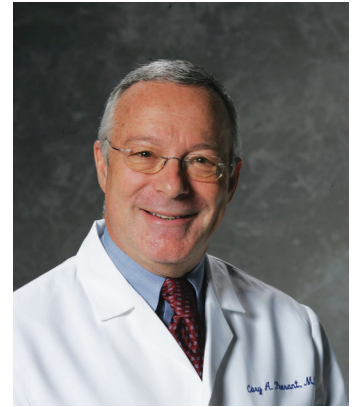


# Highlights from ASCO 2019



Oncology is a profession, a science, an art, and a healthcare subsystem—all of which are in stages of a revolutionary transformation. Accordingly, it was with great interest and excitement that I arrived in Chicago to attend the ASCO 2019 Annual Meeting and learn about the latest advances in oncology care. ASCO 2019 did not disappoint.

Presenters described momentous changes in hormonal therapy, immunotherapy, pathway-targeted therapy, companion diagnostic precision oncology, and supportive care. Skip an ASCO session, miss a seminal publication, or arrive late to a highlight presentation and you could wind up practicing out-of-date oncology. The treatment advances on display at ASCO 2019—along with the collegiality enjoyed at this annual meeting—are just the prescription for any physician’s potential burnout.

Monica Bertagnoli, MD, ASCO’s president, stressed the interconnectivity advances in oncology, emphasizing the importance of using electronic health records (EHRs) to allow CancerLinQ to produce real-world data to improve therapies. Indeed, we will all feel pressure in the coming months and years to use mCODE (minimal common oncology data elements) in our patient records to allow for the uploading of patient data and the use of AI to further generate understanding about what we are using and what is working. (I’m sure we all can’t wait for the additional training and changes that will require.)

ASCO’s keynote speaker was Atul Gawande, MD, MPH, who described oncologists as both technicians and counselors. By asking our patients about their values and goals, said Dr. Gawande, we can become better counselors for them. He added that AI will help us optimize our patients’ well-being (by improving their health), their treatment experience (by increasing satisfaction), and affordability (by making economically informed decisions).

The Karnofsky Award was given to breast cancer leader Gabriel Hortobagyi, MD. In recounting his long history of developing advancements in breast cancer care that have helped decrease the breast cancer death rate by 40 percent in the last 30 years, Dr. Hortobagyi emphasized that team science is the key to all of our successes. The best ASCO 2019 presentations demonstrated the value of this team approach. Indeed, all of our patient care, program administration, and clinical research activities require us to build the best teams possible to deliver the best care possible.

Below are the highlights I took away from ASCO 2019.

### Breast Cancer

- In **Abstract 520**, R. Chlebowski et al. presented the Women’s Health Initiative’s trial of low-fat diet vs. usual diet in 48,800 post-menopausal women. Although researchers aimed to reduce patients’ dietary fat from 32% of calories to 20%, they only achieved 25% to 28%. Grains, fruits, and vegetables were increased. Although there was a non-significant reduction in breast cancer development by 8%, there was a significant decrease in death from any cause after the development of a breast cancer, HR 0.85. After 19 years of follow-up, patient deaths from breast cancer were reduced, HR 0.79, and OS at 10 years was increased from 78% to 82%. Dietary adjustment may be as important as CT treatments, so oncologists should begin advocating low-fat diets.

### Localized disease

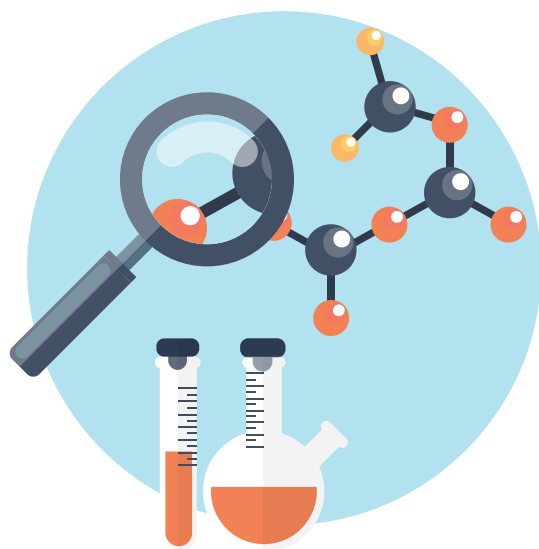
- In **Abstract 500**, S. Hurvitz et al. presented the results of the KRISTINE trial of neoadjuvant chemotherapy in patients with HER2-positive breast cancer. Therapy with TCHP (trastuzumab, CP, docetaxel, and pertuzumab) was superior

## ACRONYM LEGEND

<b>ACA:</b> Affordable Care Act	<b>ET:</b> Endocrine therapy	<b>OS:</b> Overall survival
<b>ADT:</b> Androgen deprivation therapy	<b>HER2:</b> Human epidermal growth factor receptor 2	<b>PBI:</b> Partial breast irradiation
<b>AI:</b> Artificial intelligence	<b>HR:</b> Hazard ratio	<b>pCR:</b> Pathological complete response
<b>ALL:</b> Acute lymphocytic leukemia	<b>IP:</b> Ifosfamide paclitaxel	<b>PD1:</b> Programmed death protein 1
<b>AML:</b> Acute myelocytic leukemia	<b>ipi:</b> Ipilimumab	<b>PD-L1:</b> Programmed death-ligand 1
<b>ASCO:</b> American Society of Clinical Oncology	<b>ISaPD:</b> Isatuximab plus dexamethasone	<b>pembro:</b> Pembrolizumab
<b>bev:</b> Bevacizumab	<b>IT:</b> Immunotherapy	<b>PFS:</b> Progression-free survival
<b>CBR:</b> Clinical benefit rate (CR+PR+stable disease)	<b>IV:</b> Intravenous	<b>PLd:</b> Dexamethasone
<b>CBT:</b> Cognitive behavioral therapy	<b>KRd:</b> Carfilzomib, lenalidomide, dexamethasone	<b>PR:</b> Partial response
<b>cet:</b> Cetuximab	<b>LDH:</b> Lactate dehydrogenase	<b>RR:</b> Response rate (CR+PR)
<b>CLL:</b> Chronic lymphocytic leukemia	<b>MMR:</b> Mismatch repair	<b>R/R:</b> Relapsed/refractory
<b>CP:</b> Carboplatin	<b>MPR:</b> Major pathological response	<b>RT:</b> Radiation therapy
<b>CR:</b> Complete response	<b>MRD:</b> Minimal residual disease	<b>RS:</b> Recurrence score
<b>CT:</b> Chemotherapy	<b>NCDB:</b> National Cancer Database	<b>SC:</b> Subcutaneous
<b>DCR:</b> Disease control rate	<b>NEJM:</b> New England Journal of Medicine	<b>SCLC:</b> Small cell lung cancer
<b>DFS:</b> Disease-free survival	<b>nivo:</b> Nivolumab	<b>TKI:</b> Tyrosine kinase inhibitor
<b>EGFR:</b> Epidermal growth factor receptor	<b>n.s.:</b> Not significant	<b>WBI:</b> Whole breast irradiation
<b>EHR:</b> Electronic health record	<b>NSCLC:</b> Non-small cell lung cancer	
<b>ER:</b> Estrogen receptor	<b>ONS:</b> Osteonecrosis of jaw	

to T-DM1 (trastuzumab emtansine) plus pertuzumab with less locoregional progression before surgery (0% vs. 6.7%) and better event-free survival at 3 years, 92% vs. 85%. This study was published in the *Journal of Clinical Oncology* the day of presentation.

- In **Abstract 503**, J. Sparano et al. presented an update of the TAILORx trial by integrating clinical risk with the genomic 21-gene RS. Using the division of these patients into low risk (tumor 3 cm or less and low grade, tumor less than 2 cm and intermediate grade, or tumor less than 1 cm and high grade) or high risk (all others), there was no benefit of CT adjuvant therapy in patients with RS 16-20 and at low risk. But there was a 6% to 8% CT benefit in patients (both low and high risk) with RS 21-25. This paper was published in *NEJM* the day of the presentation.
- In **Abstract 519**, A. Bui et al. used the NCDB to evaluate 76,400 patients who had stage I ER+ disease. In patients who received only adjuvant RT compared to those receiving only adjuvant endocrine therapy, OS was longer, HR 0.88,  $p = 0.0001$ . Researchers did not review combined therapy. RT prolongs OS in these patients.
- In **Abstract 504**, L. Del Mastro et al. described the GIM4 trial. Post-menopausal women who received 2 to 3 years of tamoxifen received either 2 to 3 additional years of letrozole or 5 additional years of letrozole. Eight-year DFS was better with 5 years of letrozole (77% vs. only 72%) than with 2 to 3 years of letrozole, HR 0.81,  $p = 0.05$ .
- In **Abstract 512**, A. Ferriera et al. described results of the CANTO trial, which studies long-term symptoms (physical, role, and sexual) in patients with stages I-III breast cancer. Overall, symptoms deteriorated at two years post-therapy. In pre-menopausal patients receiving CT or ET, CT was associated with worse symptoms than ET. In post-menopausal patients, ET (but not CT) was associated with deteriorated



symptoms and quality of life. At 2 years, overall ET adversely impacts more domains than CT. Physicians should advise patients of the longer-term trajectory of symptom worsening and encourage more accurate reporting of symptoms at each visit.

- In **Abstract 508**, P. Ganz et al. in trial NSABP B39 compared results of WBI vs. PBI. The in-breast tumor recurrence was less, WBI 3.9% vs. 4.6% with PBI. Patients with WBI had more fatigue and more pain, 40% vs. 25%. Worse cosmetic problems were observed with PBI.

#### Advanced disease

- In **Abstract LBA1008**, S. Hurvitz et al. reported on the MONALEESA-7 trial in pre-menopausal patients with advanced ER-positive breast cancer treated with goserelin and aromatase inhibitor or tamoxifen with or without ribociclib. OS was better with ribociclib (median not reached vs. 41 months, HR 0.71,  $p = 0.01$ ). At 42 months, OS was 70% vs. 46%. This will change standard therapy.

#### Multiple Myeloma

- In **Abstract 8001**, S. Lonial et al. reported on the E3AO6 trial in patients with smoldering multiple myeloma. Patients who received lenalidomide compared to patients on observation only had better PFS, HR 0.28,  $p = 0.0005$ . After 3 years, PFS was 91% with lenalidomide vs. 66% with observation, with no difference in quality of life. Lenalidomide seems a good option for these patients.
- In **Abstract 8002**, F. Gay et al. compared patients receiving KRd then autologous stem cell transplant, then KRd, with patients receiving KRd for 12 months alone. In good-risk patients, relapses and MRD negativity were equal. But in poor-risk patients, relapses were reduced by transplant, HR 3.6,  $p = 0.001$ .
- In **Abstract 8004**, P. Richardson et al. showed that in patients with R/R myeloma after two or more lines of therapy, ISaPD was better than PLd, with PFS 11.5 months on ISaPD vs. 6.5 months on PLd, HR 0.60,  $p = 0.001$ .
- In **Abstract 8005**, M. Mateos et al. demonstrated that SC daratumumab was equal to IV daratumumab, RR 41% vs. 37%. Infusion-related reactions were lower for SC than IV, 12.7% vs. 34.5%,  $p = 0.001$ . PFS was 5.6 months vs. 6.1 months. SC use may be preferable.
- In **Abstract LBA107**, K. Chamoun et al. used the NCDB to evaluate factors affecting OS of patients with myeloma. Multivariable analysis showed the significant factors were age (4% worse OS per additional year), 49% improved OS with treatment at an academic institution, 59% to 62% improved OS with private insurance vs. Medicaid or no insurance, and 16% who had higher OS resided in an area with a median income of more than \$46,000 per year.

#### Acute Myelocytic Leukemia

- In **Abstract 7000**, M. Levis et al. showed that in patients with AML with the FLT 3 mutation, gilteritnib was superior to



standard CT, OS 9.3 months vs. 5.6 months, HR 0.64,  $p = 0.0007$ . All patients with AML should have immediate molecular profiling to indicate best therapy (and eligibility for clinical trials). Because FLT 3 mutations change with time, re-evaluating the molecular profile at time of progression is important.

#### Acute Lymphocytic Leukemia

- In **Abstract 7006**, B. Shah et al. showed that 54 patients in the ZUMA3 trial with Philadelphia chromosome-negative precursor B cell ALL, CAR T-cell therapy produced 84% CR despite 67% with three or more prior CT regimens. All CRs were MRD negative. Twelve out of 16 remain in remission. Discussion focused on when to use CAR T vs. blinatumomab or inotuzumab.

#### Chronic Myeloid Leukemia

- In **Abstract 7005**, T. Hughes et al. updated the ENESTop trial results. After stopping TKI therapy in patients with a stable molecular remission, 50% stayed disease free. However, in relapsing patients, 93% to 95% respond again (but the remainder do not respond). It is important to note that abrupt TKI cessation is associated with musculoskeletal pain in 55%, so slow tapering of TKI is recommended.

#### Chronic Lymphocytic Leukemia/Small Cell Lymphocytic Lymphoma

- In **Abstract 7501**, T. Siddiqi et al. reported on the TRANSCEND CLL 004 trial, which treated relapsed/refractory CLL or small cell lymphocytic lymphoma with CAR T therapy using Liso-Cell JCAR017. There was only one cytokine release syndrome. Best RR was 87%, with 10 (67%) undetectable MRD by day 30.

## Colorectal Cancer

- In **Abstract 3500**, I. Sougklakos et al. showed results of the Greek subset of the IDEA trial. Adjuvant CT with CAPOX or FOLFOX for 3 vs. 6 months produced equal DFS. However, there was long-term residual neuropathy of only 1.5% in 3-month therapy, vs. 4.5% in 6-month therapy.
- Expanding on the above, T. Iveson et al. in **Abstract 3501** showed the results for the entire IDEA trial. Five-year DFS was equal in CAPOX 3 months vs. 6 months. But for FOLFOX 3-month treatment, 3-year DFS was only 79% vs. 86.5% for 6-month FOLFOX treatment, HR 1.4. Use CAPOX for 3 months but FOLFOX for 6 months, especially in stage III.
- In **Abstract 3504**, M. Seymour et al. presented the results of the FOXTROT trial. Stage T3-4 N0-2 M0 patients received either neoadjuvant FOLFOX or XELOX for 6 weeks, then surgery, then post-operative CT, vs. immediate surgery and then post-operative CT. Post-operative leak was present in 4.7% on neoadjuvant therapy vs. 7.4% with immediate surgery. R0 resection was 93% on neoadjuvant therapy but only 88% on immediate surgery. The 2-year recurrence rate was 13.6% on neoadjuvant therapy but 17.2% on immediate surgery, HR 0.78,  $p = 0.08$ . No pathological response was seen in only 27% of proficient MMR patients vs. 74% of deficient MMR patients. Five-year recurrence rates were 21% on neoadjuvant therapy vs. 27% on immediate surgery (n.s.). Neoadjuvant treatment is an option for patients.
- In **Abstract 3508**, C. Cremolini et al. showed the results of the TRIBE2 trial in previously untreated patients with potentially resectable liver metastatic colon cancer. Patients were randomized to FOLFOXIRI + bev and then hepatic resection with FOLFOXIRI + bev at recurrence vs. FOLFOX + bev then hepatic resection with FOLFIRI + bev at recurrence. R0 resections were achieved in 17% on FOLFOXIRI vs. 12% on FOLFOX. PFS after the hepatic resection was 12.0 months on FOLFOXIRI vs. 9.8 months on FOLFOX, HR 0.75,  $p = 0.001$ . PFS after the second therapy (from the time on trial) was 19.1 months on FOLFOXIRI vs. 17.5 months on FOLFOX-FOLFIRI, HR 0.74,  $p = 0.001$ . OS was 27.6 months on FOLFOXIRI vs. only 22.6 months on FOLFOX, HR 0.81,  $p = 0.03$ . FOLFOXIRI was preferred but only if patients had not received oxaliplatin adjuvant therapy previously and were younger than 75 and in good performance status. Other options can be considered after recurrence: FuLv plus bev or FOLFIRI plus bev plus cet.
- In **Abstract LBA3516**, A. Fretland et al. reported that PFS and OS were the same when patients had resection of colorectal cancer liver metastases by open technique vs. laparoscopic technique.

## Gastrointestinal Non-Colorectal and Pancreatic Cancer

- In **Abstract LBA4**, H. Kindler et al. reported on the POLO study in patients with metastatic pancreatic cancer and a germline mutation in BRCA 1 or 2. Patients without progression after first-line CT with platinum-containing CT received either



olaparib or placebo. PFS was longer after olaparib, 7.4 months vs. 3.8 months after placebo, HR 0.53,  $p = 0.004$ . Twenty-four-month PFS was 22% vs. 9.6%, and quality of life was maintained after olaparib. This study was published in *NEJM* the same day as the presentation.

- In **Abstract 4000**, the APACT trial, M. Tempero et al. studied 866 patients with an R0 or R1 resection of pancreatic cancer, CA19-9 under 100, who received either gemcitabine plus nab-paclitaxel for six cycles or gemcitabine for six cycles. DFS assessed by the principal investigator was longer with the combination, 16.6 months vs. 13.7 months, HR 0.82,  $p = 0.01$ , and OS was also longer, 40.5 months vs. 36.2 months, HR 0.82,  $p = 0.04$ . For patients who cannot tolerate FOLFIRINOX, nab-paclitaxel plus gemcitabine may be the most useful.
- In **Abstract 4002**, N. Izumi et al. in the SURF trial compared patients with hepatocellular cancer (under four nodules, 3 cm or less, Child Pugh score 7 or less) who received either surgical removal or radiofrequency ablation. PFS was equal.
- In **Abstract 4003**, A. Lamarca et al. reported on ABC-06, a trial of second-line therapy in patients with biliary tract cancers progressing after gemcitabine cisplatin. Compared to patients receiving symptom care alone, patients who received FOLFOX for 12 cycles had longer OS, 6.2 months vs. 5.3 months, HR 0.69,  $p = 0.03$ . Survival at 12 months was only 11% with symptom care vs. 26% with FOLFOX. FOLFOX should be the second-line treatment of choice.
- In **Abstract 4005**, E. Bergsland et al. presented findings from Alliance trial 021202. Patients with progressive carcinoid tumors received pazopanib vs. placebo. Patients on pazopanib had a PFS of 11.5 months vs. 8.5 months on placebo, HR 0.53,  $p = 0.005$ . This is an active regimen in second-line treatment. With crossover in the placebo arm to pazopanib, all patients were treated with pazopanib and OS was 42 months.
- In **Abstract LBA4007**, J. Tabernero et al. presented the KEYNOTE 062 trial. In patients with advanced gastric or gastro-esophageal cancer, the use of pembrolizumab plus CT (cisplatin

plus either 5FU or capecitabine) was no different than CT alone. In patients with a PD-L1 combined positive score of 10 or higher, pembrolizumab had longer OS, 17.4 months, compared to CT, 10.8 months, HR 0.69, and pembrolizumab had less toxicity.

### Genitourinary Cancer Prostate

- In **Abstract 5035**, A. Sartor et al. showed in the PROCEED trial that Sipuleucel-T resulted in an OS of 35.2 months for African American patients vs. only 29.9 months for Caucasian patients, HR 0.81,  $p = 0.03$ . There is no explanation for this observation as yet.
- In **Abstract 5006**, K. Chi et al. presented the TITAN study in patients with metastatic hormone-sensitive prostate cancer. Treatment with apalutamide plus ADT increased PFS compared to ADT alone, HR 0.48,  $p = 0.0001$ , and also improved OS, HR 0.67,  $p = 0.0053$ . There was no benefit of the combination in patients older than 65 or those with visceral metastases or prior docetaxel. This finding is important.
- In **Abstract LBA2**, C. Sweeney et al. described the ENZAMET trial (ANZUP 1304) in patients with metastatic hormone-sensitive prostate cancer. All patients received testosterone suppression plus bicalutamide (or nilutamide or flutamide) or plus enzalutamide. Patients could also receive docetaxel at the doctor's choice. Three-year OS was better with enzalutamide, 80% vs. 72%, HR 0.67,  $p = 0.002$ . Differences were not seen in patients who planned to use docetaxel early in care. This is a new option for the management of early metastatic prostate cancer, especially if ARV7 is negative. This study was published in *NEJM* on the day of the presentation.
- In **Abstract 5003**, K. Chi et al. studied patients with metastatic poor-risk prostate cancer. Patients randomized to cabazitaxel had higher DCR (88%) compared to patients receiving either abiraterone or enzalutamide (70%),  $p = 0.04$ . Patients on cabazitaxel had longer OS, 37 months, compared to patients receiving either abiraterone or enzalutamide (15.5 months), HR 0.57,  $p = 0.06$ . Patients crossed over to the alternative arm at progression.



### Genitourinary Cancer Non-Prostate

- In **Abstract 4515**, S. Pal et al. presented the patient-reported outcomes of the IMotion 150 trial of atezolizumab with or without bevacizumab vs. sunitinib in patients with renal cell cancer. Fatigue severity was less in patients receiving atezolizumab (HR 0.48) or atezolizumab with bevacizumab (HR 0.75) vs. sunitinib. All symptoms were less in atezolizumab or atezolizumab with bevacizumab compared to sunitinib. Atezolizumab with or without bevacizumab was better tolerated by patients.

### Gynecologic Cancer

- In **Abstract LBA5563**, A. Smith et al. reviewed 59,000 patients with ovarian cancer before the ACA vs. 73,000 patients after the ACA. After the ACA, there was a 1.7% increase in early diagnosis,  $p = 0.001$ , and a 1.6% increase in patients receiving therapy within 30 days of diagnosis,  $p = 0.001$ . It is possible that increased access to insurance resulted in these improvements.
- In **Abstract 5504**, J. Uppal et al. studied patients with cervical cancer who received either minimally invasive hysterectomy or abdominal hysterectomy. Relapses were more common with minimally invasive surgery, 9.3% vs. 6.9%, HR 2.24,  $p = 0.03$ . However, OS was equal.
- In **Abstract 5505**, M. Mirza et al. reported on the AVANOVA2 trial in patients with recurrent platinum-sensitive ovarian cancer receiving either niraparib or niraparib plus bevacizumab. The combination was superior with DFS 11.9 months vs. 5.5 months, HR 0.35,  $p = 0.0001$ .
- In **Abstract 5506**, R. Penson et al. presented the SOLOIII trial in patients with platinum-sensitive ovarian cancer with a germline BRCA mutation and two or more prior lines of CT. Patients who received olaparib had higher RR, 72% compared to patients receiving the physician choice of non-platinum chemotherapy, RR 51%,  $p = 0.002$ . DFS was 13.4 months vs. 9.2 months, HR 0.62,  $p = 0.013$ . Thirty-nine percent of all patients received platinum drugs in the next line of therapy.
- In **Abstract 5508**, C. Falandry et al. studied CT in ovarian cancer patients who were elderly (70 years or older) and had a high geriatric vulnerability score. Patients who received CP plus paclitaxel every 3 weeks had longer PFS, 12.5 months, vs. CP single agent, 4.8 months, or weekly CP plus paclitaxel, 8.3 months,  $p = 0.001$ . Combination therapy is still preferred in the vulnerable elderly.
- In **Abstract 5500**, M. Powell et al. evaluated patients with carcinosarcoma of the uterus or ovary treated with CP plus paclitaxel vs. IP. PFS of CP was longer than IP, 16 months vs. 12 months, HR 0.73,  $p = 0.01$ , and OS was non-inferior but slightly longer on CP, 37 months vs. 29 months. CP is preferred.
- In **Abstract 5501**, Y. Antill et al. presented the PHAEDRA trial of durvalumab in patients with advanced endometrial cancer. In patients with MMR deficiency, RR was 43% vs. only 3% in patients with MMR proficiency. One should always measure MMR in these patients to help select durvalumab therapy.

## Head/Neck Cancer

- In **Abstract 6000**, D. Rischin et al. reported on KEYNOTE 048, which compared pembro vs. pembro plus CT (cisplatin or CP plus 5FU) vs. the EXTREME regimen of CP 5FU cet followed by cet in first-line therapy. In all patients there were no differences between pembro and EXTREME. Pembrolizumab plus CT was superior to EXTREME in OS, HR 0.68,  $p = 0.0013$ . This may be practice changing.
- In **Abstract 6003**, J. Ma et al. evaluated patients with nasopharyngeal cancer with neoadjuvant gemcitabine cisplatin followed by cisplatin-RT vs. cisplatin-RT without neoadjuvant CT. Three-year PFS favored neoadjuvant CT, 85% vs. 76%,  $p = 0.003$ .
- In **Abstract 6001**, B. Li et al. reported on a very small study (10 patients) with HER2-amplified salivary gland cancer. Treatment with ado-trastuzumab produced six CRs (60%) and an RR of 90%. At a median follow-up of 12 months, median duration of response and survival had not been reached. For a very small group of rare tumors, this treatment appears very effective.

## Lung Cancer

- In **Abstract 8500**, Y. Tsutani et al. tested adjuvant therapy in 1,278 high-risk stage I patients (stage IA 76%). Five-year, cancer-specific OS favored chemotherapy over observation, 95% vs. 89%, HR 0.34,  $P = 0.01$ . Doublet therapy was better than monotherapy,  $p = 0.01$ .
- In **Abstract 8503**, D. Kwiatkowski et al. presented trial LCMC3. Neoadjuvant atezolizumab two cycles produced a major pathological response (MPR shown at definitive surgery) of 19% in stage II and III patients, which was irrespective of PDL1 staining.
- Usefulness of neoadjuvant immunotherapy was also demonstrated by T. Cascone et al. in **Abstract 8504** in the NEOSTAR trial. Neoadjuvant nivo or nivo + ipi produced an MPR of

19% and 33%, respectively. Neoadjuvant IT is now being tested in combination with CT.

- In **Abstract 8505**, L. Hart et al. showed that using trilaciclib, a CD 4/6 inhibitor that protects marrow stem cells, together with topotecan resulted in less neutropenia (40.6% compared to 75.6%) in patients receiving placebo plus topotecan,  $p = 0.016$ . Red cell transfusions were also reduced, but PFS was equal in both arms. This is an exciting potential adjuvant for chemotherapy.
- In **Abstract LBA108**, R. Harvey et al. used real-world data from ASCO CancerLinQ to show that among 10,500 patients with NSCLC, whereas 5,005 patients were excluded from participation in clinical trials by traditional exclusion criteria, only 154 patients would be excluded if the ASCO-Friends of Cancer Research expanded criteria were used. This is an interesting use of real-world data.

## Squamous Non-Small Cell

- In **Abstract LBA 9000**, R. Jotte et al. treated stage IV patients with CT alone (CP plus either paclitaxel or nab-paclitaxel) vs. atezolizumab plus the CT. PFS was 5.6 months with CT vs. 6.3 months with IT+CT, HR 0.72. Twelve-month PFS was 12% with CT but 24.7% with IT+CT.
- In **Abstract 105**, L. Paz-Ares et al. described KEYNOTE 407, in which patients with PD-L1 <50% received pembro plus CT (CP plus either paclitaxel or nab-paclitaxel) or CT alone. OS for IT CT was superior, 16 months vs. 11 months for CT, HR 0.64,  $p = 0.0001$ .

## Non-squamous Non-Small Cell

- In **Abstract 9003**, T. Seto showed that in patients who were the least stable after induction with CP, pembro, and bev, maintenance therapy with pemetrexed plus bev showed longer OS compared to bev alone, HR 0.65  $p = 0.001$ .
- In **Abstract 9002**, however, S. Ramalingam presented ECOG-ACRIN 5508. In patients not progressing after CP, paclitaxel, and bev maintenance treatments, bev, pemetrexed, or the combination were equal in PFS, HR 0.85  $p = n.s.$ , and OS was equal, HR = 0.86,  $p = 0.12$ .
- In **Abstract 9000**, K. Nakagawa et al. reported that in patients with EGFR mutations, erlotinib plus ramucirumab was better than erlotinib alone, with PFS 19.4 months vs. 12.4 months, HR 0.51,  $p = 0.0001$ .
- In **Abstract 9001**, V. Naronha et al. studied patients with EGFR mutation. Gefitinib plus pemetrexed and CP was superior to gefitinib alone, with PFS 16 months vs. 8 months, HR 0.5,  $p = 0.001$ . OS was not yet reached vs. 18 months, HR 0.79,  $p = 0.0001$ .
- **Abstract 9004** (J. Wolf) and **Abstract 9005** (P. Paik) demonstrated the successful treatment of patients with MET exon; 14 mutations were demonstrated with capmatinib or tepotinib, respectively.
- In **Abstract 1518**, K. Reckamp et al. looked at patients with adenocarcinoma and a family history of any cancer. Germline



mutations in 104 never-smokers were found in 13 (12.5%), with 2 having BRCA2 mutations. Mutations were found in 16 of 65 (25%) never-smokers with 4 BRCA2 mutations. It is important to note that earlier diagnosis of lung cancer was found in patients with BRCA2, TP53, EGFR, or Fanconi anemia gene mutations, indicating that patients with those mutations should have lung cancer screening started at a younger age.

- In **Abstract LBA9015**, E. Garon et al. showed the long-term follow-up of patients treated with single-agent pembro on KEYNOTE-001. At 60 months, patients with a PD-L1 of 50% or higher had OS rates of 30% (with no prior treatment) and 25% (with prior treatment).

### Small Cell

- In **Abstract 8506**, H. Chung et al. described KEYNOTE-158, in which patients with relapsed SCLC received pembro. PD-L1-positive patients (39% of the patients) showed OS at 12 months of 53% with an RR of 36%. In PD-L1-negative patients, the RR was only 6%.
- In **Abstract 8505**, L. Paz Ares et al. evaluated lurbinectedin in 100 second-line patients without brain metastases. The RR was 35%, with a PFS of 3.9 months and OS of 9.3 months. This is an interesting new drug with activity in SCLC. The only approved drug is topotecan, without other recent approvals.

### Skin and Melanoma

- In **Abstract 9500**, G. Fogarty et al. showed that following treatment of one to three brain metastases, adjuvant whole-brain RT does not improve outcomes vs. observation alone.
- In **Abstract 9501**, H. Tawbi et al. presented the results of CheckMate 204. Patients with brain metastases from melanoma received nivo plus ipi. Patients without neurologic symptoms had 54% PR and a CBR at 6 months of 58%. Symptomatic patients had 17% PR and 22% CBR.
- In **Abstract 9502**, C. Owen et al. demonstrated that of patients recurring after prior anti-PD1 therapy, if patients had been off therapy, repeat anti-PD1 treatment achieved PR in 2 out of 5 patients, ipi achieved PR in 2 out of 5, and 7 out of 8 responded to a combination of a BRAF (proto-oncogene BRAF) inhibitor plus a MEK (mitogen activated protein kinase) inhibitor. No patients responded to additional therapy if progression had occurred while on anti-PD1 treatment.
- In **Abstract 9503**, A. Menzies et al. showed that neoadjuvant therapy with anti-PD1 with or without ipi achieved pCR in 38%, and dabrafenib plus trametinib produced pCR in 47%.
- In **Abstract 9504**, A. Tarhini et al. presented results of E1609. Adjuvant ipi was found to be better than adjuvant interferon in OS, HR 0.78,  $p = 0.04$ .
- In **Abstract 9507**, P. Nathan et al. described the five-year results of dabrafenib plus trametinib in patients with unresectable or metastatic melanoma. PFS at five years was 19%, and OS was 34%. PFS was 25% in patients with a normal baseline LDH, but only 8% in patients with an elevated LDH.

- In **Abstract 9521**, X. Yan et al. showed that in patients with metastatic mucosal melanoma, CP plus paclitaxel and bev was an active regimen. Compared to CT alone, bev improved PFS from 3.2 months to 4.7 months,  $p = 0.001$ . OS was improved from 9.0 months to 12.9 months, HR 0.61,  $p = 0.02$ .

### Sarcoma

- In **Abstract LBA4**, W. Tap et al. presented the ANNOUNCE trial. Patients with unresectable soft tissue sarcoma received doxorubicin with or without olaratumumab. Dexrazoxone was optional and was given to 64% of patients. PFS was shorter with the combination 5.4 months vs. 6.6.8 months, HR 1.23,  $p = 0.04$ . OS was equal. This fails to confirm the prior phase II study, which was the basis for U.S. Food and Drug Administration approval.

### Developmental Therapeutics/Precision Medicine

- In **Abstract 2500**, T. Uldrick et al. showed that pembro was tolerated in patients who were HIV positive. In **Abstract 2501**, M. Gonzalez-Cao et al. also showed that durvalumab was well tolerated in patients with HIV, with 25% PR in patients, including NSCLC and anal cancer.
- In **Abstract 3003**, M. Fakih et al. showed the results of a trial of AMG 510, an inhibitor of KRAS G12C mutation. Responses were seen in NSCLC, and stable disease was achieved in patients with colorectal cancer. DCR was seen in 8 out of 10 patients. This is an exciting new drug.
- In **Abstract 3009**, M. Cristea et al. reported on the trial of mirvetuximab sorvantasin (IMGN853) plus gemcitabine in heavily pretreated patients. PR was seen in 4 out of 10 patients with ovarian cancer, 1 out of 3 patients with endometrial cancer, and 1 out of 2 patients with triple-negative breast cancer. These results are very encouraging in heavily resistant patients.

### Immunotherapy

- In **Abstract 9513**, A. Warner et al. evaluated the re-treatment of patients with melanoma with anti-PD1 drugs. Three hundred ninety-eight patients received anti-PD1 drugs initially, and 34 patients were re-treated with anti-PD1 drugs after a median of 11.6 months off treatment. Responses were seen in 2 out of 8 patients who responded to first-line anti-PD1 drugs and in 3 out of 21 patients who did not respond initially. Patients can respond to a second course of immunotherapy with anti-PD1 drugs.

### Patient Symptoms and Survivor Care

- In **Abstract 6502**, R. Talwar et al. presented the PENN study to reduce opioid usage in patients undergoing robotic renal cancer or prostatic cancer surgery. By concentrating on post-operative usage of gabapentin, acetaminophen, and/or ketorolac, 67% of patients were discharged without opioids, 24% with only tramadol, and only 8% with oxycodone. This is an important and easily implemented program with good narcotic-reducing results.



- In **Abstract 11521**, M. Dos Santos et al. compared patients with CT-induced cognitive impairment (measured by FACT-COG [functional assessment of cancer therapy-cognitive]) receiving neuropsychologist cognitive rehabilitation sessions (group A) vs. patients getting home self-administered cognitive exercises (group B) vs. patients getting only a phone call follow-up to ask how they were feeling (group C). Working memory improved in group A vs. group C,  $p = 0.001$ , but not in group A vs. group B. Depression improved more in group A than in group B or C.
- In **Abstract 11522**, J. Mao et al. treated patients who had sleep disorder and cognitive impairment with acupuncture or CBT. Attention improved more with CBT, but cognitive function improved more with acupuncture.
- In **Abstract 11501**, M. Clemons et al. compared zoledronate, pamidronate, or denosumab every 12 weeks vs. every 4 weeks. There were no differences in skeletal events (22% vs. 27%) or ONJ (0.8%) or pain or global health status.
- In **Abstract 11502**, C. Van Poznak et al. evaluated zoledronate in 3,491 patients. ONJ increased at 1% per year. Treatments every 4 weeks or less had higher ONJ rates, 3.2%, vs. every 5 weeks or more, 0.7%, HR 4.8,  $p = 0.008$ .
- In **Abstract 11503**, H. Hashimoto et al. showed that addition of olanzapine at bedtime to standard antiemetic therapy prevented nausea and/or vomiting after cisplatin, 59% vs. 48% without olanzapine,  $p = 0.001$ . This was confirmed in **Abstract 11504** where A. Rumyantsev et al. showed that olanzapine was superior to aprepitant (either used in combination with ondansetron and dexamethasone) in patients receiving highly emetogenic CT with complete control in 44% vs. 24%,  $p = 0.039$ .
- In **Abstract 11505**, E. Soto Perez de Celis et al. showed that the use of navigator supportive care plan increased the use of supportive care drugs, 73% with the navigator compared to 24% without,  $p = 0.001$ , and decreased pain, 10% vs. 33%,  $p = 0.006$ .

## Health Sciences Research

- In **Abstract LBA1**, A. Davidoff et al. compared disparities between Caucasian and African American patients after the ACA was implemented. Using a database of 280 practices using an EHR from Flatiron Corporation (2.2 million patients are in their system), investigators studied 30,000 patients regarding the fraction of patients receiving therapy within 30 days of diagnosis (which they defined as “timely treatment”). In states that did not expand Medicaid, Caucasian patients had 48.3% timely care vs. 43.5% in African American patients,  $p = 0.001$ . However, in states that expanded Medicaid under the ACA, Caucasian patients had 50.3% timely care vs. 49.6% in African American patients,  $p = 0.6$ , n.s. The investigators said that this indicated that the ACA overcame racial health disparities. (This author believes that these data could also

represent differences in managed care authorizations in implementing states versus non-implementing states and that this comparison should be studied in a more comprehensive database, such as state cancer registries.)

- In **Abstract 6509**, L. Barbera et al. studied routine structured comprehensive symptom assessment in patients with cancer compared to patients with only usual care. In 129,000 matched pairs, patients with structured symptom assessment had longer OS, HR 0.49 by multivariable regression analysis. This is important real-world data indicating that structured symptom assessment is important.
- In **Abstract 11527**, E. Ludmir et al. showed that in 302 phase III trials, trials sponsored by the pharmaceutical industry enrolled patients who were 6.5 years younger than those in non-industry-sponsored trials. Industry-sponsored trial results may not be as generalizable as other trial results.
- In **Abstract 6500**, R. Kotchetkov et al. presented the results of using standard antihistamines (S), S + rupatadine (SR), S + monteleukast (SM), or S + R + M (SRM) as prophylaxis in patients receiving the first dose of rituximab. Reactions were less in the combinations, 92% vs. 38%, 45%, and 33%, respectively. Rescue medications were not required in the combinations. SR and SM were as effective as SRM.
- In **Abstract 6501**, A. Pai et al. showed that heparin flushing of central venous access ports had fewer line occlusions vs. normal saline flushing, 0.91% vs. 2.67%,  $p = 0.01$ .
- In **Abstract LBA10502**, M. Stasenکو et al. reported the results of a survey of gynecologic oncologists. Sexual harassment during training was reported by 64% of respondents (71% of women) but only 10% reported it (17% women, 10% men). Women more often reported feelings that gender impaired their professional advancement compared to men (34% vs. 10%,  $p = 0.001$ ).

Some of the above studies have already been published in full in *The New England Journal of Medicine*, the *Journal of the American Medical Association*, *The Journal of Clinical Oncology*, and *The Lancet Oncology*. You can find full abstracts at [meetinglibrary.asco.org](http://meetinglibrary.asco.org) by searching for abstract numbers.

Edmond Ang, MD, a New Zealand oncologist who opened the meeting, quoted a Maori proverb: “What’s the most important thing in the world? The people, the people, and the people!” To me, it is the patient, the patient, the patient! Scientific advances from ASCO 2019 will help us all improve the care of our patients. This year’s annual meeting exceeded my expectations for new, imaginative, challenging, and practice-changing information. I can’t wait to see what ASCO 2020 will bring.

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