Gynecologic Cancers: ASCO20 Virtual Scientific Program Highlights for the Advanced Practitioner

Following coverage by *The ASCO Post*, **Laura Doherty, FNP-BC, AOCNP®,** of Women & Infants Hospital of Rhode Island, interprets findings from major gynecologic oncology abstracts featured in *The ASCO Post* and considers takeaways for advanced practitioners

Abstracts 6000 and 6001

Two Studies Report Secondary Surgery Extends Survival in Recurrent Ovarian Cancer: Benefit Seen Solely in Selected Patients Treated at Specialized Centers

By Alice Goodman

Visit https://meetinglibrary.asco.org/record/185438/abstract and https://meetinglibrary.asco.org/record/185448/abstract to read the full abstracts and view author disclosures.

Two phase III trials provide support for secondary cytoreductive surgery in women with recurrent ovarian cancer, with the caveats that patient selection is key and the surgery should be performed at sites of excellence. The results of the DESKTOP III and SOC1 trials, both presented during the ASCO20 Virtual Scientific Program, found cytoreductive surgery improved outcomes in selected patients.[1,2]

DESKTOP III is the first randomized phase III trial to demonstrate an improvement in survival with secondary surgery for recurrent ovarian cancer. In this study, secondary surgery prior to second-line chemotherapy extended median overall survival from 46 months with second-line chemotherapy and no surgery to 53.7 months (P = .02).[1] However, the benefit of secondary surgery was observed only in cases where a complete resection was achieved.

The phase III SOC1 trial, conducted in a slightly younger population, found that secondary cytoreductive surgery improved progression-free survival at first relapse vs chemotherapy alone (17.4 months vs 11.9 months, respectively, a 5.5-month absolute improvement and a 42% improvement in progression-free survival, P < .001), but again, the benefit was restricted to patients with no residual disease after surgery.[2]

The role of secondary surgical cytoreduction in women with recurrent ovarian cancer has been debated for some time, leading to five global phase III trials with generally similar designs to resolve this issue. Although both the DESKTOP III and the SOC1 trials support the role of secondary surgery, with the previously mentioned caveats, a third trial, GOG-0213, published in 2019, did not show an overall survival benefit.[3]

Helen MacKay, MD, Professor at the University of Toronto and Head of the Division of Medical Oncology and Hematology at Sunnybrook Odette Cancer Centre, Toronto, was enthusiastic about the results of both of these trials at a Gynecologi-

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cal Cancer Highlights session during the ASCO meeting. "We have randomized data for the first time, moving the all-important bar of overall survival. These studies provide real hope for the future to achieve our goal of getting patients to live longer and better," she stated.

DESKTOP III

The phase III DESKTOP III trial enrolled 407 women with recurrent ovarian cancer in first relapse between 2010 and 2014 at 80 centers in 12 countries. Women were randomly assigned to receive chemotherapy alone or surgery followed by chemotherapy; 90% received the suggested platinum-containing regimen.

Special criteria for secondary surgery, developed and validated by the German Gynecological Oncology Group (AGO), were used to select patients for the trial: a good performance status, complete resection at first cytoreductive surgery, and no ascites or small-volume ascites (< 500 mL). To be enrolled in the trial, patients had to have a platinum-free interval of at least 6 months; the median platinum-free interval was 19.9 months. The primary endpoint was overall survival.

"Surgeons were selected for the trial based on prior performance," said lead author Andreas du Bois, MD, PhD, Professor of Gynecologic Oncology at Kliniken Essen-Mitte, Essen, Germany. "The overall survival benefit was highest and exclusively seen in women with complete resection, indicating the importance of thorough selection of both the right patient and the right [surgical] center."

At baseline, demographic and disease characteristics were well balanced between the two arms. The median age was about 62, about 75% had stage III or IV disease, and more than 80% had grade 2 or 3 histology. Less than 5% received a poly (ADP-ribose) polymerase (PARP) inhibitor, and about 25% received bevacizumab. "PARP inhibitors and bevacizumab were not so popular when the study was designed," Dr. du Bois noted.

In the surgery-alone arm, overall survival in patients who achieved complete resection with secondary surgery was a median of 61.9 months vs 28.8 months for those with residual disease after surgery ($P < .001$). Comparing complete resection and no surgery, median overall survival was 61.9 months vs 46 months—a 15.9-month difference. "This underlines the importance of complete resection," commented Dr. du Bois.

"Remember, 50% of patients with a platinum-free interval of more than 6 months will have a positive AGO score, and 75% will end up with a complete resection of visible disease. The median survival gain in this group of patients is more than 12 months if they achieve a complete resection, and this is worth going for," he stated.

In the surgery-alone arm, 187 of 206 patients (91%) were able to undergo secondary surgery. Surgery also improved progression-free survival from 14 months with chemotherapy to 18.4 months with surgery followed by chemotherapy ($P < .001$).

No deaths were reported in the surgery-alone arm within the first 30 days, and one death occurred within 90 days. Of the control arm, 11% subsequently went on to cytoreductive surgery.

SOC1 Trial

Although secondary cytoreductive surgery is controversial in the United States, it is standard of care for recurrent ovarian cancer in China. "Secondary cytoreductive surgery in selected patients resulted in a dramatically significant extension of progression-free survival at a median follow-up of 36 months," said Rong-Yu Zang, MD, PhD, of the Division of Gynecologic Oncology, Zhongshan Hospital, Shanghai. "The interim analysis of accumulated treatment-free survival indicates secondary cytoreductive surgery might contribute to long-term survival."

SOC1 randomly assigned 356 women with recurrent ovarian cancer in first relapse to receive secondary cytoreductive surgery plus chemotherapy (docetaxel/carboplatin) or chemotherapy alone. Eligibility criteria differed from those of DESKTOP III—a platinum-free interval of at least 6 months and an integrative model score < 4.7. (The integrated model is a validated scoring algorithm that shows prognostic value of secondary cytoreductive surgery.)

The median age of patients was 54. More than 80% had stage III or IV disease. The median platinum-free interval at baseline was 16.1 months. The primary endpoint is progression-free survival,

with a hierarchical assessment of overall survival if the progression-free survival endpoint was successfully reached.

The rate of complete resection was 76.7%. Patients with no residual disease after surgery had a median progression-free survival of 19.1 months vs 12.6 months for those with residual disease (comparable to 11.9 months in the chemotherapy arm). Median overall survival results were immature. The 3-year overall survival rate was 68% vs 66%, respectively. ●

References

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The Advanced Practitioner Perspective

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Women with newly recurrent platinum-sensitive ovarian cancer will often inquire about secondary cytoreductive surgery. NCCN Guidelines identify secondary cytoreduction as a treatment option for these patients. There is support from meta-analyses; however, there have not been prospective randomized data showing an overall survival (OS) benefit prior to DESKTOP III.

GOG-0213, a phase III randomized controlled trial assessing the benefit of secondary surgical cytoreduction, found that in patients who were randomized to surgery, there was OS and progression-free survival (PFS) benefit for those who obtained complete gross resection (CGR) over those who underwent surgery and did not obtain CGR. However, a comparison of the CGR subpopulation with the entire no-surgery group did not show a benefit with respect to OS. There was a benefit with respect to PFS.

All three trials show that CGR will provide the greatest chance of benefit from secondary cytoreduction, and DESKTOP III data tell us that there is a particular woman who will benefit greatly from secondary cytoreduction. Accurate patient selection is crucial. Explaining the importance of complete resection at first cytoreductive surgery, no ascites or small-volume ascites (< 500 mL) at recurrence, 6 month + platinum free interval, performance status, and surgeon selection are essential in helping the patient comprehend your treatment recommendations.

If practicing in a medical oncology office, facilitating referral to a highly skilled gynecological oncologist for surgical consultation is imperative. And with the new guidelines that offer the option of PARP inhibitor maintenance following initial treatment for all women who presented with advanced disease, there is a need for continued evaluation of the role of secondary cytoreduction with these new variables in play. Detecting recurrences as early as possible becomes more important if we are considering secondary cytoreduction for our patients. We continue to have ever-increasing reasons to be hopeful for extended survival for our patients with ovarian cancer.

Disclosure: Ms. Doherty has served on the speakers bureau for Merck.

Abstract 6002

Maintenance Olaparib Shows Overall Survival Benefit in Ovarian Cancer

By The ASCO Post Staff

Visit https://meetinglibrary.asco.org/record/185419/abstract to read the full abstract and view author disclosures.

In the final, preplanned, overall survival analysis in the randomized phase III SOLO2/ENGOT-ov211 trial, maintenance treatment with the PARP inhibitor olaparib extended overall survival by an unprecedented 12.9 months, compared with placebo. This marks the first time that overall survival has been improved with maintenance therapy involving a poly (ADP-ribose) polymerase

(PARP) inhibitor in patients with platinum-sensitive recurrent ovarian cancer associated with *BRCA1/2* mutations.[1]

Andrés Poveda, MD, of Initia Oncology, Hospital Quirónsalud, Valencia, Spain, announced the results at the Plenary Program of the ASCO20 Virtual Scientific Program. "A long-term treatment benefit was seen with olaparib vs placebo, with an overall survival hazard ratio of 0.74 in the full-analysis set, which was unadjusted for crossover," Dr. Poveda stated.

"SOLO2 is the first phase III trial to provide final overall survival data on maintenance PARP inhibitor therapy. A median overall survival improvement of nearly 13 months is impressive in ovarian cancer and brings a substantial benefit to our patients," he commented.

Olaparib is approved as maintenance therapy for patients with platinum-sensitive relapsed ovarian cancer, regardless of BRCA mutation status, in numerous countries.

ASCO Chief Medical Officer and Executive Vice President Richard L. Schilsky, MD, FACP, FSCT, FASCO, commented in the press briefing: "These results, while they will not change access to the drug because it's already approved, are comforting in showing that the treatment confers a significant survival benefit. That's good news for women with ovarian cancer harboring BRCA1/2 mutations, which generally has a poor prognosis."

SOLO2 Details

The current report is the preplanned, final, overall survival analysis of the study, which was conducted in the germline BRCA-mutated subset and finalized February 3, 2020, with data maturity of 61%. SOLO2 had already shown that maintenance treatment with olaparib significantly improved median progression-free survival by 13.6 months vs placebo (hazard ratio [HR] = 0.30; $P < .0001$).[2] The time to second disease progression or death significantly improved as well, and a quality-adjusted progression-free survival benefit was observed.

The study enrolled 295 patients with relapsed BRCA-related high-grade serous ovarian cancer or high-grade endometrioid cancer, including primary peritoneal or fallopian tube cancer. All had received at least two prior lines of therapy and were in response to their most recent platinum-based regimen. Women were randomly assigned to receive maintenance olaparib (300 mg twice daily; n = 195) or placebo (n = 99), continued until disease progression.

Crossover was noted for 39% of the placebo arm; 11% of the olaparib arm received a subsequent PARP inhibitor. Patients were followed for a median of 65 months.

Survival Benefit Shown

Olaparib extended overall survival, which was a secondary endpoint, by approximately 13 months, compared with placebo, and this was consistent across three analyses: the full-analysis set, which was unadjusted for crossover; the full, prespecified sensitivity analysis of patients with germline *BRCA*-mutated disease; and the post hoc sensitivity analysis that used stratification variables based on electronic case reports to correct for patients who had been erroneously stratified at randomization (Table 1). At 5 years, 42% of the olaparib arm was alive, compared with 33% of the placebo arm (HR = 0.74; $P = .0537$), Dr. Poveda reported.

The toxicity was consistent with the known side effects of olaparib. The most common grade ≥ 3 treatment-emergent adverse event was anemia, which led to dose interruptions in 50% of patients (vs 19% with placebo), dose reduction in 28% (vs 3%), and treatment discontinuations in 17% (vs 3%). ●

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The Advanced Practitioner Perspective

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Olaparib is approved for maintenance therapy in the frontline and recurrent setting for patients with germline or somatic *BRCA* mutations. We know from the results of SOLO1 that olaparib greatly extends PFS for *BRCA*-mutated patients in the frontline maintenance setting. At 41 months of follow-up, the median PFS for patients treated with olaparib was not reached compared to 13.8 months for patients treated with placebo. Overall survival data have not matured in that patient population. The results of SOLO2 now provide us with OS data regarding maintenance in the recurrent setting, to further support the use of olaparib in this patient population. As providers, we will be advising the use of olaparib in the frontline maintenance setting and recurrent maintenance setting with confidence of its efficacy in prolonging survival.

The advanced practitioner has a valuable role in counseling patients regarding this data to encourage adoption of maintenance therapy. Equally important is to support patients during the initiation of, and treatment with, these therapies. As we know from practice, side effects including anemia, nausea, and fatigue must be adequately addressed to ensure the patient can stay compliant with her therapy and derive this excellent benefit.

Disclosure: Ms. Doherty has served on the speakers bureau for Merck.

Abstract 6003

Cediranib/Olaparib vs Standard-of-Care Chemotherapy for Platinum-Sensitive Ovarian Cancer

By The ASCO Post Staff

Visit https://meetinglibrary.asco.org/record/185456/abstract to read the full abstract and view author disclosures.

Results of the NRG Oncology phase III clinical trial NRG-GY004 indicated that the addition of the investigational agent cediranib to olaparib and standard platinum-based chemotherapy did not improve PFS outcomes for women with platinum-sensitive ovarian cancer; however, activity between the treatments was similar in patients. These results were recently presented by Joyce F. Liu, MD, and colleagues during the ASCO20 Virtual Scientific Program.

Study Background and Methodology

NRG-GY004 was designed to expand upon the findings of a phase II trial that indicated a combination of cediranib and olaparib improved progression-free survival outcomes compared to olaparib alone for women with platinum-sensitive, high-grade serous/endometrioid ovarian cancer, regardless if they had a *BRCA* mutation.

In NRG-GY004, women were randomly assigned to one of three treatment regimens. Participants randomly assigned to the first treatment arm received standard-of-care chemotherapy with either carboplatin and paclitaxel, carboplatin and gemcitabine, or carboplatin and pegylated lipsomal doxorubicin. The participants on the experimental treatment arms either received olaparib at 300 mg twice a day or olaparib at 200 mg twice a day with cediranib at 30 mg twice a day. The primary endpoint of this study was to assess the progression-free survival benefit of cediranib and olaparib treatment compared to chemotherapy for women with platinum-sensitive ovarian cancer.

Between March 2016 and June 2018, 565 patients had enrolled in NRG-GY004 and, of those patients, 528 initiated treatment; 23.7% of the patients had a germline *BRCA* mutation.

Results

At a median follow-up of 29.1 months, the hazard ratio for progression-free survival was 0.856 (95% confidence interval [CI] = 0.66–1.11, P = .08, 1-tail) for the combination of cediranib and olaparib compared to chemotherapy treatment. The hazard ratio for progression-free survival was 1.20 (95% CI = 0.93–1.54) for olaparib alone compared to chemotherapy treatment. Median progression-free survival for patients was 10.3

months for the standard of care, chemotherapy; 8.2 months for olaparib alone; and 10.4 months for patients receiving cediranib plus olaparib. In a predefined biomarker subset analysis of women with a germline *BRCA* mutation, the progression-free survival hazard ratio was 0.55 (95% CI = 0.73–1.30) for combined cediranib and olaparib compared to chemotherapy and 0.63 (95% CI = 0.37–1.07) for olaparib alone vs standard chemotherapy. In women without a germline *BRCA* mutation, the progression-free survival hazard ratio was 0.97 (95% CI = 0.73–1.30) for cediranib plus olaparib compared to chemotherapy and 1.41 (95% CI = 1.07–1.86) for olaparib alone vs standard chemotherapy.

"This is the first phase III trial comparing a completely oral non–platinum-based therapy regimen to standard of care platinum-based chemotherapy in platinum-sensitive ovarian cancer. While the combination of cediranib and olaparib was not found to improve progression-free survival compared to [the] standard-of-care chemotherapy, the findings of this study suggest that non–platinum-based alternatives have potential in this setting, especially in appropriate biomarker subgroups such as patients with *BRCA* mutations," stated Dr. Liu, of the Dana-Farber Cancer Institute.

There were no overall survival differences between the treatment arms. Patients who received cediranib and olaparib in addition to the standard of care did experience a higher frequency of grade 3 or higher gastrointestinal, hypertension, and fatigue adverse events. ●

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Although the combination of olaparib and cediranib did not lead to extended PFS compared with traditional chemotherapy, we see again a benefit for women with germline *BRCA* mutations with the use of PARP inhibitor. As noted in the abstract, in women with a germline *BRCA* mutation, the PFS hazard ratio was 0.55 for combined cediranib and olaparib compared with chemotherapy and 0.63 for olaparib alone vs. standard chemotherapy. Combination therapies will continue to be trialed in the hopes of discovering better treatment options for patients who are not *BRCA* mutated or homologous recombination deficient and subsequently do not see the more significant benefits derived from PARP inhibitor therapy.

Disclosure: Ms. Doherty has served on the speakers bureau for Merck.

Abstract 6005

Final Results from the KEYNOTE-100 Trial of Pembrolizumab in Patients With Advanced Recurrent Ovarian Cancer

By The ASCO Post Staff

Visit https://meetinglibrary.asco.org/record/189536/abstract to read the full abstracts and view author disclosures.

Ursula A. Matulonis, MD, of Dana-Farber Cancer Institute, discusses an important study focusing on single-agent pembrolizumab in patients with advanced recurrent ovarian cancers. Below is a transcript of her interview with *The ASCO Post* that has been edited for length.

Commentary by Ursula A. Matulonis, MD

This is an international study of single-agent pembrolizumab in patients with recurrent ovarian cancer. Patients were split into 2 cohorts. Cohort A enrolled 285 patients. Patients had to receive between 1 and 3 prior lines of therapy and have a platinum-free or treatment-free interval of at least 3 months and then up to 12 months. The first 100 patients enrolled into Cohort A represented the training set, and this was to determine the appropriate PD-L1 cutoffs. Cohort B was 91 patients. They were more heavily pretreated (between 4 and up to 6 prior lines of treatment), and they had to have a platinum-free or treatment-free interval of at least 3 months, with no upper limit on the interval.

The primary endpoint of the study was response rate by cohort (Cohort A vs. B) and by PD-L1 status. PD-L1 status was determined by the combined positive score, and that's the number of PD-L1–positive cells (could be cancer cells, lymphocytes, macrophages) divided by the total number of cancer cells × 100.

What we found by cohort was that the response rate in Cohort A was 8.1% and in Cohort B was 9.9%. For all 376 patients enrolled, the overall response rate was 8.5% with pembrolizumab as a single agent in these patients.

In a subgroup analysis, it was shown that higher PD-L1 expression and clear-cell histology predicted for a higher overall response rate. However, neither the number of prior lines nor the level of platinum-level sensitivity impacted the level of response. So really, you can see responses in all types of patients within the recurrent ovarian cancer population.

We also looked at CPS score (1 or higher or 10 or higher). In Cohort A, in patients with a CPS score of 1 or higher, the response rate was 6.9%, and in patients with a CPS score of 10 or higher, it was 11.6%. In Cohort B, we saw slightly higher response rates overall. In patients with a CPS score of 1 or higher, the response rate was 10.2%, and if patients had a CPS score of 10 or higher in Cohort B, the response rate was 18%.

We also showed that PFS in these patients was around 2.1 months, and the CPS score did not impact that at all.

The key points of this study are that single-agent pembrolizumab shows modest response rates as a single agent in recurrent ovarian cancer. This has been shown with other immunotherapy agents as well. In addition, the response rates were irrespective of the level of platinum sensitivity/resistance and how heavily pretreated the patient was. ●

The Advanced Practitioner Perspective

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We continue to lack a broadly effective immunotherapy treatment option for women with ovarian cancer. These patients have often been so heavily pretreated with cytotoxic chemotherapy that they are suffering from residual side effects.

Pembrolizumab has the potential to be better tolerated in this population than further cytotoxic treatment. The response rate to single-agent pembrolizumab in recurrent ovarian cancer seen in KEYNOTE-100 is low, with an overall response rate of 8.6% between the two cohorts. Encouragingly, in those who did respond, the median duration was 10.2 months. There is a biomarker analysis underway, with the hopes to identify the women who will benefit from treatment with pembrolizumab.

Disclosure: Ms. Doherty has served on the speakers bureau for Merck.

Abstract LBA6008

Avelumab Shown Effective in Rare Chemotherapy-Resistant Gynecologic Tumor in TROPHIMMUN Trial

By The ASCO Post Staff

Visit https://meetinglibrary.asco.org/record/189060/abstract to read the full abstract and view author disclosures.

Almost 50% of patients resistant to single-agent chemotherapy responded in the first trial of immunotherapy for gestational trophoblastic tumors, reported French investigators in an abstract presented during the ASCO20 Virtual Scientific Program.[1] Benoit You, MD, PhD, of Lyon University Hospital, Lyon Investigational Center for Treatments in Oncology and Hematology, and the French Gestational Trophoblastic Center, offered an initial presentation of the results of the phase II TROPHIMMUN trial during a press briefing in advance of the meeting.

"We may have actually cured some of these women with chemoresistant disease. Avelumab may be a new therapeutic option," said Dr. You, who further reported the first occurrence of a healthy pregnancy after immunotherapy for gestational trophoblastic tumor. "We had a happy event in the TROPHIMMUN trial, where about 2 years after discontinuation of avelumab, she delivered a healthy baby. This provides reassuring data about the impact of immunotherapy on subsequent fertility."

Gestational trophoblastic tumor is a rare malignancy that develops in placental tissue. Standard treatments rely on chemotherapy: single agents for low-risk disease and polychemotherapy for high-risk disease or disease resistant to single agents.

"Chemotherapy has a high cure rate but is associated with significant toxicity. There is a need for innovative treatments in patients with gestational trophoblastic tumors," Dr. You said.

PD-L1 is constitutively expressed in all subtypes of gestational trophoblastic tumors, suggesting this malignancy may be well suited for treatment with an anti–PD-L1 monoclonal antibody such as avelumab. In addition to the common PD-1/PD-L1 inhibition effect, avelumab triggers cytotoxicity through natural killer cells, which are involved in gestational trophoblastic tumor immune surveillance, Dr. You explained.

The objective of the phase II TROPHIMMUN trial was to assess the efficacy of avelumab in the cohort of patients who are resistant to single-agent chemotherapy. A second cohort resistant to polychemotherapy will be assessed later. The median number of avelumab cycles was eight, and the median follow-up was 25 months.

Study Details

In the academic multicenter phase II trial, led in collaboration with the national network of the French Gestational Trophoblastic Center, avelumab was given at 10 mg/kg every 2 weeks. Avelumab was prescribed until normalization was observed in human chorionic gonadotropin (hCG), which is elevated in gestational trophoblastic tumors and is the common criterion for assessing treatment efficacy in these tumors. The drug was continued for another three cycles for consolidation. The primary endpoint was the rate of patients with hCG normalization.

Over 2 years, 15 patients were available for both treatment and assessment. Within this group, 53% had stage I disease, and 47% had stage III. The FIGO (International Federation of Gynecology and Obstetrics) score was 0 to 4 in 33% of patients, 5 to 6 in 47%, and higher than 6 in 20%. All patients experienced disease progression on methotrexate, and one patient also had been treated with actinomycin D.

Some Patients Potentially Cured

Successful normalization of hCG was observed in eight patients (52%), enabling avelumab to be discontinued. "With a 29-month median follow-up, no subsequent relapses were seen, despite the discontinuation of avelumab. These patients are potentially cured," Dr. You said. "One patient among the eight who experienced successful normalization of blood hCG subsequently developed a normal pregnancy 1 year later and delivered a healthy baby."

Among the eight patients who were successfully treated with avelumab were five with high hCG or resistance to both single agents who would have otherwise been treated with toxic polychemotherapy, such as an EMA-CO regimen (etoposide, methotrexate, dactinomycin, cyclophosphamide, vincristine). "Participation in the TROPHIMMUN trial was beneficial to these patients, as they escaped the adverse events of polychemotherapy," Dr. You said.

The remaining seven patients (47%) developed resistance to avelumab and were managed with chemotherapy with or without surgery. Normalization of hCG was accomplished in 42% with actinomycin D and in 57% with surgery and/or polychemotherapy. To date, none of the patients in the study has died.

The likelihood of success with avelumab was not related to the FIGO score or the disease stage. The tolerability of avelumab was "very satisfactory," according to Dr. You, and dose reductions or delays were not necessary due to toxicity. Adverse events included fatigue, nausea/vomiting, diarrhea, infusion-related reaction, and dry eye. Three patients experienced immunologic toxicity.

Dr. You indicated a phase I/II study is being done to assess the safety and efficacy of combining atezolizumab and methotrexate (the stan-

dard treatment in Europe) upfront. "The idea is to avoid the resistance to chemotherapy, and the objective is to cure 95% of patients. With methotrexate alone, we estimate we cure about 70%," he added. ●

Reference

1. You B, Bolze PA, Lotz JP, et al: Avelumab in patients with gestational trophoblastic tumors resistant to monochemotherapy. ASCO20 Virtual Scientific Program. Abstract LBA6008. Presented during press briefing before meeting on May 26, 2020.

The Advanced Practitioner Perspective

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We know that combination therapy with EMA-CO, commonly used for resistant GTN disease, can lead to unwanted side effects both during and after completion of treatment. During therapy, women frequently experience hematologic toxicities, including anemia requiring blood transfusion and neutropenia requiring GCSF support, as well as alopecia, which can be especially challenging for young women. Long-term side effects can include secondary malignancies, including acute myeloid leukemia, cervical malignancy, and gastric adenocarcinoma as seen in previous analyses. It is encouraging that with avelumab, we may now have an option that is effective and better tolerated during treatment.

Continued follow-up will give us more information about the long-term side effects of avelumab in this patient population. A phase III trial will help us to better understand the benefits compared to standard of care.

Disclosure: Ms. Doherty has served on the speakers bureau for Merck.