EPICS

EPICS 2022 – Global Perspectives on Melanoma, Squamous Cell Carcinoma (SCC), and Basal Cell Carcinoma (BCC)

Saturday, November 19, 2022: 08.00am – 12.00pm EDT / 14.00 – 18.00 CET (4 hrs)

Chair: Jeffrey S. Weber, MD, PhD (US)

Proposed faculty:

- Jason Luke (US)
- Alexander Eggermont, (The Netherlands)
- Axel Hauschild (Germany)
- Omid Hamid (US)
- Reinhard Dummer (Switzerland)
- Caroline Robert (France)
- Hussein A. Tawbi TBC

AGENDA

Time EDT	Topic	Speaker/Moderator
8.00 – 8.05 am	**Introduction to the Meeting**	Jeffrey S. Weber
8.05 – 8.15 am	**Session 1. Prognostic and predictive markers in melanoma** ESMO abstracts to consider: • 871P - Predictive role of neutrophil-lymphocyte ratio (NLR) in patients (pts) with metastatic melanoma: A post hoc exploratory analysis from phase 3 COMBI-i trial D. Schadendorf et al. • 788O - Association of Pre-Treatment ctDNA with Disease Recurrence and Clinical and Translational Factors in Patients with Stage IIIB-D/IV Melanoma Treated with Adjuvant Immunotherapy (CheckMate 915) G. Long et al.	Jason Luke
8.15 – 8.30 am	**Key Questions and Topics for Discussion** • What are the most useful prognostic and predictive markers and what is new on the	All

	horizon? Do we have any new biomarkers for toxicity? • What is the prognostic value of biomarkers (eg, exosomal MIA (ie, melanoma inhibitory activity), serum S100B, AMLo signatures, TMB, neutrophil/lymphocyte ratio, IL8/IL6, and mRNA signatures); what is their reliability and practical usefulness? • What prognostic and predictive biomarkers are you consider as *a must be used vs the ones that can be useful in certain circumstances*?	
8.30 – 8.35 am	Summary of Key Takeaways	
8.35 – 8.45 am	**Session 2. Adjuvant and Neoadjuvant Therapies in Melanoma: what is new there?** ESMO abstracts to consider: • 793P - NeoPeLe: A Phase 2 Trial of Neoadjuvant (NAT) Pembrolizumab (Pembro) Combined with Lenvatinib (Lenva) In Resectable Stage III Melanoma G. Long et al. • 798P - NeoTrio - Optimal neoadjuvant (NAT) sequencing of Anti-PD-1 and BRAF targeted therapy (TT) in BRAF mutant stage III melanoma: Results of histopathological analysis. J. Bradenet al • 803P - Patient-reported outcomes in patients with resected, stage III BRAF V600+ melanoma treated with adjuvant dabrafenib + trametinib: COMBI-Aplus study. J.J. Grob et al • LBA6 - Neoadjvuant versus adjuvant pembrolizumab for resected stage III-IV melanoma (SWOG S1801). S. Patel et al.	Alexander Eggermont
8.45 – 9.05 am	***Key Questions and Topics for Discussion*** • What are the most impactful data recently presented ((EADO, ASCO, ESMO) for high-risk resected and early-stage melanoma, and are any of these data considered practice-changing? • What is your current treatment strategy for high-risk resected and early-stage melanoma? • Do all patients that are eligible receive adjuvant therapy? How do you decide? What is your preferred adjuvant option and why? • What are the unmet needs in this population? What are the current and emerging roles of	All

	immunotherapy and targeted therapy in the adjuvant setting?
	• How are neoadjuvant combination strategies evolving in melanoma?
	  ○ Checkpoint inhibitor combinations
	  ○ Targeted therapy combinations
	  ○ Role of chemotherapy if any
	• Is there a need for adjuvant therapy when neoadjuvant treatments induce a MPR?
	• Should one switch treatment sif there is less than a MPR	

9.05 – 9.10 am	Summary of Key Takeaways	
9.10 – 9.20 am	**Session 3. Evolution of Immunotherapy for 1L Metastatic Melanoma** ESMO abstracts to consider: • 817P - Nivolumab (NIVO) + relatlimab (RELA) vs NIVO in previously untreated metastatic or unresectable melanoma: additional response outcomes from RELATIVITY-047. F.S. Hodi et al. • 822P - Phase II Clinical trial: Safety and efficacy study of tocilizumab (Toci) in combination with ipilimumab (Ipi) 3mg/kg plus nivolumab (Nivo) 1mg/kg in patients (pts) with metastatic melanoma (MM) N. Abdel-Wahab et al. • LBA3 - Treatment with tumor-infiltrating lymphocytes (TIL) versus ipilimumab for advanced melanoma: Results from a multicenter, randomized phase III trial. J. Haanen et al.	Michael Atkins
9.20 – 9.40 am	***Key Questions and Topics for Discussion*** • What are the most impactful data recently presented (EADO, ASCO, ESMO) for 1st-line melanoma, and are any of these data considered practice-changing? • Is there evidence for predictors of response and resistance to checkpoint inhibitors? Are any of them clinically relevant? • What is your current treatment strategy for 1st line metastatic melanoma? Is there still a place for single agent checkpoint inhibition? • How do you treat a first line patient with a allograft transplant or history of autoimmune disease if BRSAF WT? • How are combination strategies evolving in	All

	melanoma? ○ Checkpoint inhibitor combinations ○ Targeted therapy combinations ○ Role of chemotherapy if any	
9.40 – 9.45 am	Summary of Key Takeaways	
9.45 – 9.55 am	**Session 4. Emerging Insights in Relapsed/Refractory Metastatic Melanoma** ESMO abstracts to consider: • 835P - Efficacy of checkpoint inhibitors and targeted therapy depending on the line of treatment in patients with advanced / metastatic melanoma. B. Cybulska-Stopa et al. • 845P - Vidutolimod + Pembrolizumab as 2L+ Treatment in Patients With Anti–PD-1–Refractory Melanoma and Adrenal Insufficiency: Subgroup Analyses of a Phase 1b Study. J. Kirkwood et al. • 790MO - Phase 1 study of fianlimab, a human lymphocyte activation gene-3 (LAG-3) monoclonal antibody, in combination with cemiplimab in advanced melanoma (mel) O. Hamid et al.	Omid Hamid
9.55 – 10.15 am	***Key Questions and Topics for Discussion*** • What are the most impactful data recently presented ((EADO, ASCO, ESMO) for RR melanoma, and are any of these data considered practice-changing? • Are there promising agents in the PD-1–refractory metastatic melanoma setting? Role of tumor infiltrating lymphocytes (TILs)? Others? • Are there promising immunotherapy agents beyond checkpoint inhibitors? • What have we learned from intralesional immunotherapy in metastatic melanoma? • What is your approach to the sequencing options in RR melanoma? How do you make a decision?	All
10.15 – 10.20 am	Summary of Key Takeaways	All
10.20 – 10.30 am	**BREAK**	
10.30 – 10.40 am	***Session 5. BRAF*-Mutated Melanoma – new developments or stagnation?** ESMO abstracts to consider:	Caroline Robert

	• 813P - Time to Development of Central Nervous System (CNS) Metastases (mets) With Atezolizumab (A) or Placebo (P) Combined With Vemurafenib (V) + Cobimetinib (C): Updated Results From the Phase 3 IMspire150 Study. K. Lewis et al. • 819P - Efficacy of dabrafenib (D) trametinib (T) plus spartalizumab (S) by baseline site of metastases in patients (pts) with previously untreated BRAF V600-mutant unresectable or metastatic melanoma: Post hoc analysis of Phase III COMBI-i trial. P. Nathan et al. • 829P - A proof of concept study of sequential treatment with the HDAC inhibitor vorinostat plus BRAF and MEK inhibitors in BRAFV600 mutated melanoma. A. Embaby et al.	
10.40 – 10.55 am	***Key Questions and Topics for Discussion*** • What are the most impactful data recently presented (EADO, ASCO, ESMO) for BRAF-Mutated melanoma, and are any of these data considered practice-changing? • Is there a role for triplet therapy in *BRAF*-mutated metastatic melanoma? • Can immunotherapy overcome resistance to *BRAF*-inhibition in *BRAF*-mutated metastatic melanoma? • What are the optimal sequencing strategies with immunotherapy and targeted therapies? • What is your strategy for third line treatment in IO and targeted resistant stage IV BRAF mutated melanoma	All
10.55 – 11.00 am	Summary of Key Takeaways	
11.00 – 11.10 am	**Session 6. New Perspectives in the Management of SCC** ESMO abstracts to consider: • 814P - Phase 2 study of cemiplimab in patients with advanced cutaneous squamous cell carcinoma (CSCC): Final analysis from EMPOWER-CSCC-1 Groups 1, 2 and 3. M. Migden et al. • 825P - CemiplimAb-rwlc Survivorship and Epidemiology (CASE): A prospective study of the safety and efficacy of cemiplimab in patients (pts) with advanced cutaneous	Axel Hauschild

	squamous cell carcinoma (CSCC) in a real-world setting. G. Rabinowits et al. • 885TiP - The I-PACE study: Imgatuzumab in PAtients with advanCEd cutaneous squamous cell carcinoma (aCSCC). C. Robert et al. • 789O - Neoadjuvant cemiplimab in patients (pts) with stage II–IV (M0) cutaneous squamous cell carcinoma (CSCC): Primary analysis of a Phase 2 study. N. Gross et al.	
11.10 – 11.25 am	**Key Questions and Topics for Discussion** • What are the most impactful data recently presented (EADO, ASCO, ESMO) for SCC, and are any of these data considered practice-changing? • What are your views on how the management of advanced SCC is evolving? • Has neoadjuvant immune therapy reached the mainstream? • Can we define the mechanisms of resistance to immunotherapy in advanced SSC, and how to overcome them? • What upcoming novel therapies are likely to be useful for treating high-risk SCC?	All
11.25 – 11.30 am	Summary of Key Takeaways	
11.30 – 11.40 am	**Emerging Advances in the Management of BCC** ESMO abstracts to consider: • 794P - Efficacy and tolerability of neoadjuvant treatment with T-VEC in difficult to resect primary basal cell carcinoma: a phase II clinical trial (NeoBCC). J. Ressler et al. • 820P - Nivolumab (NIVO) +/- relatlimab (RELA) or ipilimumab (IPI) for patients (pts) with advanced treatment-naïve or -refractory basal cell carcinoma (BCC). K. Schenk et al.	Reinhard Dummer
11.40 – 11.55 am	**Key Questions and Topics for Discussion** • What are the most impactful data recently presented (EADO, ASCO, ESMO) for BCC, and are any of these data considered practice-changing? • What are your views on how the management of advanced BCC is evolving? • What first-line treatment options are emerging for high-risk BCC patients? • What is the role for immunotherapy in the treatment of BCC? Neoadjuvant or adjuvant therapy?	All

11.55 – 12.00 pm	Summary of Key Takeaways	
12.00 pm	**Closing Remarks**	Jeffrey S. Weber, MD, PhD