

# EPICS

## Conference Coverage: ASCO GI 2023 Highlights

Wednesday, January 25, 2023, 10.00 AM – 1.00 PM EST/16.00 – 19.00 CET

Virtual

**Chair:** John Marshall, MD – Georgetown Lombardi Comprehensive Cancer Center, Washington, DC  
**Faculty**

- Tanios Bekaii-Saab, MD, FACP – Mayo Clinic, Phoenix, AZ
- David H. Ilson, MD, PhD – Memorial Sloan Kettering Cancer Center, New York, NY
- Reetu Mukherji, MD – Georgetown Lombardi Comprehensive Cancer Center
- Sunnie Kim, MD – University of Colorado Comprehensive Cancer Center, Aurora, CO
- Manish A. Shah, MD – Weill Cornell Medicine, New York, NY
- Michael A. Morse, MD, FACP – Duke Cancer Center, Durham, NC

### AGENDA

Time (EST)	Topic	Speaker/ Moderator
10.00 AM – 10.05 AM (5 minutes)	<b>Welcome and Introductions</b>	John Marshall, MD
10.05 AM – 10.10 AM (5 minutes)	<b>Metastatic Colorectal Cancer – Targeted Therapy and Immunotherapy</b> <ul style="list-style-type: none"> <li>• Abstract LBA8 – Results from a phase 1a/1b study of botensilimab (BOT), a novel innate/adaptive immune activator, plus balstilimab (BAL; anti-PD-1 antibody) in metastatic heavily pretreated microsatellite stable colorectal cancer (MSS CRC). El-Khoueiry, et al</li> <li>• Abstract 11 – Negative hyperselection of patients with RAS wild-type metastatic colorectal cancer for panitumumab: A biomarker study of the phase III PARADIGM trial. Shitara, et al</li> <li>• Abstract 4 – Trifluridine/tipiracil plus bevacizumab for third-line treatment of refractory metastatic colorectal cancer: The phase 3 randomized SUNLIGHT study. Tabernero, et al</li> </ul>	Sunnie Kim, MD
10.10 AM – 10.25 AM (15 minutes)	<b>Discussion: Metastatic Colorectal Cancer (CRC) – Targeted Therapy and Immunotherapy</b> <ul style="list-style-type: none"> <li>• Are any of the new data potentially practice changing in the near future?</li> <li>• Are there any immediate clinical implications of the biomarker data from PARADIGM? What can we learn from the trial data presented?</li> <li>• What are your thoughts on the botensilimab-balstilimab combination in MSS CRC? Does this combination have the potential to extend the utility of immunotherapy to MSS mCRC?</li> </ul>	Moderator: John Marshall, MD

	<ul style="list-style-type: none"> <li>Is the improvement in OS associated with the addition of bevacizumab to trifluridine-tipiracil clinically meaningful? Is this now a new standard?</li> </ul>	
10.25 AM – 10.30 AM (5 minutes)	<b>Key Takeaways: CRC – Targeted Therapy and Immunotherapy</b>	Sunnie Kim, MD
10.30 AM – 10.40 AM (10 minutes)	<b>Colorectal Cancer – Chemotherapy, Surgery, and Radiation</b> <ul style="list-style-type: none"> <li>Abstract 132 – Preoperative chemotherapy prior to primary tumor resection for asymptomatic synchronous unresectable colorectal liver-limited metastases: A multicenter randomized controlled trial. Lin, et al</li> <li>Abstract 5 – Kinetics of postoperative circulating cell-free DNA and impact on minimal residual disease detection rates in patients with resected stage I-III colorectal cancer. Cohen, et al</li> <li>Abstract 10 – Organ preservation and total neoadjuvant therapy for rectal cancer: Investigating long-course chemoradiation versus short-course radiation therapy. Romesser, et al</li> <li>Abstract 12 – A double-blind, randomized, placebo-controlled, parallel study to investigate the auxiliary effects of fucoidan in patients with locally advanced rectal cancer who receive neoadjuvant concurrent chemoradiotherapy before surgery. Wang, et al</li> <li>Abstract 6 – Do nonoperative modality (NOM) treatments of rectal cancer compromise the chance of cure? Final surgical salvage results from OPERA phase 3 randomised trial (NCT02505750). Myint, et al</li> <li>Abstract 7 – Long-term results from NRG-GI002: A phase II clinical trial platform using total neoadjuvant therapy (TNT) in locally advanced rectal cancer (LARC). George, et al</li> </ul>	Michael A. Morse, MD, FACP
10.40 AM – 10.55 AM (15 minutes)	<b>Discussion: CRC – Chemotherapy, Surgery, and Radiation</b> <ul style="list-style-type: none"> <li>Are any of the new data potentially practice changing in the near future?</li> <li>Does the use of preoperative chemotherapy and primary tumor resection make a meaningful impact on outcomes in patients with unresectable liver-limited metastases?</li> <li>What do the kinetics of cfDNA postoperatively tell us about MRD detection and monitoring? What are the implications for patient management?</li> <li>How does short-course radiation compare with long-course chemoradiation for the treatment of rectal cancer? Which option is preferred?</li> <li>Does fucoidan affect either the efficacy or tolerability of neoadjuvant chemoradiation for rectal cancer? How would you counsel a patient interested in taking this supplement?</li> <li>What impact do NOM treatments for rectal cancer have on outcomes and chances for cure? What can we learn from the OPERA and NRG-GI002 trials?</li> </ul>	Moderator: John Marshall, MD

10.55 AM – 11.00 AM (5 minutes)	<b>Key Takeaways: CRC – Chemotherapy, Surgery, and Radiation</b>	Michael A. Morse, MD, FACP
11.00 AM – 11.05 AM (5 minutes)	<b>Pancreatic Cancer and Biliary Tract Cancer</b> <ul style="list-style-type: none"> <li>• Abstract LBA661 – NAPOLI-3: A randomized, open-label phase 3 study of liposomal irinotecan + 5-fluorouracil/leucovorin + oxaliplatin (NALIRIFOX) versus nab-paclitaxel + gemcitabine in treatment-naïve patients with metastatic pancreatic ductal adenocarcinoma (mPDAC). Wainberg, et al</li> <li>• Abstract 494 – Nanvuranlat, an L-type amino acid transporter (LAT1) inhibitor for patients with pretreated advanced refractory biliary tract cancer (BTC): Primary endpoint results of a randomized, double-blind, placebo-controlled phase 2 study. Furuse, et al</li> <li>• Abstract LBA490 – SWOG 1815: A phase III randomized trial of gemcitabine, cisplatin, and nab-paclitaxel versus gemcitabine and cisplatin in newly diagnosed, advanced biliary tract cancers. Shroff, et al</li> <li>• Abstract 491 – IMbrave151: A phase 2, randomized, double-blind, placebo-controlled study of atezolizumab with or without bevacizumab in combination with cisplatin plus gemcitabine in patients with untreated, advanced biliary tract cancer. El-Khoueiry, et al</li> </ul>	Manish A. Shah, MD
11.05 AM – 11.25 AM (20 minutes)	<b>Discussion: Pancreatic Cancer and Biliary Tract Cancer</b> <ul style="list-style-type: none"> <li>• Are any of the new data potentially practice changing in the near future?</li> </ul> <p><i>Pancreatic</i></p> <ul style="list-style-type: none"> <li>• Is the OS benefit seen with NALIRIFOX clinically meaningful? Should this become the new standard? If so, is it appropriate for all patients?</li> </ul> <p><i>Biliary Tract</i></p> <ul style="list-style-type: none"> <li>• What is your impression of the efficacy and safety of nanvuranlat? Should this agent be developed further in biliary tract cancers?</li> <li>• On the basis of the results of SWOG 1815, does the addition of <i>nab</i>-paclitaxel to gem-cis confer a clinically meaningful effect on efficacy? What is the impact on toxicity?</li> <li>• What are your thoughts on the results of IMbrave151? Is there a meaningful benefit associated with the addition of atezolizumab, with or without bev, to gem-cis for untreated biliary tract cancers?</li> </ul>	Moderator: John Marshall, MD
11.25 AM – 11.30 AM (5 minutes)	<b>Key Takeaways: Pancreatic Cancer and Biliary Tract Cancer</b>	Manish A. Shah, MD

<p>11.30 AM – 11.35 AM (5 minutes)</p>	<p><b>Hepatocellular Carcinoma</b></p> <ul style="list-style-type: none"> <li>• Abstract LBA492 – Canadian Cancer Trials Group HE.1: A phase III study of palliative radiotherapy for symptomatic hepatocellular carcinoma and liver metastases. Dawson, et al</li> <li>• Abstract 493 – Adjuvant transarterial chemoembolization with sorafenib for patients with hepatocellular carcinoma with portal vein tumor thrombus after surgery: A phase III, multicenter, randomized, controlled trial. Kuang, et al</li> <li>• Abstract 495 – Tislelizumab versus sorafenib in first-line treatment of unresectable hepatocellular carcinoma: Impact on health-related quality of life in RATIONALE-301 population. Finn, et al</li> <li>• Abstract 489 – NRG/RTOG 1112: Randomized phase III study of sorafenib vs. stereotactic body radiation therapy (SBRT) followed by sorafenib in hepatocellular carcinoma (HCC). Dawson, et al</li> <li>• Phase III IMbrave050 study, "Roche press release, Jan 18, 2022".</li> </ul>	<p>Tanios Bekaii-Saab, MD, FACP</p>
<p>11.35 AM – 11.55 AM (20 minutes)</p>	<p><b>Discussion: Hepatocellular Carcinoma (HCC)</b></p> <ul style="list-style-type: none"> <li>• Are any of the new data potentially practice changing in the near future?</li> <li>• Is there a role for palliative radiotherapy for patients with symptomatic liver metastases with HCC? Do results show a meaningful benefit?</li> <li>• Is there a role for adjuvant TACE with sorafenib in patients with portal vein tumor thrombus?</li> <li>• How does QOL with tislelizumab compare with sorafenib? How do you perceive this ICI compared with other immunotherapies in use for unresectable HCC? Are there any perceived advantages or disadvantages?</li> <li>• Is there a role for SBRT in the management of HCC, based on NRG/RTOG 1112 results?</li> <li>• What are your initial thoughts on the IMbrave050 press release? What would be a clinically meaningful outcome?</li> </ul>	<p>Moderator: John Marshall, MD</p>
<p>11.55 AM – 12.00 PM (5 minutes)</p>	<p><b>Key Takeaways: HCC</b></p>	<p>Tanios Bekaii-Saab, MD, FACP</p>
<p>12.00 PM – 12.05 PM (5 minutes)</p>	<p><i>Break</i></p>	

<p>12.05 PM – 12.10 PM (5 minutes)</p>	<p><b>Gastric and Gastroesophageal Junction (GEJ) Cancers – Chemotherapy and Targeted Therapy</b></p> <ul style="list-style-type: none"> <li>• Abstract LBA294 – INTEGRATE IIa: A randomised, double-blind, phase III study of regorafenib versus placebo in refractory advanced gastro-oesophageal cancer (AGOC)—A study led by the Australasian Gastro-intestinal Trials Group (AGITG). Pavlakis, et al</li> <li>• Abstract 295 – Neo-AEGIS (Neoadjuvant Trial in Adenocarcinoma of the Esophagus and Esophago-Gastric Junction International Study): Final primary outcome analysis. Lowery, et al</li> <li>• Abstract 381 – Five-year follow-up results of a randomized phase III trial comparing 4 and 8 courses of S-1 adjuvant chemotherapy for pathological stage II gastric cancer: JCOG1104 (OPAS-1). Nunobe, et al</li> <li>• Abstract LBA292 – Zolbetuximab + mFOLFOX6 as first-line (1L) treatment for patients (pts) with claudin-18.2+ (CLDN18.2+) / HER2- locally advanced (LA) unresectable or metastatic gastric or gastroesophageal junction (mG/GEJ) adenocarcinoma: Primary results from phase 3 SPOTLIGHT study. Shitara, et al</li> </ul>	<p>Reetu Mukherji, MD</p>
<p>12.10 PM – 12.30 PM (20 minutes)</p>	<p><b>Discussion: Gastric and GEJ Cancers – Chemotherapy and Targeted Therapy</b></p> <ul style="list-style-type: none"> <li>• Are any of the new data potentially practice changing in the near future?</li> <li>• What are your thoughts on the INTEGRATE IIa results? Is there a role for regorafenib in the management of refractory GEJ cancers?</li> <li>• Are the updated results from Neo-AEGIS consistent with earlier results? For patients with potentially curative disease, do you prefer a multimodal approach or perioperative chemotherapy alone?</li> <li>• Is there a clinically meaningful difference in outcomes with 4 vs 8 cycles of adjuvant S-1 in stage II gastric cancer?</li> <li>• What is your impression of zolbetuximab based on the SPOTLIGHT results? If this agent becomes available, where would this combination fit into your treatment algorithm? Does Claudin18.2 represent a viable new target in gastric (G)/GEJ cancer?</li> </ul>	<p>Moderator: John Marshall, MD</p>
<p>12.30 PM – 12.35 PM (5 minutes)</p>	<p><b>Key Takeaways: Gastric and GEJ Cancers – Chemotherapy and Targeted Therapy</b></p>	<p>Reetu Mukherji, MD</p>
<p>12.35 PM – 12.40 PM (5 minutes)</p>	<p><b>Gastric and GEJ Cancers – Immunotherapy</b></p> <ul style="list-style-type: none"> <li>• Abstract 291 – Nivolumab (NIVO) plus chemotherapy (chemo) vs chemo as first-line (1L) treatment for advanced gastric cancer/gastroesophageal junction cancer/esophageal adenocarcinoma (GC/GEJC/EAC): 3-year follow-up from CheckMate 649. Janjigian, et al</li> <li>• Abstract 290 – Nivolumab (NIVO) plus chemotherapy (chemo) or ipilimumab (IPI) vs chemo as first-line (1L) treatment for advanced esophageal squamous</li> </ul>	<p>David H. Ilson, MD, PhD</p>

	<p>cell carcinoma (ESCC): 29-month (mo) follow-up from CheckMate 648. Kato, et al</p> <ul style="list-style-type: none"> <li>• Abstract 286 – Rationale 305: Phase 3 study of tislelizumab plus chemotherapy vs placebo plus chemotherapy as first-line treatment (1L) of advanced gastric or gastroesophageal junction adenocarcinoma (GC/GEJC). Moehler, et al</li> <li>• Abstract 289 – HERIZON: A phase 2 study of HER-Vaxx (IMU-131), a HER2-targeting peptide vaccine, plus standard of care chemotherapy in patients with HER2-overexpressing metastatic or advanced gastric/GEJ adenocarcinoma— Overall survival analysis. Maglakelidze, et al</li> <li>• Abstract 358. INFINITY: A multicentre, single-arm, multi-cohort, phase II trial of tremelimumab and durvalumab as neoadjuvant treatment of patients with microsatellite instability-high (MSI) resectable gastric or gastroesophageal junction adenocarcinoma (GAC/GEJAC). Pietrantonio, et al</li> </ul>	
12.40 PM – 12.55 PM (15 minutes)	<p><b>Discussion: Gastric and GEJ Cancers – Immunotherapy</b></p> <ul style="list-style-type: none"> <li>• Are any of the new data potentially practice changing in the near future?</li> <li>• Where do you see the role of ICIs in the treatment of metastatic GEJ cancer? <ul style="list-style-type: none"> <li>– Are there any surprises from the longer follow-up of CheckMate 649? Do you use this regimen in the clinic, and if so, in which patients?</li> <li>– Are there any surprises from the longer follow-up of CheckMate 648? What is your preferred 1L regimen for advanced ESCC?</li> <li>– What is your impression of tislelizumab in G/GEJ cancer, based on the RATIONALE 305 results? How does this ICI compare with other ICIs already in use? Do you envision a role for tislelizumab if it becomes available?</li> </ul> </li> <li>• Do you see a role for ICIs in neoadjuvant therapy for G/GEJ cancers? What is your impression of the IO-IO combination evaluated in the INFINITY trial in MSI-high G/GEJ cancers?</li> <li>• What is the current role of ICIs in HER2-negative gastric cancer, and do they have a future in HER2-positive disease?</li> </ul>	Moderator: John Marshall, MD
12.55 PM – 12.58 PM (3 minutes)	<b>Key Takeaways: Gastric and GEJ Cancers – Immunotherapy</b>	David H. Ilson, MD, PhD
12.58 PM – 1.00 PM (2 minutes)	<b>Summary and Closing Remarks</b>	John Marshall, MD

**Total time: 3 hours**