any comments or feedback.

Kind Regards

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CheckMate 067: 6.5-year outcomes in patients (pts) with advanced melanoma

Authors: Wolchok JD, et al

Summary: This presentation reported 6.5-year efficacy and safety outcomes of the phase 3 CheckMate 067 trial. Patients with previously untreated unresectable stage III or IV melanoma were randomised to nivolumab + ipilimumab followed by nivolumab (n = 314), nivolumab + placebo (n = 316), or ipilimumab + placebo (n = 315) until progression or unacceptable toxicity. The median overall survival (OS) was 72.1 months with nivolumab + ipilimumab, 36.9 months with nivolumab, and 19.9 months with ipilimumab. Median time from randomisation to subsequent systemic therapy was not reached with nivolumab + ipilimumab, 25.2 months with nivolumab, and 8.0 months with ipilimumab; 36%, 49%, and 66% of patients, respectively, received any subsequent systemic therapy. Median treatment-free interval was 27.6 months, 2.3 months and 1.9 months with nivolumab + ipilimumab, nivolumab, and ipilimumab, respectively. Of the patients alive and in follow-up, 112/138 (81%; nivolumab + ipilimumab), 84/114 (74%; nivolumab), and 27/63 (43%; ipilimumab) were off treatment and never received subsequent systemic therapy; 7, 8, and 0 patients, respectively, were still on treatment. Grade 3/4 treatment-related adverse events (AEs) were reported in 59% of nivolumab + ipilimumab-treated patients, 24% of nivolumab-treated patients, and 28% of ipilimumab-treated patients.

Comment: It is impressive that it has taken this long for the combination arm of patients receiving ipilimumab and nivolumab to reach a median OS (median OS of 72 months). In particular, the melanoma specific survival curves for combination therapy were appearing "flat" with further follow up. Survival outcomes were improved if patients experienced a complete response (CR) or partial response (PR) so this response can help predict outcomes. BRAF mutation positive melanoma patients benefited from combination immunotherapy with more impressive separation of the curves compared with patients with BRAF wild type disease. Less requirement on subsequent therapy in the combination arm was the flow on effect of these good responses. It is important to note that median duration of treatment was only 3.6 months in the combination arm reflecting presumably patients stopping for toxicity in the main, but these patients still had superior outcomes despite this. Higher numbers of patients were alive and treatment free at 6.5 years in the combination arm and this really does tick the boxes in terms of goals for treating our patients. There were no new additional safety issues. The 6.5-year results of Checkmate 067 are the benchmark for future melanoma trials.

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9506)
Abstract

Relatlimab (RELA) plus nivolumab (NIVO) versus nivolumab in first-line advanced melanoma: Primary phase III results from RELATIVITY-047 (CA224-047)

Authors: EJ Lipson, et al

Summary: The study cohort, with previously untreated advanced melanoma, were randomised to receive relatlimab + nivolumab (n = 355) or nivolumab monotherapy (n = 359). Patients were stratified by LAG-3 expression, PDL-1 expression, BRAF mutation status and AJCC M stage. Median follow-up was 13.2 months. The investigators reported median progression-free survival (PFS) in the relatlimab + nivolumab group (10.1 months) was significantly longer than in the nivolumab group (4.6 months; HR, 0.75; P = 0.0055). In addition, PFS rates at 12 months were 47.7% and 36.0% for relatlimab + nivolumab and nivolumab, respectively. They noted the incidence of grade 3/4 treatment-related AEs was higher in the relatlimab + nivolumab group (18.9%) versus nivolumab (9.7%). There were 3 treatment-related deaths with relatlimab + nivolumab and 2 with nivolumab. Treatment-related AEs led to treatment discontinuation in 14.6% and 6.7% of patients in the relatlimab + nivolumab and nivolumab alone groups, respectively.

Comment: Discovering a combination of immunotherapy agents with minimal additional toxicity and higher efficacy than single agent PD-1 inhibitor therapy is very desirable. This study is a first line study of a fixed dose combination of a LAG3 inhibitor (relatlimab) with PD-1 inhibitor (nivolumab) compared with nivolumab alone. There was an impressive superior PFS seen by blinded independent central radiology review for the patients receiving the combination. Immune related adverse events (irAEs) were more frequent, but not exceptionally so. It will be important to await results of objective response rate (ORR), OS and duration of response of this study before it is adopted as a standard of care. It was promising to see presented results of this combination in the neoadjuvant and adjuvant setting (abstract 9502) and of another combination, fianlimab and cemiplamib, in the metastatic setting both first line and for patients with PD-1 inhibitor resistant disease (abstract 9515).

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9503)
Abstract

Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti-PD-1 therapy

Authors: Larkin J, et al

Summary: The C-144-01 trial was an open-label phase 2 study of lifileucel in patients with advanced melanoma who have progressed on anti-PD-1 therapy and BRAFi ± MEKi, if BRAF V600+. Professor Larkin presented the long-term follow results of this study in a cohort of 66 patients. The baseline characteristics of the study cohort were: 3.3 mean prior therapies, high baseline tumour burden, 42% liver/brain lesions, 40.9% lactate dehydrogenase (LDH) > ULN. ORR was 36.4% and median duration of response (mDOR) was not reached at median follow-up of 28 months. In responders, the median cumulative duration and median prior lines of anti-PD-1 therapy was 4.4 months and 1.5. Professor Larkin showed results demonstrating a meaningful increase in DOR to TIL with primary anti-PD-1 resistance and lower duration of time on prior anti-PD-1 therapy. It was noted there were no new safety risks identified for lifileucel.

Comment: An effective treatment for patients with CTLA-4 and PD-1 inhibitor resistant and BRAF and MEK inhibitor resistant (if BRAF mutation positive) melanoma is very much needed. Patients in this phase II study presented by Professor Larkin from the UK were heavily pre-treated with a large proportion having high LDH liver and/or brain metastases. The median follow up now is at 33.1 months and median duration of response is yet to be reached. In terms of a reduction in tumour burden this was an impressive 81%. The toxicities experienced and the need for management of these are not for the faint of heart but seem to be short lived occurring within the first two weeks in the main and being predominantly related to haematological toxicity. With the caveat of no personal experience with this treatment, I do believe the data shows valid efficacy even in patients with high LDH, liver and brain metastases. Having this treatment available in specialised centres in Australia for our patients would be an additional tool in the toolbox of available treatments. There is an ongoing trial of pembrolizumab with lifileucel in the first line setting to also note.

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9505)
Abstract

Two dosing regimens of nivolumab (NIVO) plus ipilimumab (IPI) for advanced (adv) melanoma: Three-year results of CheckMate 511

Authors: Lebbé C, et al

Summary: Professor Lebbé presented the 3-year safety/efficacy results of the CheckMate 511 trial. Patients with previously untreated unresectable stage III/IV melanoma were randomised to receive nivolumab 3 mg/kg plus ipilimumab 1 mg/kg (NIVO3 + IPI1) 3 weekly for 4 cycles (n = 180) or nivolumab 1 mg/kg plus ipilimumab 3 mg/kg (NIVO1 + IPI3) 3 weekly for 4 cycles (n = 178); both followed by nivolumab 480 mg 4 weekly until progression/unacceptable toxicity. At a median follow-up of 44.4 and 43.9 months in the NIVO3 + IPI1 and NIVO1 + IPI3 groups, respectively, treatment related AEs led to treatment discontinuation in 26% and 39% of patients; 57% and 42% of patients had received maintenance therapy. Grade 3–5 treatment related AEs incidence remained significantly lower with NIVO3 + IPI1 than NIVO1 + IPI3 (33.9% vs 48.3%; OR 0.55). The most frequent treatment related AEs (any grade) were diarrhoea (27%), fatigue (26%), and pruritus (26%) with NIVO3 + IPI1 and diarrhoea (31%), pruritus (29%), and rash (27%) with NIVO1 + IPI3. Professor Lebbé noted descriptive analyses found OS and treatment-free outcomes were similar in the two groups.

Comment: The 3-year results of Checkmate 511 were presented for which patients were randomised to different dosing regimens, either nivolumab 3 mg/kg with ipilimumab 1mg/kg three weekly for four cycles then nivolumab four weekly or to nivolumab 1 mg/kg with ipilimumab 3 mg/kg three weekly our standard protocol. Primary endpoint was to look at Grade 3-5 AEs and these were fewer with nivolumab 3 mg/kg arm, not unexpectedly (34% vs 48%). The study was not designed to evaluate for non-inferiority between the groups, unfortunately, as this may have provided practice changing information. However, descriptive review showed that ORR (47.2% vs 52.8%), PFS (38% vs 43%) and OS (59% vs 61%) was numerically similar between the two groups as were the patients who were able to be "treatment free". This provides useful information on the benefit to risk profile of these two dosing regimens. I believe this to be an important study for that reason.

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9516)
Abstract

Five-year overall survival (OS) in COLUMBUS: A randomized phase 3 trial of encorafenib plus binimetinib versus vemurafenib or encorafenib in patients (pts) with BRAF V600-mutant melanoma

Authors: Dummer R, et al

Summary: In the COLUMBUS trial patients (n = 577) with advanced/metastatic BRAF V600-mutant melanoma, untreated or progressed after first-line immunotherapy, were randomised 1:1:1 to encorafenib 450 mg QD + binimetinib 45 mg BID, encorafenib 300 mg QD alone, or vemurafenib 960 mg BID alone. The updated analysis was presented after minimum follow-up of 65.2 months. There were 131 (68%), 117 (60%), and 145 (76%) deaths in the encorafenib + binimetinib, encorafenib alone and vemurafenib alone treatment arms, respectively. The median OS and 5-year OS rate with encorafenib + binimetinib were 33.6 months and 34.7%, respectively (median follow-up: 70.4 months). It was noted the 5-year OS rate in encorafenib + binimetinib patients who had normal LDH levels at baseline was 45.1%. For encorafenib + binimetinib, encorafenib alone and vemurafenib alone, the 5-year PFS rate was 22.9%, 19.3%, and 10.2%; ORR was 64.1%, 51.5%, and 40.8%; and the mDOR was 18.6, 15.5, and 12.3 months, respectively. Safety results were consistent with the known tolerability profile of encorafenib + binimetinib.

Comment: The five year OS data of the COLUMBUS study was presented showing superior five year OS of 34.7 months for patients receiving encorafenib and binimetinib compared with 21.4 months for vemurafenib (and 34.9 months for encorafenib alone). Patients with normal LDH values and less tumour burden had better outcomes, which was not unexpected. There were no new toxicity signals to be reported. Further treatments received by patients were outlined. Numerically, the five year survival outcomes are similar to other BRAF and MEK inhibitor combinations with differences occurring with regards to types of toxicity experienced.

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9507)
Abstract

Lenvatinib (len) plus pembrolizumab (pembro) for patients (pts) with advanced melanoma and confirmed progression on a PD-1 or PD-L1 inhibitor: Updated findings of LEAP-004

Authors: Arance AM, et al

Summary: Dr Arance, of the Hospital Clínic de Barcelona, presented updated data from LEAP-004 study. The open-label, single-arm, phase 2 study included 103 patients with advanced melanoma with confirmed progressive disease (PD) within 12 weeks of the last dose of a PD-L1 inhibitor given alone or with anti–CTLA-4 or other therapies. Patients received lenvatinib 20 mg once daily plus ≤35 doses of pembrolizumab 200 mg 3-weekly until PD or unacceptable toxicity. Of the study cohort 68.0% of patients had stage M1c/M1d disease, 55.3% had LDH > ULN, 58.3% received ≥2 prior treatments, 94.2% received therapy for advanced disease, and 32.0% received BRAF ± MEK inhibition. The initial LEAP-004 study reported ORR was 21.4% with a 6.3-months median DOR; ORR was 31.0% in patients with PD on prior anti–PD-1 + anti–CTLA-4. With the updated analysis 17.5% of patients were still receiving study drug at median follow-up of 15.3 months. ORR remained 21.4%, however, CR increased from 2% to 3%. Median DOR increased to 8.2 months. It was also noted ORR was 33.3% in patients with PD on prior anti–PD-1 + anti–CTLA-4 (n = 30), 18.2% in patients whose only prior anti–PD-1/L1 was in the adjuvant setting (n = 11), 22.6% in patients with primary resistance (n = 62), and 22.7% in patients with secondary resistance (n = 22). Median PFS and OS in the total population were 4.2 months and 14.0 months. The safety profile was consistent with prior studies with the incidence of treatment-related AEs reported as: 96.1% any grade, 45.6% grade 3-4, 1.0% grade 5 (decreased platelet count).

Comment: The study design clearly defined PD-1 inhibitor refractory patients for this trial and over half of the patients had elevated LDH and a third had three or more lines of prior treatment. Objective response rates looked impressive for this group of patients (21.4%), however, median duration of response was a little underwhelming at 8.3 months, albeit higher than that seen when this study was previously reported. Nevertheless, approximately 15% of patients were still on treatment at the median study follow up of 15.3 months. A concern is the toxicity of this regimen with significant grade 3-5 toxicity with many dose interruptions and dose reductions being required. Determining patients who may be more likely to benefit from this combination will be important, but this is a toxic regimen and improving on these results desirable.

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9504)
Abstract

Overall survival benefit from tebentafusp in patients with best response of progressive disease

Authors: Joshua AM, et al

Summary: The investigators analysed OS in a cohort of patients (n = 378) with best overall response (BOR) of PD randomised in a 2:1 ratio to tebentafusp versus control arm of investigator's choice. Best overall response was assessed by investigators using RECIST v1.1. They found by Day 100, PD as BOR occurred in 52% of the tebentafusp group compared to 60% of the control group. More patients received treatment beyond first disease progression (TBP) among the tebentafusp group (53%) versus pembrolizumab (16%). Furthermore, median duration of TBP was longer for tebentafusp (7 weeks) versus pembrolizumab (3 weeks). The investigators also reported OS was superior for the tebentafusp treated group versus the pembrolizumab group; HR 0.41. OS analysis of these patients beginning on first day of subsequent therapy, prior tebentafusp was associated with better OS versus prior investigator's choice; HR 0.59. It was noted the safety profile of tebentafusp patients during TBP was similar to all tebentafusp-treated patients.

Comment: Tebentafusp, a T cell receptor agent which re-directs T cells to gp100 melanocytic cells, has been shown to improve OS in the refractory disease that is uveal melanoma. Unusually, this seems to be across all categories of RECIST response and it was described that even in patients with radiological progression, it can still result in improved outcomes compared with standard of care options. Many patients were able to be treated beyond progression and this seems to be an appropriate course of action with no additional significant toxicity experienced. A reduction in ctDNA was even seen in patients with radiological progression and may identify patients with better OS. This is contrary to usual practice and so more investigation into the reasons behind these findings may be useful and potentially alternate radiological assessment with PET imaging could be considered.

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9509)
Abstract

Independent commentary by Rachel Roberts-Thomson

Rachel is a Medical Oncologist at The Queen Elizabeth Hospital and with Adelaide Oncology and Haematology. She has a specific interest in treating patients with Melanoma and Thoracic malignancies and being an Investigator on trials to do with these malignancies. She has a particular interest in intralesional treatments and immunotherapeutics as well as issues around patient care and follow up in the adjuvant setting. She enjoys teaching and supervising trainees.

Final analysis of overall survival (OS) and relapse-free-survival (RFS) in the intergroup S1404 phase III randomized trial comparing either high-dose interferon (HDI) or ipilimumab to pembrolizumab in patients with high-risk resected melanoma

Authors: Grossmann KF, et al

Summary: The researchers investigated whether adjuvant pembrolizumab given over one year would improve OS and RFS in comparison to high dose ipilimumab or high-dose interferon. The study cohort included 1,345 patients with 11%, 49%, 34%, and 6% stage IIIA(N2), IIIB, IIIC and IV, respectively. Two treatment arms were assigned based on stratification by stage, PD-L1 status (positive vs negative vs unknown), and intended control arm (high dose ipilimumab or high-dose interferon). Patients were randomised to either the control arm [(1) interferon alfa-2b 20 MU/m^2 IV days 1-5, weeks 1-4, followed by 10 MU/m^2/d SC days 1, 3, and 5, weeks 5-52 (n=190), or (2) ipilimumab 10 mg/kg IV q3w for 4 doses, then q12w for up to 3 years (n=465)], or the experimental arm [pembrolizumab 200 mg IV q3w for 52 weeks (n=648)]. This final analysis was performed 3.5 years from the date the last patient was randomised, with 512 RFS and 199 OS events. The researchers concluded the pembrolizumab group had a statistically significant improvement in RFS compared to the control group (high dose ipilimumab or high-dose interferon) with HR 0.740. They found there was no statistically significant improvement in OS in the 1,303 eligible randomised overall patient population with HR 0.837, or among the 1,070 (82%) patients with PD-L1 positive baseline biopsies with HR 0.883. Grade 3/4/5 event rates were: high-dose interferon 69/9/0%, high dose ipilimumab 43/5/0.5% and pembrolizumab 17/2/0.3%, respectively.

Comment: SWOG S1404 study was an important study presented at ASCO 2021 with OS results presented with this being a primary endpoint of the study. To note, this trial included patients with resected Stage IIIA through IVC disease (AJCC 7th edition) and pembrolizumab was compared with known active treatments being high dose interferon or, in the majority of cases (71%), ipilimumab at 10mg/kg for three years. The study reinforced the improvement in RFS with a hazard ratio comparable to Checkmate 238 adjuvant study. There was less toxicity in the pembrolizumab arm. The study found that one year of pembrolizumab did not improve OS (HR 0.84, 0.62-1.13) compared to high dose interferon or ipilimumab likely due to effective post progression treatment with 52% of patients receiving immune checkpoint inhibitor therapy and an additional 30% of patients having no recording of post progression treatment. Potentially there was also the impact of patients having an active treatment comparator arm, albeit with more toxicity experienced. This data adds to the strength of the RFS benefit with my personal practice still being to make recommendations to pursue adjuvant systemic therapy in appropriately selected patients.

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9501)
Abstract

Crossover and rechallenge with pembrolizumab in recurrent patients from the EORTC 1325-MG/Keynote-054 phase 3 trial, pembrolizumab versus placebo after complete resection of high-risk stage III melanoma

Authors: Eggermont AM, et al

Summary: The phase 3 double-blind 1325/KEYNOTE-054 trial evaluated pembrolizumab (n = 514) versus placebo (n = 505) every 3 weeks for a total of 18 doses (~1 year) in stage III cutaneous melanoma patients with complete resection of lymph nodes. This presentation reviewed the outcomes of a subset of patients who had a recurrence and crossed over or were rechallenged with pembrolizumab (every 3 weeks for a maximum of 2 years). At the clinical cut-off 298 (59%) patients had a disease recurrence in the placebo group; 155 patients participated in the crossover. A total of 297 (58%) patients completed the 1-year pembrolizumab adjuvant treatment, of whom 47 had a recurrence ≥6 months from the stop of treatment and 20 entered in the rechallenge part of the trial. Pembrolizumab treatment after crossover yielded a 39% ORR in evaluable patients and an overall 3-yr PFS of 32%, but after rechallenge the efficacy was lower. Among 175 patients who started pembrolizumab in crossover/rechallenge substudy, 160 discontinued due to completion of therapy (n = 24), disease progression (n = 88), toxicity (n = 20), investigator's decision (n = 21), or other reason (n = 7); 15 patients were still on-treatment. Among the 175 patients, 51 (29%) had a grade 1-4 irAE and 11 (6%) a grade 3-4 irAE.

Comment: There was a further update of the KEYNOTE-054 study at ASCO 2021 of two groups being presented; the patients who progressed in the placebo receiving group (n=155) and then crossed over to receive pembrolizumab whether they had resectable disease or not (n=50 with resectable disease) and the group of patients (n=20) who had received pembrolizumab for 12 months and then progressed after 6 months with either resectable disease (n=7) or not. The two different groups responded very differently to pembrolizumab, not unsurprisingly, with the treatment naïve group experiencing predicable responses and outcomes compared to other first line single agent PD-1 inhibitor studies. The group of patients, although small, who had previously received adjuvant pembrolizumab but who relapsed after a minimum of 6 months had quite inferior PFS or responses (1 patient had a CR) demonstrating the need for a different approach to treatment and supporting the need for combination therapy in this patient group.

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9500)
Abstract

Neoadjuvant and adjuvant nivolumab (nivo) with anti-LAG3 antibody relatlimab (rela) for patients (pts) with resectable clinical stage III melanoma

Authors: Amaria RN, et al

Summary: In this investigator-initiated single arm study patients with clinical stage III or oligometastatic stage IV melanoma surgically-resectable disease received nivolumab 480 mg IV with relatlimab 160 mg IV on weeks 1 and 5. Radiographic response was assessed after completion of neoadjuvant therapy and surgery was conducted at week 9 with specimens assessed for pathologic response. Patients received up to 10 additional doses of nivolumab and relatlimab after surgery, with scans every 3 months to assess for recurrence. The study cohort included 30 patients with clinical stage IIIB/IIIC/IIID/IV (M1a) in 18/8/2/2 patients, respectively. 29 patients underwent surgery; 1 patient developed distant metastatic disease while on neoadjuvant therapy. Pathologic complete response (pCR) rate was 59% and near pCR (< 10% viable tumour) was 7% for a major pathologic response (MPR, pCR + near pCR) of 66%. 7% of patients achieved a pathologic partial response (pPR, 10-50% viable tumour) and 27% a pathologic non-response (pNR, ≥50% viable tumour). The investigators reported ORR was 57%. With a median follow up of 16.2 months, the 1 -year event-free survival (EFS), was 90%, RFS was 93%, and OS was 95%. 1-year RFS for MPR was 100% compared to 80% for non-MPR patients (p = 0.016). It was noted there were no treatment related grade 3/4 AEs that arose during neoadjuvant therapy; 26% of patients had a grade 3/4 AE during adjuvant treatment.

Comment: This small but important study had patients (n = 30) with resectable stage III or IV melanoma receiving two cycles of four weekly nivolumab and relatlimab followed by surgery and then up to 10 cycles of adjuvant therapy. One patient was not able to proceed to surgery due to the development of new metastatic disease. The radiological ORR was positive at 57% and pCR and near pCR findings (66%) were impressive in this small patient group. Safety signals were not alarming with no treatment related grade III or above AEs during the neo-adjuvant phase and this does add to the potential future benefit of this approach over other combinations. Overall, this study adds to the body of data being accumulated in the neoadjuvant space which may suggest that there is an improved immune response due to an intact tumour microenvironment and that pathological response predicts for improved outcomes (16 month follow up only for this study). This study also adds to the evidence of the effectiveness of this combination of immunotherapy agents i.e. PD-1 inhibitor with anti-LAG inhibitor for patients with melanoma.

Reference: J Clin Oncol 39, 2021 (suppl 15; abstr 9502)
Abstract

