YOUR GUIDE TO THE LATEST CANCER RESEARCH AND TREATMENTS

Highlights from the 2017 Annual Meeting of the American Society of Clinical Oncology

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How To Use This Booklet

Each year, Cancer*Care*® publishes a special edition of the Cancer*Care* Connect Booklet Series that presents research highlights from the Annual Meeting of the American Society of Clinical Oncology. The information contained in these pages is intended for discussion with your doctor. He or she can tell you whether these advances in cancer treatment affect your treatment plan and whether a clinical trial is right for you.

Some of the treatments discussed in this booklet are still in the very early stages of research and may not be available to the general public outside of a clinical trial. The advances in treatment that have come about are because of the many people who have taken part in such studies. If current drugs or other types of cancer treatment no longer benefit you, you may wish to explore joining a clinical trial. The members of your health care team will help you fully understand the possible risks and benefits involved.

On page 59 you will find a list of resources, including websites where you can search for a clinical trial. If your particular type of cancer is not discussed in this booklet and you wish to take part in a study, these websites can help.

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The content of this booklet was taken from Cancer*Care's* two-part Connect Education Workshop 2017 ASCO Highlights series, during which the following leading experts presented:

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The Importance of Clinical Trials

Clinical trials are the standard by which we measure the worth of new treatments and the quality of life of patients as they receive those treatments. For this reason, doctors and researchers urge people with cancer to take part in clinical trials.

Your doctor can guide you in making a decision about whether a clinical trial is right for you. Here are a few things that you should know:

- Often, people who take part in clinical trials gain access to and benefit from new treatments.
- Before you participate in a clinical trial, you will be fully informed as to the risks and benefits of the trial.
- Most clinical trials are designed to test a new treatment against a standard treatment to find out whether the new treatment has any added benefit.
- You can stop taking part in a clinical trial at any time for any reason.

When considering participation in a clinical trial, it's important to consult with your primary care physician and your oncologist, and to make sure that all of your questions are answered.

This is a very exciting time in cancer research, and there are clinical trials underway to study newer treatment approaches, such as immunotherapy and targeted treatments. In immunotherapy, the immune system's ability to seek out and destroy cancer cells is enhanced. Targeted treatments are designed to target the specific cell mechanisms that are important for the growth and survival of tumor cells.

Brain Cancer

Researchers reported a number of important findings in brain cancer treatment at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **A number of studies are evaluating immunotherapy for the treatment of glioblastoma and other high-grade brain tumors** (page 10).
- **The development of personalized peptide vaccines based on specific mutations in glioblastomas is being studied** (page 11).
- **A phase II trial evaluated the anti-tumor effect of the investigational drug VB-111 on recurrent glioblastomas** (page 12).
- **A trial will study whether adding an investigational targeted therapy drug to standard therapy improves the survival of patients with newly-diagnosed, EGFR-positive glioblastoma** (page 12).

Immunotherapy being evaluated in the treatment of glioblastoma and other high-grade brain tumors

Immunotherapy is a promising area of research for the treatment of brain cancer, including glioblastoma and other high-grade brain tumors. There are more than a dozen trials underway that are studying immunotherapies such as T-cell therapies, anti-PD-1 drugs, checkpoint inhibitors, and combinations of different types of immunotherapies.

One of these studies is KEYNOTE-028, which is evaluating the immunotherapy pembrolizumab in patients with recurrent disease. In early results, pembrolizumab produced a higher overall response rate than the FDA-approved bevacizumab, a drug that reduces the blood supply in tumors. Pembrolizumab also showed a more durable response than bevacizumab.

What Patients Need to Know

Pembrolizumab is also being tested as a treatment for glioblastoma in several trials that combine it with bevacizumab, precision radiation, the chemotherapy temozolomide, and other treatments.

Personalized peptide vaccines being studied for the treatment of refractory glioblastomas

A number of studies are focused on identifying specific mutations in refractory (not responding to treatment) glioblastomas and developing personalized peptide vaccines that are matched to the mutation. The specific mutations are identified through "whole genome sequencing," the mapping of a person's unique DNA.

What Patients Need to Know

Peptides are short chains of amino acids; peptide vaccines are designed to mount a response against the glioblastoma tumor. An area of focus is the effectiveness of administering peptide vaccines after other therapies, such as radiation and the chemotherapy temozolomide, and to add immunotherapy to the regimen.

Investigational targeted therapy being tested for the treatment of recurrent glioblastomas

A phase II multi-center trial was designed to determine the safety, tolerability, and efficacy of the investigational targeted therapy VB-111 (ofranergene obadenovec) in patients with recurrent glioblastoma.

A total of 46 patients were enrolled in two cohorts. In the first cohort, patients were treated with one dose of VB-111 and, upon progression of the cancer, were switched to the targeted therapy bevacizumab. In the second cohort, patients continued to receive treatment with VB-111 after progression of the cancer, in combination with bevacizumab.

What Patients Need to Know

The data pointed to a favorable anti-tumor effect of ongoing treatment with VB-111 in terms of both regression rate and overall survival, compared to brief exposure to VB-111 with subsequent bevacizumab monotherapy, and to historical results of bevacizumab monotherapy.

Trial to study addition of targeted therapy drug to standard therapy for newly-diagnosed glioblastomas

The phase IIb/III Intellance1 trial will seek to determine if ABT-414 (depatuxizumab mafodotin), given in combination with radiation and the chemotherapy temozolomide, improves the survival of patients with newly-diagnosed, epidermal growth factor receptor (EGFR)-positive glioblastoma.

Participants in the trial will be randomized to one of two groups, receiving either intravenous ABT-414 combined with the standard therapy of oral temozolomide plus radiation (the experimental group) or oral temozolomide and radiation plus a placebo (the comparison group).

What Patients Need to Know

ABT-414 is an investigational targeted therapy drug; specifically, a monoclonal antibody drug conjugate. Participants in the experimental arm will also receive ABT-414 plus oral temozolomide during a second phase of treatment.

Breast Cancer

Researchers reported a number of important findings in breast cancer treatment at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **A trial showed that the targeted treatment abemaciclib, when given with the targeted treatment fulvestrant, significantly improved progression-free survival in women with ER-positive, HER2-negative advanced breast cancer** (page 15).
- **For women with early-stage HER2-positive breast cancer, the addition of pertuzumab to the standard-of-care trastuzumab may improve outcomes, although the benefit is modest** (page 15).
- **Compared to standard therapy, a phase III trial showed that olaparib prolonged progression-free survival in women with HER2-negative metastatic breast cancer that has a mutation of the BRCA1 or BRCA2 gene** (page 16).
- **A phase II trial showed that the addition of the immunotherapy pembrolizumab to standard therapy was effective in the treatment of women with triple-negative or hormone receptor-positive/HER2-negative breast cancer** (page 17).

Targeted treatments used in combination effective in treating certain types of advanced breast cancer

Both abemaciclib and fulvestrant are targeted treatments called CDK4/6 inhibitors; they are designed to interrupt enzymes that promote the growth of cancer cells. The phase III MONARCH 2 trial showed that abemaciclib, given in combination with fulvestrant, was effective in treating women with ER-positive, HER-2 negative advanced breast cancer whose disease had progressed while being treated with endocrine therapy.

What Patients Need to Know

Progression-free survival (PFS), the length of time that the cancer does not grow or spread, was 16.4 months when abemaciclib and fulvestrant were given in combination, compared to 9.3 months when fulvestrant was given alone. The safety profile of the combination treatment was generally tolerable.

Only modest benefit in adding second drug in treatment of early-stage HER2-positive cancer

The phase III Aphinity trial showed that the addition of pertuzumab to the standard of care trastuzumab in the treatment of early-stage HER2-positive breast cancer reduced the incidence of developing invasive disease, but only by a small percentage. After three years, 94.1 percent of the women who were treated with the two drugs were free of invasive breast cancer, compared with 93.2 percent who were treated with trastuzumab only.

The rates of serious side effects were low in both groups.

What Patients Need to Know

Pertuzumab and trastuzumab are both targeted treatments that find and attach to HER2-positive cancer cells, slowing or stopping their growth. Researchers are continuing to study the possible long-term benefits of using pertuzumab in combination with trastuzumab.

PARP inhibitor prolonged progression-free survival in BRCA-mutated HER2-negative metastatic breast cancer

PARP is a type of enzyme that helps repair DNA. PARP inhibitors are designed to prevent cancer cells from repairing their damaged DNA; this prevention can cause the cancer cells to die.

When compared with standard single agent chemotherapy treatment, the phase III study OlympiAD showed that the PARP inhibitor olaparib prolonged progression-free survival (PFS) in women with HER2-negative metastatic breast cancer containing a mutation of the BRCA1 or BRCA2 gene.

What Patients Need to Know

Median PFS was 2.8 months longer and the risk of disease progression or death was 42 percent lower in the group that received olaparib. Olaparib is currently approved by the FDA for the treatment of BRCA-related ovarian cancer.

Immunotherapy in combination with chemotherapy effective in certain types of breast cancer

The phase II I-SPY 2 trial investigated the use of the immunotherapy pembrolizumab, in combination with standard chemotherapy treatment, as neoadjuvant (pre-surgery) treatment for women with locally advanced triple-negative or hormone receptor-positive/HER2-negative breast cancer.

What Patients Need to Know

The results showed that the addition of pembrolizumab to the chemotherapy regimen tripled the rate of complete pathological response (absence of all detectable cancer). Due to the positive outcome of this early-stage trial, further research will be conducted.

Colorectal Cancer

Researchers reported a number of important findings in colorectal cancer treatment at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **A trial showed that for stage III lymph node-positive colon cancer patients who have a relatively lower risk of recurrence, a shortened course of post-surgery chemotherapy was nearly as effective as the current, longer standard of chemotherapy** (page 18).
- **A phase III trial showed no significant difference in overall survival between two types of immunotherapy (cetuximab and bevacizumab) as part of a first-line treatment regimen for advanced KRAS wild-type colorectal cancer** (page 19).
- **Preliminary data from the phase III BEACON trial supported adding binimetinib to encorafenib and cetuximab in treatment of BRAF-mutated colorectal cancer** (page 20).
- **Nivolumab provided a long-lasting positive response, disease control, and long-term survival in patients with MSI-H mutations who had received at least one prior treatment** (page 21).

Shorter course of chemotherapy post-surgery nearly as effective in certain patients

A study called the IDEA Collaboration, which looked at data from 6 prior studies, showed that 3 months of chemotherapy after surgery was nearly as effective as the current standard of 6 months of chemotherapy in patients with stage III lymph

node-positive colon cancer who have a relatively lower risk of recurrence. Additionally, the shorter course of therapy caused fewer side effects than the longer course.

The standard chemotherapy after colon cancer surgery is a combination of leucovorin, fluorouracil, and oxaliplatin (FOLFOX) or capecitabine and oxaliplatin (CAPOX).

What Patients Need to Know

In patients considered to have a low risk of recurrence, 83.1 percent of patients who received a 3-month course of chemotherapy were free of colon cancer after three years, compared with 83.3 percent who received the standard 6-month course.

No significant difference between cetuximab and bevacizumab in treatment for advanced KRAS wild-type colorectal cancer

A phase III trial concluded that when cetuximab or bevacizumab were added to a first-line chemotherapy regimen for patients with advanced or metastatic KRAS wild-type colorectal cancer, there was no significant difference in overall survival.

In the open-label trial, 1,137 patients chose to receive one of two standard chemotherapy regimens: leucovorin, fluorouracil, and oxaliplatin (FOLFOX) or leucovorin, fluorouracil, and irinotecan (FOLFIRI). They were then randomized to receive cetuximab or bevacizumab.

What Patients Need to Know

Median overall survival was 30 months in the cetuximab group vs. 29 months in the bevacizumab group.

Results of phase III trial showed benefit of 3-drug combination for BRAF-mutated colorectal cancer

Patients with BRAF-mutated colorectal cancer often do not respond to some of the currently available treatments.

The randomized phase III BEACON trial evaluated the combination of binimetinib, encorafenib, and cetuximab vs. encorafenib and cetuximab in patients with BRAF-mutated colorectal cancer, whose disease had progressed after one or two prior treatment regimens.

What Patients Need to Know

Preliminary trial data supported the benefit of adding binimetinib to encorafenib and cetuximab, and the 3-drug combination was found to be well tolerated.

Nivolumab studied in the treatment of MSI-H metastatic colorectal cancer

About 4 percent of patients with metastatic colorectal cancer have a type called microsatellite instability high (MSI-H), caused by a deficiency in the DNA mismatch repair system. These patients may be less responsive to conventional chemotherapy than patients who do not have this type of metastatic colorectal cancer.

According to updated results from the CheckMate 142 trial, nivolumab, an immunotherapy treatment, provided a long-lasting positive response, disease control, and long-term survival in patients with MSI-H metastatic colorectal cancer who had received at least one prior treatment.

What Patients Need to Know

A recent amendment to the National Comprehensive Cancer Network (NCCN) guidelines recommended that all metastatic colorectal cancer patients be tested for MSI-H, and that patients with MSI-H colorectal cancer be considered, after initial treatment, for either nivolumab or pembrolizumab (another immunotherapy treatment).

Leukemia

Researchers reported a number of important findings in leukemia treatment at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **A CAR-T therapy, tisagenlecleucel, has been approved by the FDA for the treatment of B cell precursor acute lymphoblastic leukemia** (page 22).
- **A small, early-stage trial is studying the use of CAR-T cell therapy to treat multiple myeloma, with promising results** (page 24).
- **A phase III trial showed that bosutinib, as a first-line treatment for chronic myelogenous leukemia, results in higher rates of major molecule response than imatinib, but with an increase in certain side effects** (page 24).

CAR-T cell therapy approved for B cell precursor acute lymphoblastic leukemia

Tisagenlecleucel, a chimeric antigen receptor (CAR) T cell therapy, has been approved by the FDA for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that has recurred more than once or is refractory (not responding to treatment).

CAR-T cell therapy is an immunotherapy that uses a patient's own T cells to directly target cancer. Tisagenlecleucel reprograms the patient's T cells with a transgene that encodes a CAR, while identifying and removing cancerous cells that express the B-lymphocyte antigen CD19, a protein found on the surface of B cells.

What Patients Need to Know

Certain steps are followed in CAR-T cell therapy, including drawing blood, separating out and genetically modifying the T cells, multiplying those cells in a laboratory, and infusing them back into the patient, where they attack cancer cells.

CAR-T cell therapy studied for treatment of multiple myeloma

In an ongoing phase I trial in China, 33 out of 35 (94 percent) of patients had clinical remission of multiple myeloma, a blood cancer related to lymphoma and leukemia, upon receiving chimeric antigen receptor (CAR) T cell therapy that targeted the B cell maturation protein (BCMA). The first signs of treatment efficacy appeared as early as 10 days after the initial injection of CAR-T cells, and most patients had only mild side effects.

What Patients Need to Know

Although this was a small, early-stage trial, the data presented held promise that CAR-T cell therapy can send multiple myeloma into remission, and that this type of immunotherapy may be helpful in treating many types of cancers.

Phase III trial compared bosutinib to imatinib in newly diagnosed chronic myeloid leukemia

In patients with newly diagnosed chronic myeloid leukemia (CML), the open-label, randomized phase III trial BFORE evaluated the targeted treatment bosutinib as a first-line treatment compared to the chemotherapy imatinib. The results showed that a 400-mg dose of bosutinib was associated with higher rates of major molecular response (MMR) and complete cytogenetic response (CCyR) than imatinib.

What Patients Need to Know

Dose interruptions and dose reductions were more frequent with bosutinib than with imatinib, and higher rates of gastrointestinal events and liver enzyme abnormalities were recorded in patients who received bosutinib.

Lung Cancer

Researchers reported a number of important findings in lung cancer treatment at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **The first-line standard of care may be changing for non-small cell lung cancer patients with the anaplastic lymphoma kinase (ALK) gene** (page 25).
- **A trial concluded that some patients can resume immunotherapy after their side effects have been resolved** (page 26).
- **A trial showed that immunotherapy with a PD-1 inhibitor is safe and feasible prior to surgery for non-small cell lung cancer** (page 27).
- **For specific stages of EGFR-positive non-small cell lung cancer, a phase III clinical trial showed that targeted treatment after surgery increases disease-free survival as compared to chemotherapy** (page 27).
- **A study showed that using a web-based tool to communicate symptoms improved survival in patients with metastatic lung cancer** (page 28).

Alectinib may become the first-line standard of care for ALK-positive non-small cell lung cancer (NSCLC)

The ALK-inhibitor alectinib is approved by the FDA as a second-line treatment for ALK-positive NSCLC in patients whose disease has progressed after being treated with the first-line treatment crizotinib.

The randomized open-label phase III J-ALEX trial, consisting of just over 200 patients, compared alectinib to the ALK-inhibitor crizotinib as a front-line treatment for ALK-positive NSCLC. Compared to crizotinib, alectinib reduced the risk of disease progression or death, with fewer side effects.

What Patients Need to Know

In September 2016, the FDA granted alectinib Breakthrough Therapy Designation (BTD) for the first-line treatment of people with advanced ALK-positive NSCLC, and the latest results from the J-ALEX trial will be submitted to the agency for evaluation.

Trial evaluated the safety of resuming immunotherapy after side effects have resolved

"Checkpoint inhibitors," a type of immunotherapy, are an effective treatment option for some patients with lung cancer, but one-quarter to one-third of these patients will develop side effects that result in the stoppage of treatment.

The RETROSPECTIVE trial was conducted to determine if treatment can safely resume for these patients once the side effects are resolved. The trial determined that resuming treatment is feasible and safe (with some caveats) in selected patients with non-small cell lung cancer (NSCLC) treated with anti-programmed cell death protein 1 (PD-1) and anti-programmed cell death ligand 1 (PD-L1) checkpoint inhibitors.

What Patients Need to Know

The RETROSPECTIVE trial also indicated that resuming treatment may not add any additional benefit if the patient was an "early responder" to the immunotherapy, and had experienced a major shrinkage of the cancer.

As additional side effects could be experienced, the decision whether or not to resume treatment is made on a case-by-case basis.

Nivolumab before surgery is safe and feasible for early non-small cell lung cancer (NSCLC)

Results of a new trial indicated that neoadjuvant (prior to surgery) immunotherapy with nivolumab, an immunotherapy treatment, is safe and feasible for early stage NSCLC. This was the first trial of this type of drug as neoadjuvant therapy in early stage lung cancer; previous studies were conducted on the effect of nivolumab and similar immunotherapy drugs in metastatic or advanced lung cancer.

What Patients Need to Know

The trial included 20 patients who received two doses of nivolumab at four and two weeks prior to surgical resection of the tumor. The trial found that there were no significant safety concerns and that the treatment was feasible, as it did not delay surgery.

Post-surgery, the targeted therapy gefitinib appears to be more effective than chemotherapy in preventing recurrence of EGFR-positive NSCLC

Chemotherapy is the current standard of care in preventing recurrence of lung cancer after surgery. A phase III clinical trial showed that the targeted treatment gefitinib appears to be more effective than chemotherapy for patients with epidermal growth factor (EGFR)-positive, stage II to stage IIIA non-small cell lung cancer (NSCLC).

What Patients Need to Know

The median time for disease-free survival was 28.7 months for patients who received gefitinib after surgery, compared to 18 months for patients who received chemotherapy after surgery. With gefitinib, 12 percent of patients experienced severe side effects, compared to 48 percent with chemotherapy.

Web-based tool to communicate symptoms improves survival in patients being treated for metastatic lung cancer

According to the findings of a randomized trial, patients receiving treatment for metastatic lung cancer who used a web-based tool to report their symptoms to their health care team lived an average of five months longer than patients whose symptoms were monitored in a standard way.

The results showed that patients who used the tool were also able to stay on their chemotherapy longer, had fewer emergency visits, and experienced better quality of life and physical function.

What Patients Need to Know

Between visits, patients who are experiencing symptoms are often hesitant to contact their health care team unless those symptoms become severe. Even during visits, symptoms are often not fully communicated. The web-based tool allowed for better communication between patient and their health care team.

Lymphoma

Researchers reported a number of important findings in lymphoma treatment at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **In a phase III trial, brentuximab vedotin showed promise as part of a frontline chemotherapy regimen for advanced classical Hodgkin lymphoma** (page 30).
- **Copanlisib, a targeted treatment, was approved by the FDA for the treatment of adults with relapsed follicular lymphoma who have received at least two prior systemic therapies** (page 30).
- **A phase IIIb trial showed that treatment with a combination of lenalidomide and rituximab resulted in favorable activity and tolerability in patients with refractory or relapsing follicular lymphoma** (page 31).
- **A phase I trial evaluated venetoclax, a targeted treatment, in patients with multiple subtypes of relapsed or refractory non-Hodgkin lymphoma; further studies are ongoing** (page 32).
- **A CAR-T therapy, axicabtagene ciloleucel, has been approved by the FDA for the treatment of patients with certain types of large B-cell lymphomas** (page 32).

Brentuximab vedotin evaluated as part of a frontline chemotherapy regimen for advanced classical Hodgkin lymphoma

ECHELON-1 is a randomized, multicenter phase III trial designed to evaluate brentuximab vedotin as part of a frontline chemotherapy regimen for previously untreated advanced classical Hodgkin lymphoma (HL).

The trial compared the combination of AVD (adriamycin, vinblastine and dacarbazine) plus brentuximab vedotin to the current standard of care, ABVD (AVD plus bleomycin).

What Patients Need to Know

Trial participants treated with AVD plus brentuximab vedotin demonstrated a statistically significant improvement in modified progression-free survival (the length of time that the cancer does not grow or spread) compared to those treated with ABVD.

The safety profile of brentuximab vedotin in combination with AVD appeared consistent with what was previously found for brentuximab vedotin used as single agent.

Copanlisib granted accelerated approval for treatment of relapsed follicular lymphoma

The CHRONOS-1 trial studied copanlisib for the treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma who had received at least two prior treatment types. Copanlisib is a targeted treatment that works by blocking several enzymes that promote cell growth.

In the trial, 59 percent of patients had a complete or partial response for a median of 12.2 months.

What Patients Need to Know

In September 2017, the FDA granted accelerated approval to copanlisib for the treatment of adults with relapsed follicular lymphoma who had received at least two prior systemic therapies. Further trials are required to confirm copanlisib's clinical benefit.

Combination of lenalidomide and rituximab showed favorable results for treatment of follicular lymphoma

The phase IIIb MAGNIFY trial showed that treatment with a combination of the chemotherapy lenalidomide and the antibody therapy rituximab, followed by maintenance therapy, resulted in favorable activity and tolerability in patients with refractory (not responding to treatment) or relapsing follicular lymphoma.

The MAGNIFY trial is also evaluating the combination of lenalidomide and rituximab followed by maintenance therapy in patients with marginal zone lymphoma and mantle cell lymphoma.

What Patients Need to Know

The primary endpoint of the trial was progression-free survival (PFS), the length of time that the cancer does not grow or spread. The 1-year PFS was 70 percent for all follicular lymphoma patients, 65 percent for double-refractory follicular lymphoma patients, and 49 percent for early-relapse follicular lymphoma patients.

Venetoclax studied for treatment of NHL subtypes

A phase I trial evaluated the targeted treatment venetoclax in patients with relapsed or refractory (not responding to treatment) non-Hodgkin lymphoma (NHL), including those with mantle cell lymphoma, follicular lymphoma, diffuse large B-cell lymphoma, marginal zone lymphoma, and Waldenstrom macroglobulinemia.

Early results suggest a favorable response rate, but further studies of venetoclax (alone and in combination therapy) are ongoing.

What Patients Need to Know

In April 2016, the FDA approved venetoclax for the treatment of patients with chronic lymphocytic leukemia (CLL) who have the "17p deletion" chromosomal abnormality and who have been treated with at least one prior therapy.

CAR-T cell therapy approved for certain large B-cell lymphomas

Chimeric antigen receptor (CAR) T cell therapy is a type of immunotherapy that uses a patient's own T-cells to directly target lymphomas. The most common target of CAR-T cell therapies is the B-lymphocyte antigen CD19, a protein found on the surface of nearly all B-cell lymphomas.

A CAR-T therapy, axicabtagene ciloleucel, has been approved by the FDA for the treatment of patients with certain types of large

B-cell lymphomas that are refractory (not responding to treatment) or that have recurred after at least two other kinds of treatment.

What Patients Need to Know

Certain steps are followed in CAR-T cell therapy, including drawing blood, separating out and genetically modifying the T cells, multiplying those cells in a laboratory, and infusing them back into the patient, where they attack cancer cells.

CAR-T cell therapy continues to be studied as a treatment approach for other types of lymphoma.

Melanoma

Researchers reported a number of important findings in melanoma treatment at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **A phase III trial, MSLT-II, concluded that, compared to ongoing monitoring, "completion dissection" (the removal of the remaining lymph nodes after sentinel node removal) in sentinel node metastasis was not associated with increased survival** (page 34).
- **Higher-dose ipilimumab administered after resection (removal) did not improve recurrence-free survival and resulted in more toxicity** (page 35).
- **Results from the CheckMate 238 trial showed that post-resection nivolumab is superior to the standard of care in patients with stage III/IV melanoma who are at high risk of relapse** (page 36).
- **The COMBI-AD trial showed that the targeted therapies dabrafenib and trametinib, used in combination to treat stage III BRAF-mutant melanoma, had a clear advantage over placebo (a look-alike containing no active ingredient) in recurrence-free survival and other trial endpoints** (page 36).

"Completion dissection" not associated with increased survival in sentinel node metastasis

Sentinel nodes are the first few lymph nodes into which a tumor drains. In melanoma patients with sentinel node metastasis, the results of the phase III MSLT-II trial showed that "completion dissection" (the removal of the remaining lymph nodes after

sentinel node removal) was not associated with increased melanoma-specific survival, compared to ongoing monitoring.

What Patients Need to Know

The investigators concluded that while immediate completion dissection did not increase survival in melanoma patients with sentinel node metastasis, it did increase the rate of regional disease control (the prevention of the cancer spreading to nearby parts of the body) and provided information about the patient's prognosis.

Higher-dose adjuvant ipilimumab did not improve recurrence-free survival

A randomized phase III trial, E1609, compared ipilimumab, a type of immunotherapy, for resected (removed) high-risk melanoma at doses of 3mg/kg and 10mg/kg. The results showed that the higher dose of ipilimumab did not improve recurrence-free survival (RFS). The 3-year RFS rate was 54 percent with the 10mg/kg dose and 56 percent with the 3mg/kg dose.

What Patients Need to Know

Adjuvant (post-resection) ipilimumab administered in the higher dose was associated with higher rates of serious treatment-related adverse events: 57 percent as compared to 36.4 percent in the patients who received the lower dose. Discontinuation of treatment was also higher with the 10mg/kg dose: 53.8 percent compared to 35.2 percent with the 3mg/kg dose.

Study showed that adjuvant nivolumab is superior to the standard of care in a subset of melanoma patients

Results from the randomized, double-blind, phase III CheckMate 238 trial showed that using nivolumab after resection was better than the standard of care (ipilimumab) in patients with stage III/IV melanoma who are at high risk of relapse. Nivolumab led to better relapse-free survival than did ipilimumab, with fewer side effects.

What Patients Need to Know

Adjuvant therapy is given after initial cancer treatment with the goal of preventing metastases (the spread of the cancer to another part of the body). Both nivolumab and ipilimumab are immunotherapies, and both are approved by the FDA for the treatment of metastatic melanoma.

Targeted therapies had clear advantage over placebo in treatment of BRAF-mutant melanoma

The phase III trial COMBI-AD compared the combination of targeted therapies dabrafenib and trametinib to a placebo (a look-alike containing no active ingredient) in patients with stage III BRAF-mutant melanoma who had previously undergone complete resection (removal) of their melanoma. The treatment duration was one year and the primary endpoint was relapse-free survival (RFS).

What Patients Need to Know

The combination of dabrafenib and trametinib had a clear advantage over placebo in RFS and other trial endpoints, such as distant metastases-free survival (surviving without the cancer spreading to other parts of the body) and overall survival.

Myeloproliferative Neoplasms

Researchers reported a number of important findings in the treatment of myeloproliferative neoplasms (MPNS) at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **A phase III trial studied an extended-release anagrelide (blood thinner) formulation and results supported early intervention for certain essential thrombocythemia (ET) patients** (page 38).
- **A randomized phase III trial did not show that pegylated interferon-alpha-2a was superior to hydroxyurea in the frontline treatment of patients with high-risk essential thrombocythemia and high-risk polycythemia vera** (page 39).
- **The results of a phase III trial showed that ruxolitinib, as a second-line therapy for polycythemia vera, provided rapid and durable clinical benefits** (page 39).
- **In a phase III trial, the investigational drug pacritinib achieved significant reduction in spleen volume in myelofibrosis patients with low blood platelet counts** (page 40).

Anagrelide formulation compared to placebo in intermediate risk essential thrombocythemia

The randomized, multicenter phase III trial ARETA compared a novel, extended-release anagrelide (blood thinner) formulation to a placebo (a look-alike containing no active ingredient) for early intervention in essential thrombocythemia (ET) patients with intermediate risk status. The results showed platelet count normalization and delayed progression to high risk status.

What Patients Need to Know

Data from ARETA supported the "treat early" concept for ET patients for whom the reduction of platelet counts and/or symptoms is a goal. Additionally, the extended-release anagrelide formulation was found to be as safe as the immediate-release formulations.

Pegylated interferon-alpha-2a compared with hydroxyurea in the treatment of high-risk essential thrombocythemia and polycythemia vera

A randomized phase III trial, MPD-RC 112, compared pegylated interferon-alpha-2a (an antiviral medication approved by the FDA to treat hepatitis C and hepatitis B) with the chemotherapy hydroxyurea in the frontline treatment of patients with high-risk essential thrombocythemia (ET) and high-risk polycythemia vera (PV). The comparison of these drugs is important because of their different mechanisms of action and toxicity profiles.

What Patients Need to Know

Interim trial results indicated that both drugs were active in controlling platelet counts and helping to decrease the risk of blood clots and bleeding, but it was not clear if one drug was superior to the other. It is not yet known whether pegylated interferon-alpha-2a will provide better long-term disease control than hydroxyurea; this will be continued to be studied in the MPD-RC 112 trial.

Ruxolitinib studied as second-line therapy for advanced polycythemia vera

RESPONSE 2, a global, randomized phase III trial, compared ruxolitinib with the best available therapy in patients with advanced polycythemia vera (PV) whose disease is resistant to the chemotherapy hydroxyurea.

The results showed that ruxolitinib, as a second-line therapy, provided rapid and durable clinical benefits and was superior to the best available therapy at controlling the volume of red blood cells and improving spleen enlargement.

What Patients Need to Know

The RESPONSE 2 trial also included patients who could not continue to take hydroxyurea because of side effects. Results from the trial indicated that ruxolitinib was generally well tolerated.

Phase III trial compared pacritinib to best available therapy in subset of myelofibrosis patients

The phase III PERSIST-2 trial compared the investigational drug pacritinib with the best available therapy in the treatment of high-risk myelofibrosis patients who have thrombocytopenia (a low blood platelet count).

Pacritinib met the primary endpoint of the trial, achieving a significant reduction in spleen volume as compared with the best available therapy, including the targeted treatment ruxolitinib.

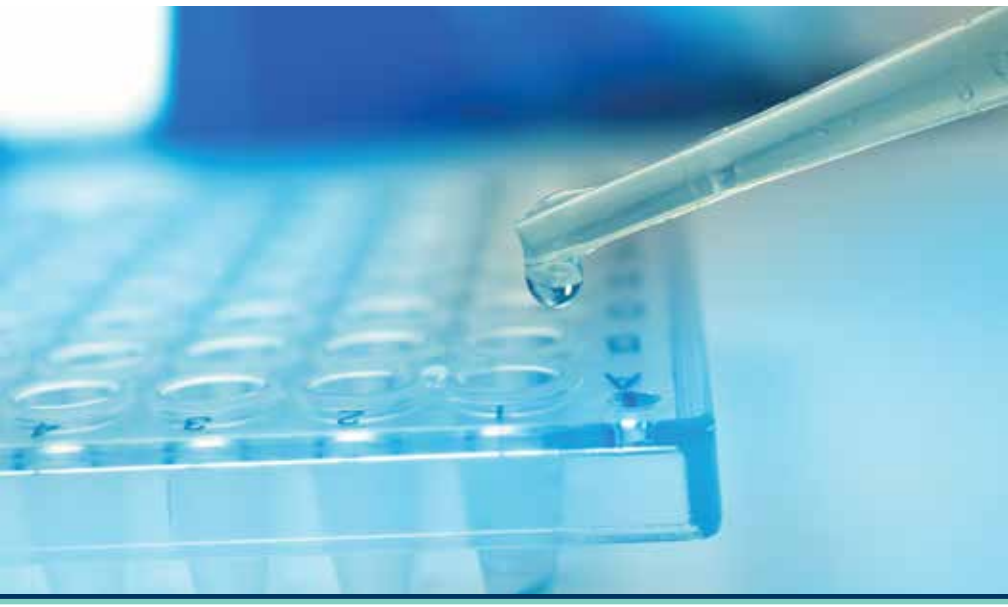
What Patients Need to Know

Ruxolitinib is approved by the FDA for treatment of intermediate-risk or high-risk myelofibrosis, but it is not indicated for people with thrombocytopenia. Research is continuing to determine if pacritinib might play a role in the treatment of this group of patients.

Oral, Neck, and Head Cancers

Researchers reported a number of important findings in the treatment of oral, neck, and head cancers at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **Results from a phase III trial showed the immunotherapy nivolumab improved overall survival in patients with recurrent or metastatic head and neck cancer** (page 42).
- **A phase III trial is studying the immunotherapy durvalumab compared to standard treatment as first-line therapy for recurrent or metastatic head and neck squamous cell carcinomas** (page 42).
- **An ongoing phase II trial is evaluating the effectiveness of chemotherapy followed by immunotherapy in treating patients with stage III or IV human papillomavirus (HPV)-related oropharyngeal cancer** (page 43).



Trial shows immunotherapy drug improved overall survival in certain head and neck cancers

The randomized phase III trial CheckMate 141 trial showed that the immunotherapy nivolumab improved overall survival in patients with current or metastatic head and neck cancer when compared with a single-agent chemotherapy.

What Patients Need to Know

CheckMate 141 compared nivolumab with one of three single-agent chemotherapies (cetuximab, methotrexate, or docetaxel) in 361 patients with disease that had progressed within 6 months of platinum-based therapy. Overall survival was determined to be significantly longer with nivolumab compared with the standard single-agent chemotherapy.

Immunotherapy being evaluated in first-line setting for recurrent or metastatic head and neck squamous cell carcinomas

Results are pending from the global, multi-center, phase III KESTREL trial that evaluated the immunotherapy durvalumab,

with or without the immunotherapy tremelimumab, as a first-line treatment for recurrent or metastatic head and neck squamous cell carcinomas.

Durvalumab was compared with the standard treatment of platinum-based chemotherapy plus cetuximab, another type of chemotherapy.

What Patients Need to Know

The results of the KESTREL trial are highly anticipated, as immunotherapy in the first-line setting is a new approach in the treatment of head and neck cancers. The primary endpoints of the trial are progression-free survival and overall survival.

Effectiveness of chemotherapy and immunotherapy studied in patients with certain forms of oropharyngeal cancer

The ongoing phase II trial OPTIMA is evaluating the effectiveness of the chemotherapies nab-paclitaxel and carboplatin followed by the immunotherapy nivolumab in treating patients with stage III or IV human papillomavirus (HPV)-related oropharyngeal cancer (cancer that forms in the tissues of the throat). Depending on the response to this initial regimen, patients receive a specific form and dose of radiation or chemoradiotherapy.

What Patients Need to Know

Giving nab-paclitaxel and carboplatin followed by nivolumab may make tumors smaller, reducing the amount of chemotherapy and radiation therapy subsequently needed. Giving lower doses of radiation or chemoradiotherapy to patients who are responding well to the initial regimen may help reduce the occurrence of side effects.

Ovarian Cancer

Researchers reported a number of important findings in the treatment of ovarian cancer at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **Data pooled from prior analyses showed that an antibody-drug conjugate may complement available therapies in the treatment of FRα-positive epithelial ovarian cancer (EOC)** (page 44).
- **Research is ongoing on how to best incorporate immunotherapy into the treatment of ovarian cancer** (page 45).
- **An ongoing trial is assessing an approach that employs T-cell engineering to stimulate the immune system against ovarian cancer** (page 46).
- **A trial showed the targeted therapy cediranib was not associated with significant improvement in overall survival in women with platinum-sensitive relapsed ovarian cancer** (page 46).

Investigational drug shows promise in the treatment of platinum-resistant FRα-positive epithelial ovarian cancer

A review of data pooled from four prior analyses showed promising safety and efficacy of mirvetuximab soravtansine for the treatment of FRα-positive epithelial ovarian cancer (EOC) that had become resistant to platinum compounds, such as cisplatin or carboplatin.

Mirvetuximab soravtansine is an investigational drug belonging to a class of medications known as antibody-drug conjugates (ADCs). The data showed that mirvetuximab soravtansine may complement available treatments, particularly the targeted therapy bevacizumab and the immunotherapy pembrolizumab.

What Patients Need to Know

The data observed with mirvetuximab soravtansine showed results consistent with outcomes typically achieved with currently available single-agent therapies for platinum-resistant ovarian cancer. Additional studies are planned.

Immunotherapy continues to be studied as a treatment approach for ovarian cancer

Although chemotherapy has proven to be effective in treating ovarian cancer, there is a high risk of recurrence and few options for treatment if the cancer does recur. As ovarian cancer is an immune-dependent cancer, immunotherapy is being studied as an alternative treatment approach.

Early findings have been encouraging, and have led to ongoing research on how best to incorporate immunotherapy into the treatment of ovarian cancer.

What Patients Need to Know

Several ongoing clinical trials are exploring the immunotherapy nivolumab, in combination with other immunotherapies, for women with recurrent ovarian cancer.

T-cell engineering being studied for recurrent, treatment-resistant ovarian cancer

The premise behind an ongoing phase I/II clinical trial is to "teach" the immune system of patients with recurrent or treatment-resistant ovarian cancer to recognize and attack ovarian cancer cells. The approach uses T cell engineering, in which a patient's blood is drawn, the T cells separated out and modified, and then infused back into the patient.

What Patients Need to Know

The trial is assessing both the safety and antitumor activity of engineering T cells (a type of white blood cell) as a treatment approach for recurrent or treatment-resistant ovarian cancer.

Targeted therapy cediranib not associated with significant improvement in overall survival in relapsed ovarian cancer

According to data from the ICON6 trial, the investigational targeted therapy cediranib, used as a maintenance therapy, was not associated with a statistically significant improvement in overall survival (OS) in women with platinum-sensitive relapsed ovarian cancer.

At a median follow-up of 25.6 months, the OS results for maintenance cediranib, given concurrently with chemotherapy, were not significantly better than the results for chemotherapy and placebo.

What Patients Need to Know

Cediranib, an oral drug, is a type of targeted therapy called a vascular endothelial growth factor receptor (VEGFR)-2 inhibitor. Cediranib maintenance therapy is undergoing further study in the clinical trial ICON9.

Pancreatic Cancer

Researchers reported a number of important findings in pancreatic cancer treatment at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **The immunotherapy pembrolizumab is being studied for the treatment of pancreatic cancer tumors with mismatch-repair (MMR) deficiency** (page 48).
- **A phase II trial showed that adding an experimental drug called PEGPH20 to a standard chemotherapy regimen increased progression-free survival (the length of time that the cancer does not grow or spread) in a subset of patients with metastatic pancreatic cancer** (page 48).
- **Platinum agents and/or PARP inhibitors are being tested in the treatment of pancreatic cancer that has the BRCA2 mutation** (page 49).
- **The immunotherapy pegilodecakin, in combination with a chemotherapy regimen, is being evaluated in clinical trials with promising results** (page 49).

Pembrolizumab is being studied for treatment of certain pancreatic cancer tumors

The immunotherapy pembrolizumab is being studied for the treatment of pancreatic cancer tumors (as well as other solid tumors) with mismatch-repair (MMR) deficiency. In the trial, all patients had received at least one prior treatment and had evidence of progressive disease.

What Patients Need to Know

Early results found pembrolizumab to be "active" across a range of solid tumors with MMR deficiency, in terms of objective response, complete response, and disease stabilization. Other cancer types being studied include colorectal, osteosarcoma, gastroesophageal, and prostate.

Experimental drug increases progression-free survival in subset of patients with metastatic disease

According to a phase II clinical trial, adding an experimental drug called pegylated recombinant human hyaluronidase (PEGPH20) to a standard chemotherapy regimen increased progression-free survival (the length of time that the cancer does not grow or spread) in a subset of patients with metastatic pancreatic cancer. PEGPH20 is designed to reduce the high internal pressure that can collapse blood vessels and prevent cancer-killing drugs from penetrating the tumor.

What Patients Need to Know

When given to trial participants whose tumors had high levels of PEGPH20's target molecule, those participants had 4 more months of progression-free survival than did those in the control group, who received only standard chemotherapy. Based on these results, the research will continue in phase III trials.

Promising activity in DNA repair for pancreatic cancer

There is growing interest in DNA repair as a therapy for pancreatic cancer. Ongoing clinical trials are testing platinum agents and/or PARP inhibitors in the subset of patients with BRCA2 or other gene mutations.

What Patients Need to Know

About 9 percent of patients with pancreatic cancer have BRCA1/BRCA2 gene mutations. Targeting the pancreatic cancer "microenvironment" is an active area of research, with early evidence of promising activity.

Immunotherapy being evaluated in combination with chemotherapy regimen

In ongoing trials, the immunotherapy pegilodecakin (PEGylated human interleukin-10) is being evaluated in combination with the chemotherapy FOLFOX (leucovorin, fluorouracil, and oxaliplatin) as treatment for patients with advanced pancreatic cancer.

What Patients Need to Know

The combination of pegilodecakin and FOLFOX is being evaluated in phase I/Ib and phase III clinical trials. It has demonstrated promising efficacy and safety data, with a 1-year survival rate of 47 percent.

Prostate Cancer

Researchers reported a number of important findings in prostate cancer treatment at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **Results from two trials suggested that men with high-risk metastatic prostate cancer benefit from the addition of abiraterone to standard hormonal therapy** (page 50).
- **A phase III trial is investigating the targeted therapy rucaparib for the treatment of metastatic prostate cancer with specific gene mutations** (page 51).
- **Studies indicated that new guidelines for genetic testing are needed** (page 52).

Adding abiraterone to standard therapy for men with high-risk metastatic disease improves overall survival

According to results from the LATITUDE and STAMPEDE clinical trials, adding the drug abiraterone to the current standard of care (hormonal therapy) had benefit in the treatment of men with locally advanced or hormone-sensitive metastatic prostate cancer.

The STAMPEDE trial showed that adding abiraterone to standard hormonal therapy resulted in an improvement in overall survival (OS) of 37 percent. In the LATITUDE trial, the OS rate at three years was 66 percent with abiraterone and prednisone, compared to 49 percent with standard hormonal therapy.

In the last few years, the chemotherapy docetaxel has been added to hormonal therapy for some patients with significantly advanced disease. The results of the LATITUDE and STAMPEDE trials suggested that abiraterone added to hormonal therapy results in a level of effectiveness comparable to hormonal therapy plus docetaxel, with fewer side effects.

What Patients Need to Know

While abiraterone was found to be generally well-tolerated, several severe side effects were more common when abiraterone was added to the standard hormonal therapy, including high blood pressure, low potassium level, and liver enzyme abnormalities.

Targeted therapy being studied for treatment of gene-mutated mCRPC

A phase III trial, TRITON3, is investigating the targeted therapy rucaparib for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in men who received hormonal therapy as initial treatment, and who have a mutation in the BRCA1, BRCA2, or ATM genes.

The trial will compare the effectiveness of rucaparib as a single agent against one of three standard drugs: abiraterone or enzalutamide (both of which are hormonal treatments) or the chemotherapy docetaxel.

Rucaparib is a PARP inhibitor. This type of drug is designed to prevent cancer cells from repairing their damaged DNA; this prevention can cause the cancer cells to die.

What Patients Need to Know

In December 2016, the Food and Drug Administration (FDA) approved rucaparib for the treatment of women with recurrent ovarian cancer that expresses BRCA gene mutations. Prior studies have shown PARP inhibitors to be effective in treating mCRPC.

Studies show that reevaluation of genetic testing protocols is needed

Recent studies have shown that a substantial percentage of prostate cancer patients have clinically significant genetic variants that would not have been identified through genetic testing.

In some cases, the variants would have been missed because, under current guidelines, patients would not be considered qualified to undergo genetic testing. One study found that 17.2 percent of patients exhibited genetic variants across a number of genes; among these patients, 37 percent would not have qualified for testing under current guidelines.

In other cases, the patient does qualify for genetic testing, but has variants that are not included in the testing. The only two genes tested under current guidelines are BRCA1/2, but the majority of variants (66 percent) occur in genes other than BRCA1/2.

What Patients Need to Know

The conclusion from the studies is that a reevaluation is needed of how prostate patients are tested for genetic variants. Gene variations may be associated with more aggressive disease, and information about those variants has implications for treatment decisions.

Sarcoma

Researchers reported a number of important findings in the treatment of sarcoma (cancers of the body's connective tissue) at the 2017 Annual Meeting of the American Society of Clinical Oncology:

- **Results from a phase II trial showed that the immunotherapy pembrolizumab is a potentially viable treatment for a subset of sarcomas** (page 54).
- **The combination of two immunotherapies, nivolumab and ipilimumab, was tested in patients with metastatic sarcoma** (page 55).
- **A phase III trial evaluated the chemotherapy aldoxorubicin as treatment for relapsed/refractory soft tissue sarcomas** (page 56).
- **A phase I trial evaluated the investigational drug BLU-285 as a treatment for advanced gastrointestinal stromal tumors (GIST)** (page 56).

Pembrolizumab shows promise in phase II trial for subset of sarcomas

SARC028 is a phase II multicenter trial that evaluated the immunotherapy pembrolizumab given as a single agent in patients with advanced soft tissue sarcomas and bone sarcomas. The trial's primary endpoint (assessment goal) was objective response rate. Secondary endpoints included progression-free survival and overall survival.

What Patients Need to Know

Pembrolizumab is a type of immunotherapy called a PD-1 checkpoint inhibitor. SARC028 showed that the drug is a potentially viable treatment for a subset of sarcomas, with promising activity in undifferentiated pleomorphic sarcoma (UPS) and liposarcoma.

Immunotherapy drugs given in combination evaluated in metastatic sarcoma

A phase II multicenter trial, ALLIANCE A091401, evaluated the combination of the immunotherapies nivolumab and ipilimumab in patients with heavily treated metastatic sarcoma.

What Patients Need to Know

The combination of nivolumab plus ipilimumab induced an objective response rate (ORR) of 16 percent, compared to an ORR of 5 percent with nivolumab given as a single agent. Researchers reported that the combination of immunotherapies had a manageable toxicity profile, as determined by the number and severity of adverse events.

Investigational chemotherapy evaluated in treatment of soft tissue sarcomas

A phase III trial showed that the investigational chemotherapy aldoxorubicin prolonged progression-free survival (PFS) in patients with liposarcoma and leiomyosarcoma (L-sarcoma), compared with standard chemotherapy treatments.

The trial compared aldoxorubicin, given every 3 weeks, with the investigator's choice of pazopanib, gemcitabine/docetaxel, dacarbazine, doxorubicin, or ifosfamide.

What Patients Need to Know

In addition to prolonging PFS, aldoxorubicin had a favorable cardiac toxicity profile as compared to doxorubicin.

Drug evaluated for treatment of advanced gastrointestinal stromal tumors (GIST)

Phase I findings from a trial evaluating the investigational drug BLU-285 in patients with advanced gastrointestinal stromal tumors (GIST) supported earlier findings that the drug exhibited strong clinical activity and an encouraging safety profile.

BLU-285 is a selective KIT and PDGFRα inhibitor. An estimated 80 percent of GISTs have a mutation of the KIT gene, and 10 percent have a mutation of the PDGFRα gene.

What Patients Need to Know

A global, randomized phase III clinical trial of BLU-285 as a third-line treatment for GIST is planned for the first half of 2018.

Notes

Resources

Cancer*Care*®
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www.cancercare.org

American Cancer Society
800-227-2345
www.cancer.org

Cancer.Net
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Cancer Support Community
888-793-9355
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National Cancer Institute
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National Comprehensive Cancer Network
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