

# Research Round-Up Annual meeting of the American Society of Clinical Oncology (ASCO)

"Delivering Discoveries: Expanding the Reach of Precision Medicine" June 1-5, 2018 in Chicago, Illinois

By Annie Ellis, ovarian cancer survivor, research advocate, and OCRFA Scientific Advisory Committee Member

"Every year, the ASCO Annual Meeting attracts the best and brightest in oncology to McCormick Place Convention Center in Chicago, IL, where more than 39,000 attendees from around the world gather to network and hear the latest innovations in cancer care. There is no better forum to learn about and discuss the important issues and ongoing controversies in cancer care across a variety of disease sites, treatment approaches, and disciplines."

Carson Rolleri, ASCO Connection

"We commonly think of our interventions in terms of responses, ... but as I said before, we must keep in mind that we are actually trying to make our patients live better as well as longer lives."

Dr. Bruce Johnson, ASCO President

Thanks to Conquer Cancer Foundation, I received a <u>Patient Advocate Scholarship</u> to attend the ASCO annual meeting for the first time. Dr. Bruce Johnson's <u>Presidential Address</u> was extremely moving as he shared details of his own cancer diagnosis, living with uncertainty and the importance of survivorship issues. In addition to patient advocate meetings with the National Cancer Institute (NCI) and the Food and Drug Administration (FDA), I attended sessions on <u>Patient Reported Outcomes</u> (PROs) and Patient-Clinician Communication. There were several ovarian cancer sessions that included clinical trial results and discussion of ongoing issues, which I will try to summarize.

#### **Complicated Ovarian Cancer Treatment Landscape**

First, a reminder that ovarian cancer and the current treatment landscape are complicated. Women diagnosed with ovarian cancer are living longer and have access to more therapeutic options than ever before. Within the last few years, the FDA has approved several targeted therapies (PARP inhibitors and anti-angiogenesis agents) for treatment of active disease and for maintenance of remission or stable disease, in both first-line and recurrent settings. For those who need multiple lines of treatment, it is not always clear which treatment or combination individual patients should receive at any given time, and in which order. Targeted therapies continue to be studied as well as new therapeutics, like immunotherapy, as well as different treatment strategies combining multiple new and old agents. Communication with our medical teams is essential to understand why a particular treatment is recommended and how it might impact future treatment should the need arise.

Another area that remains unclear is surgery. Much discussion continues on whether newly diagnosed patients should receive primary debulking (surgery before chemotherapy) or

neoadjuvant therapy (chemotherapy followed by surgery followed by chemotherapy), and the benefits of surgery in the recurrent setting.

Clinical trials are ongoing to attempt to shed light on many of these areas. As gynecologic oncologist Dr. Emily Dickson <u>tweeted on June 5</u>:

Bottom line—oral plenary sessions today at #ASCO18 generate more questions than answers. Must move forward in getting those answers for our patients #gyncsm

## **Early Immunotherapy Trial Results**

Dr. Panagiotis Konstaninopoulos of Dana-Farber Cancer Institute reported the results of <u>TOPACIO/Keynote-162</u>, a phase I/II study of niraparib (a PARP inhibitor) and pembrolizumab (an anti-PD-1 immunotherapy). For recurrent ovarian cancer, the overall response rate was 25% with a duration of response of 9.3 months. Patients with platinum resistant disease had similar overall response rates even if they were not BRCA mutation carriers (24%) or if their cancer was HRD negative (27%). Further study of this combination is planned.

Dr. Ursula Matulonis of Dana-Farber Cancer Institute reported the interim results of Keynote-100, a phase II study of pembrolizumab as a single agent in recurrent ovarian cancer. Overall response rate (ORR) was 9% and those with higher PD-L1 expression had higher ORR of 14%.

Dr. Lukas Rob of University Hospital Kralovske Vinohradu in the Czech Republic presented the interim analysis of a phase II study of Dendritic Cell Vaccine (<u>DCVAC/Ovca</u>) in first line ovarian cancer. DVAC/Ovca was well tolerated and the maintenance arm showed a gain of 6 months in progression free survival. A phase III study is being planned.

Dr. Oliver Dorigo of Stanford Cancer Institute presented data from the phase I <u>DeCidE Trial</u> which combined anti-cancer vaccine DPX-Survivac, cyclophosphamide and epacadostat for recurrent ovarian cancer. The combination was well tolerated and with stable disease achieved in 3 of 10 patients with disease control in 2 patients for over 12 months, warranting further development.

## Other clinical trial results

Dr. Sandro Pignata of the IRCCS National Cancer Institute "Fondazione G. Pascale" in Naples, Italy presented results of MITO-16, a randomized phase III study of chemotherapy plus or minus bevacizumab for platinum-sensitive ovarian cancer patients recurring after a bevacizumab containing first line treatment. There were no unexpected toxicities when patients were treated with bevacizumab for a second time. PFS was 8.8 months and 11.8 months without and with bevacizumab, respectively. OS was 27.1 months and 26.7 months without and with bevacizumab, respectively.

During the poster discussion session, Dr. Robert Burger of University of Pennsylvania reported the final overall survival (OS) analysis of NRG/GOG 218, a phase III international randomized trial evaluating bevacizumab (BEV) in the primary treatment of advanced ovarian cancer. In front-line ovarian cancer therapy, there were no survival differences between patients receiving bevacizumab in combination with carboplatin and paclitaxel compared with patients receiving chemotherapy alone.

Dr. David M. O'Malley from The Ohio State University College of Medicine, presented a poster on the findings of <u>FORWARD II</u>, a phase Ib study of mirvetuximab soravtansine (a folate receptor alpha targeting agent) in combination with bevacizumab in patients with platinum-resistant ovarian cancer. In this safety study, the overall response rate (ORR) is 43%, with patients with high expression of folate receptor alpha at 49% ORR. Duration of response was nearly 11 months.

Dr. Kathleen Moore of the University of Oklahoma Health Sciences Center presented a poster on the findings of the <u>QUADRA</u>, a phase II study of niraparib in heavily pre-treated recurrent ovarian cancer. The overall response rate (ORR) was 27% and duration of response (DoR) of 9.2 months for the target population (fourth-line therapy or beyond for homologous recombination deficiency (HRD)-positive, platinum-sensitive tumors).

Dr. Deb Zajchowsk, Clearity Foundation Scientific Director, along with collaborators from NYU Langone Medical Center, and Foundation One presented a poster entitled "Genomic mutation profiles of paired ovarian cancers across time." This study compared ovarian cancer tumor samples from the same patient collected at front-line surgery and at recurrences to find differences that may occur over time. Genomic testing of recurrent disease could help identify clinical trial options.

#### Surgery

Dr. Robert L. Coleman of MD Anderson Cancer Center <u>discussed the findings of the surgical component</u> of <u>GOG 213</u>, a phase III study of secondary surgical cytoreduction followed by platinum-based combination chemotherapy, with or without bevacizumab, in platinum-sensitive, recurrent ovarian cancer. This was the first prospective phase III trial that included surgery for recurrent disease. (All others were retrospective analysis or single-institution studies.) When all the cancer was removed with surgery, patients had 2 months more progression free survival (PFS) than patients who did not have surgery. However, patients who did not receive surgery had 14 months more overall survival (OS). Further analysis is underway.

Dr. Takashi Onda of Kitasato University School of Medicine presented the results of <u>Japan Clinical Oncology Group's phase III</u> randomized trial comparing survival between upfront primary debulking surgery (PDS) versus neoadjuvant chemotherapy (NACT) for stage III/IV ovarian, tubal and peritoneal cancers. Overall survival differed for patients receiving PDS was 4 months longer than those receiving NACT and non-inferiority of the NACT arm was not confirmed. Further studies may be necessary.

#### **Genetics and Risk Reducing Strategies**

Dr. Christine Walsh from Cedars-Sinai Medical Center in Los Angeles provided an overview of genetic testing in gynecologic cancers, including a comprehensive breakdown of specific mutations tested by different panels currently available, including direct to consumer tests. SGO and NCCN guidelines recommend that all patients with epithelial ovarian cancer undergo genetic testing. As more genes are tested, more variants of unknown significance will be found and it's important to use a company that is also studying variants and will contact patients when information about risk is updated.

Dr. Leslie Randall of the University of California, Irvine reviewed current guidelines for risk-reducing salpingo-oophorectomy (RRSO) and the study of salpingectomy (removal of fallopian tubes) with delayed oophorectomy (removal of ovaries) to preserve quality-of-life. Dr. Noah Kauff from Memorial Sloan Kettering discussed rationale and timing of risk reducing measures and shared that the <a href="NCCN Guidelines on High Risk Assessment">NCCN Guidelines on High Risk Assessment</a> for Breast and Ovarian Cancer have been updated to include Lynch Syndrome and mutations beyond BRCA1 and BRCA2.

#### Survivorship

Dr. Deanna Teoh of the University of Minnesota presented <u>Mindfulness in Patients with Gynecologic Cancer</u>. Almost half of cancer patients report that emotional distress is greater than physical effects. Mindfulness-based programs may increase the ability to cope and reduce stress. High-quality studies are needed to see if mindfulness can improve affect the physical function and outcomes in cancer patients.

Dr. Thomas Smith from Johns Hopkins University presented ongoing research and strategies to prevent and treat neuropathy, as well as <u>his own approach</u> to treating neuropathy.

### Additional ASCO coverage:

OncLive Video—Dr. Douglas Levine on the PARP Inhibitor Landscape for Ovarian Cancer: <a href="https://www.onclive.com/onclive-tv/dr-levine-on-the-parp-inhibitor-landscape-for-ovarian-cancer">https://www.onclive.com/onclive-tv/dr-levine-on-the-parp-inhibitor-landscape-for-ovarian-cancer</a>

ASCO 2018 Opening Ceremony speech by NCI Director Dr. Ned Sharpless. Includes the agency's focus on Basic Science, Big Data, Innovative Clinical Trial Designs and Developing the Workforce of investigators to further progress in cancer research. <a href="https://www.youtube.com/watch?v=ILt8njmNru0">https://www.youtube.com/watch?v=ILt8njmNru0</a>

ASCO 2018 Opening Ceremony speech by FDA Commissioner Dr. Scott Gottlieb. Includes the agency's efforts to streamline the drug review process more efficient while maintaining scientific rigor to serve all patients, including those with rare cancers. <a href="https://www.youtube.com/watch?v=t9jKwlx5MwY">https://www.youtube.com/watch?v=t9jKwlx5MwY</a>

Practice Update ASCO 2018 Best in Ovarian Cancer: <a href="https://www.practiceupdate.com/content/asco-2018-best-in-ovarian-cancer/69767">https://www.practiceupdate.com/content/asco-2018-best-in-ovarian-cancer/69767</a>

Survivor Dee Sparacio follows meetings via Twitter and shares on her Women of Teal Blog: <a href="https://womenofteal.blogspot.com/2018/06/asco18-twitter-highlights-june-1-2-2018.html">https://womenofteal.blogspot.com/2018/06/asco18-twitter-highlights-june-3-2018.html</a> <a href="https://womenofteal.blogspot.com/2018/06/asco18-twitter-highlights-june-4-2018.html">https://womenofteal.blogspot.com/2018/06/asco18-twitter-highlights-june-4-2018.html</a>

#### For more information on finding a clinical trial:

https://ocrfa.org/patients/clinical-trials/look-clinical-trial/