

Your Guide to the Latest Cancer Research and Treatments

Highlights From the
2014 Annual Meeting
of the American Society
of Clinical Oncology



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This special edition of the CancerCare Connect Booklet Series highlights cutting-edge research presented at the 2014 Annual Meeting of the American Society of Clinical Oncology, which took place May 30 to June 3 in Chicago, Illinois.

The CancerCare Connect Booklet Series offers up-to-date, easy-to-read information on the latest treatments, managing side effects and coping with cancer.

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Your Guide to the Latest Cancer Research and Treatments

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How to Use This Booklet

Each year, CancerCare® publishes a special edition of the CancerCare 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 77, 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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Brain Cancer

Researchers reported a number of important findings in brain cancer treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

According to three separate clinical trials, using vaccines alone or combined with other treatments can increase survival in patients with glioblastoma, a common and fast-growing type of brain tumor. More research is needed to confirm the results from these early studies (*page 7*).

When combined with temozolomide, a new medication called ABT-414 may be effective in treating people whose glioblastoma has returned or cannot be removed by surgery. Although this clinical trial included just a few patients, these early results are important because the standard treatment of temozolomide alone had not benefited them (*page 8*).

In people with low-grade gliomas who received temozolomide before surgery, the tumors grew more slowly and were less likely to come back after treatment. This clinical trial used a new type of brain-scanning technique to monitor tumors; in the future, this technique could help doctors decide on the best treatment (*page 9*).

When researchers gave etirinotecan pegol to people with high-grade glioma, the tumor did not continue to grow in 50 percent of the patients. In this early clinical trial, the people who took part had already been treated with bevacizumab (*page 10*).

Combining newer or standard chemotherapy medications with radiation treatment seems to increase survival in patients with high-grade glioblastoma or low-grade glioma. In the future, these combination treatments may be beneficial for people with these types of brain cancer (*page 11*).

Vaccines Combined With Other Medications for Glioblastoma

According to three separate clinical trials, using vaccines alone or combined with other treatments can increase survival in patients with glioblastoma, a common and fast-growing type of brain tumor.

In the first clinical trial, 24 people with glioblastoma received fractionated radiotherapy (a radiation dose divided and given over a number of treatments) and temozolomide (Temodar and others). Four weeks later, the same group of patients received a tumor vaccine and treatment with temozolomide for five days. They continued to receive temozolomide for an additional five days every 28 days. After completing treatment, 33 percent of these patients survived 24 months or longer.



Temozolomide is a type of chemotherapy called an alkylating agent. Unlike many other chemotherapy drugs, it can reach the brain from the bloodstream. Temozolomide slows or stops the growth of cancer cells.

In the second clinical trial, 22 people with glioblastoma received dendritic cell immunotherapy, another type of tumor vaccine. These patients had previously received radiation treatment and temozolomide. Many of the patients survived longer than 20 months after receiving the vaccine.

In the third clinical trial, 10 people with glioblastoma that had come back after treatment with bevacizumab (Avastin) received a modified poliovirus vaccine. This vaccine contains special viruses that kill tumor cells. It is injected directly into the tumor. In total, the brain cancer in eight patients responded to treatment. Two of the people who took part in the clinical trial survived 19 months or longer.

What Patients Need To Know

Vaccines may be a useful addition to the treatment of glioblastomas. Their use alone or in combination with other standard treatments appears to increase survival. Even though these trials are at a very early stage, the results are promising. Further study is needed.

ABT-414 for Glioblastoma

A new medication called ABT-414 may be effective in treating people whose brain cancer has returned or cannot be removed by surgery. ABT-414 is a targeted treatment; it focuses on specific cell mechanisms thought to be important for the growth and survival of tumor cells. Unlike chemotherapy, targeted treatments are designed to spare healthy tissues and cause less severe side effects.

In the study, 12 patients received ABT-414 plus temozolomide. In one patient the tumor stopped growing; in two patients the tumor grew somewhat.

What Patients Need To Know

Although this clinical trial included just a few patients, these early results are important because the standard treatment of temozolomide alone had not benefited them. ABT-414 appeared to offer some improvement. Larger clinical trials are needed to confirm these results.

Temozolomide Before Surgery for Low-Grade Gliomas

People with low-grade gliomas who receive temozolomide before surgery seem to do better after surgery, according to a clinical trial. Low-grade gliomas grow more slowly and are less likely to come back after treatment.

In this clinical trial, 19 patients either had surgery to remove their tumor or did not have surgery. They received six weeks of temozolomide treatment during a 12-week period. In total, 17 of the patients were able to have surgery after completing treatment with temozolomide.

The researchers used diffusion tensor imaging (DTI) to gather specific information about each tumor. DTI is a newer scanning technique that can provide detailed images of the brain.

What Patients Need To Know

Doctors are very encouraged by the results of this small clinical trial. Most of the patients were able to have surgery after temozolomide treatment. Moving forward, DTI may help



doctors decide which treatment would be best for people with low-grade gliomas.

Etirinotecan Pegol for High-Grade Glioma

Etirinotecan pegol may benefit people with high-grade gliomas, according to a clinical trial. Etirinotecan pegol was given to patients with this type of brain tumor after their cancer did not respond to treatment with bevacizumab. High-grade brain tumors grow quickly and are more likely to come back after treatment.

In the study, 20 people with high-grade glioma received etirinotecan pegol. In 50 percent of the patients, the tumor did not continue to grow.

Etirinotecan pegol works by blocking an important enzyme called topoisomerase that cells, including cancer cells, need to grow.

What Patients Need To Know

Although etirinotecan pegol is still being studied, in the future it may be beneficial in treating patients with high-grade gliomas. In this clinical trial the medication was effective, and the patients who received it had few or no side effects.

Radiation as Part of Treatment for Glioblastoma and Glioma

Treatment with radiation combined with medication helps keep brain cancer from coming back, according to a clinical trial and a long-term follow-up study.

In the clinical trial, 91 people with high-grade glioblastoma received radiation alone or radiation plus a new medication called APG101. People who received radiation plus APG101 survived longer without their cancer coming back than people who received radiation alone (4.5 months versus 2.5 months).

In the long-term follow-up study, 251 people with low-grade glioma received radiation alone or radiation followed by six cycles of PCV (procarbazine [Matulane], lomustine [Gleostine], and vincristine). People who received radiation plus PCV survived longer compared with those who received radiation alone (13.3 years versus 7.8 years).

What Patients Need To Know

Combining newer or standard chemotherapy medications with radiation treatment seems to increase survival in patients with high-grade glioblastoma or low-grade glioma. Although the results are being studied further, in the future, these combination treatments may be beneficial for people with these types of brain cancer.

Breast Cancer

Researchers reported a number of important findings in breast cancer treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

Exemestane and triptorelin were found to be more effective than tamoxifen and triptorelin in preventing early-stage breast cancer from coming back in premenopausal women.

Triptorelin is a medication that temporarily shuts down the function of the ovaries and the production of female hormones, which fuel certain types of breast cancer (*page 12*).

Using goserelin to temporarily shut down the ovaries in younger women about to start chemotherapy helped these organs recover. The women who took this drug also had a higher chance of becoming pregnant later and surviving longer (*page 14*).

Combining lapatinib and trastuzumab after chemotherapy for women with HER2-positive breast cancer offered the same benefit as receiving either medication alone. However, when given together, they caused more side effects (*page 16*).

Taking zoledronic acid every three months to treat breast tumors that have spread to the bone is just as effective and safe as taking zoledronic acid every month. By taking this medication less often, patients may avoid serious side effects and still receive the full benefit of the drug (*page 17*).

Exemestane and Triptorelin to Prevent the Return of Breast Cancer

In two clinical trials, exemestane (Aromasin and others) and triptorelin (Trelstar) were found to be more effective than tamoxifen and triptorelin in preventing early-stage

breast cancer from coming back in premenopausal women. Triptorelin is a medication that temporarily shuts down the function of the ovaries and the production of female hormones, which fuel certain types of breast cancer.

More than 4,600 women took part in these two studies, known as SOFT (Suppression of Ovarian Function Trial) and TEXT (Tamoxifen Exemestane Trial). In each study, one group of women received exemestane and triptorelin; the other group received tamoxifen and triptorelin. In the SOFT study, a third group received tamoxifen alone, without a drug to shut down their ovaries.

Researchers found that after five years, cancer did not return in 91 percent of women receiving exemestane plus triptorelin, compared with 87 percent of women who received tamoxifen plus triptorelin. Side effects such as muscle and joint pain and fractures were common in women receiving exemestane. Blood clots were more common in women receiving tamoxifen.

The women in these studies had estrogen receptor-positive breast cancer. The female hormone estrogen fuels the growth of these types of breast tumors. The receptors, which work like doorways to the tumors' cells, allow the hormone to enter.

In the SOFT study, the women who benefited most from shutting down their ovaries were those who were diagnosed when they were under age 35, as well as those who were at high risk of their cancer coming back and who had received chemotherapy. For women diagnosed in their 40's who had not received chemotherapy, tamoxifen alone seemed to be beneficial.

What Patients Need to Know

The combination of exemestane and triptorelin may be an option for women with early-stage estrogen receptor-positive

breast cancer. However, treatment with tamoxifen remains the standard of care for women with estrogen receptor-positive breast cancer. Patients should speak with their doctors about which treatment is right for them. Women with this type of breast cancer may also want to discuss the side effects of hormonal treatments, which can differ depending on the type of medication used.

Preventing Early Menopause in Young Women With Breast Cancer

Treatment with the hormone goserelin (Zoladex) seems to prevent early menopause in younger women receiving chemotherapy for breast cancer, according to a recent clinical trial. Goserelin is a medication that temporarily shuts down the function of the ovaries. Called early menopause, it is a common side effect of chemotherapy and prevents pregnancy. In this study the menopause was temporary and could be reversed.



Sometimes, the ovaries recover after chemotherapy, and the menstrual period resumes. The Prevention of Early Menopause Study (POEMS) found that temporarily shutting down the ovaries in premenopausal women about to start chemotherapy helped these organs recover and reduced the chance of developing early menopause.

More than 250 women with early-stage breast cancer took part in POEMS. Half of the women received goserelin, and the others did not. After two years of treatment, only 8 percent of women who received goserelin had early menopause. Twenty-two percent of women who did not receive goserelin had early menopause. More women who received goserelin were able to become pregnant eventually, compared with the women who did not receive goserelin.

Goserelin also helped the study participants survive longer. Four years after treatment, the women who received goserelin were 50 percent more likely to have survived after starting chemotherapy, compared with those women who did not receive goserelin. Women in the study started taking goserelin before their chemotherapy began and continued taking it throughout their cancer treatment.

What Patients Need to Know

Younger women faced with making decisions about whether chemotherapy will affect their chances of getting pregnant may have the option to take goserelin to reduce their chances of experiencing early menopause. In addition, treatment with goserelin appears to increase their chance of getting pregnant and having a successful pregnancy after they finish their cancer treatment. Also, researchers found that goserelin may help these young women survive longer.

Lapatinib Plus Trastuzumab to Prevent the Return of HER2-Positive Breast Cancer

Combining two different medications after chemotherapy for women with HER2-positive breast cancer offered the same benefit as receiving either of these medications alone, according to a recent clinical trial.

The two medications, lapatinib (Tykerb) and trastuzumab (Herceptin), were given to women after they completed their chemotherapy to help prevent their cancer returning. Both lapatinib and trastuzumab are targeted treatments, which focus on specific cell mechanisms thought to be important for the growth and survival of tumor cells. More than 8,000 women took part in this clinical trial, known as ALTTO. They were divided into four groups, receiving trastuzumab alone, lapatinib alone, trastuzumab followed by lapatinib, or trastuzumab plus lapatinib.

After four years of treatment, there was no major difference in results among the four different treatment groups. Over that same period, most women had survived, no matter which treatment they received. But the women who received trastuzumab plus lapatinib had more side effects such as rash, diarrhea and liver problems.

What Patients Need to Know

The ALTTO study showed that the current treatment for HER2-positive breast cancer is working well. Researchers were surprised to learn that combining trastuzumab and lapatinib did not benefit women any more than if they had taken either drug alone. In other clinical trials, combining these two medications after chemotherapy led to better outcomes. It's possible that the additional side effects caused many women



in this clinical trial to stop taking trastuzumab and lapatinib before any benefit occurred.

Taking Zoledronic Acid Less Often to Treat Cancer That Has Spread to the Bones

Women with breast cancer who have taken zoledronic acid (Zometa and others) monthly for one year may be able to safely take the drug only once every three months, according to a clinical study. The women in this study, called OPTIMIZE 2, had breast cancer that had metastasized (spread) from the breast to the bone.

Zoledronic acid often is used to prevent the bones from becoming thin and more prone to breaking as a result of tumors that have spread to the bone. It is part of a class of medications known as bisphosphonates.

Researchers conducted the study due to some concerns that taking zoledronic acid every month over a long period may increase the risk of side effects to the kidney and jawbone.

More than 400 women took part in this clinical trial; they were divided into two groups. One group received zoledronic acid every month, and the other group received zoledronic acid every three months. There was no difference between the two groups in terms of the health of their bones. There also was no difference in the levels of bone pain experienced by the two groups. However, two patients in the group taking zoledronic acid every month developed osteonecrosis of the jaw—a serious side effect in which it is difficult for the bone to heal.

What Patients Need to Know

Taking zoledronic acid every three months was just as safe and effective as taking zoledronic acid every month, according to the results of this study. By taking zoledronic acid less often, patients may avoid serious side effects and still receive the full benefit of the medication. Women with breast cancer that has spread to the bone should discuss with their doctors whether taking zoledronic acid monthly or once every three months is right for them.



Colorectal Cancer

Researchers reported a number of important findings in colorectal cancer treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

Adding oxaliplatin to chemotherapy and radiation in people with locally advanced rectal cancer lengthened the time after treatment during which there were no signs or symptoms of their cancer. This medication may help stop rectal cancer from returning in select groups of patients (*page 19*).

Combining capecitabine and bevacizumab as maintenance treatment in people with metastatic colorectal cancer may prove to be beneficial. The positive effect was seen in certain types of patients. The study also found that for some patients, breaks from treatment can be helpful (*page 21*).

When added to standard treatment, both bevacizumab and cetuximab may extend survival for certain people with metastatic cancer of the colon or rectum. Researchers will need to conduct further clinical trials before deciding who will benefit the most from these medications (*page 23*).

Oxaliplatin for Locally Advanced Rectal Cancer

Adding oxaliplatin (Eloxatin and others) to chemotherapy and radiation in people with locally advanced rectal cancer lengthened the time after treatment during which there were no signs or symptoms of their cancer (what doctors call disease-free survival, or DFS). These results are from two clinical trials, one conducted in Germany and the other in South Korea.



Previous studies established combined chemotherapy and radiation treatment (known as CRT), rectal surgery and chemotherapy with fluorouracil as standard treatment for locally advanced rectal cancer, or LARC. (In LARC, the cancer has spread outside the rectum but has not yet spread to distant parts of the body.)

About 1,200 patients with LARC took part in the first clinical trial. About half received fluorouracil plus preoperative CRT. The other half received fluorouracil and preoperative CRT plus oxaliplatin. After three years, the rate of DFS in the first group of patients was 71.2 percent. The rate of DFS in the second group was 75.9 percent. The researchers concluded that adding oxaliplatin for people with LARC did improve DFS.

Over 300 patients with stage II/III rectal cancer took part in the second clinical trial. All had received preoperative CRT. About half received fluorouracil plus leucovorin (commonly known as folic acid). The other half received fluorouracil plus oxaliplatin. After three years, the rate of DFS in the first group of patients was 62.9 percent. The rate of DFS in the second

group was 71.6 percent. The researchers concluded that adding oxaliplatin for people with stage II/III rectal cancer improved DFS.

Stage II rectal cancer has spread through the muscle layer of the rectal wall and may or may not have broken through the outer wall and reached nearby organs. Stage III rectal cancer has spread to nearby lymph nodes and may or may not have penetrated the rectal wall.

What Patients Need to Know

Adding oxaliplatin may help stop rectal cancer from returning in patients with stage II or stage III cancer.

Capecitabine and Bevacizumab for Metastatic Colorectal Cancer

Combining capecitabine (Xeloda and others) and bevacizumab (Avastin) as maintenance treatment in people with metastatic colorectal cancer may prove to be beneficial, according to a clinical trial. Metastatic cancer has spread from its original site to other parts of the body. Maintenance treatment is the ongoing use of chemotherapy or other treatment to help lower the risk of recurrence (return of cancer) after it has disappeared following treatment. Maintenance treatment also may be used for people with advanced cancer to help keep it from growing and spreading further.

More than 550 people with metastatic colorectal cancer first received chemotherapy with **capecitabine**, **oxaliplatin** and **bevacizumab**. This combination of medications is commonly known as CAPOX-B.

After the first CAPOX-B treatment, half of the patients were given maintenance treatment with capecitabine and bevacizumab. They did not receive oxaliplatin. The other half

received no additional medication but were followed to see if there was any return of their cancer.

The cancer came back in fewer patients who received additional maintenance treatment than in those who did not. Those who received the additional treatment with capecitabine plus bevacizumab survived longer than those who did not (25 months versus 18 months). The researchers noted that maintenance treatment did have a positive effect. But this effect was noted only in certain patients.

What Patients Need to Know

To help prevent the return of cancer after it is first treated, doctors often give people with advanced cancer additional treatment. This type of treatment is called maintenance therapy and is often given over a long time. In some patients, breaks from treatment can be of benefit, especially after having received long stretches of chemotherapy. This study suggests that having a break from treatment can often be done without compromising long-term survival.



Researchers will study this maintenance therapy further to confirm the benefits in controlling the growth of metastatic colorectal cancer.

Bevacizumab or Cetuximab for Cancer of the Colon or Rectum

Both bevacizumab and cetuximab (Erbix) added to standard chemotherapy were equally beneficial for people with metastatic cancer of the colon or rectum, according to a clinical trial. The standard treatment was FOLFOX, a combination of **f**olinic acid (leucovorin), **f**luorouracil and **o**xaliplatin.

Patients in this study had non-mutated KRAS genes in their tumor. KRAS is a protein needed for cell growth. Mutated (changed) KRAS genes are known to play a role in cancer.

More than 1,100 patients took part in this clinical trial. Half of the patients received bevacizumab and FOLFOX. The other half received cetuximab and FOLFOX. Patients receiving cetuximab survived more than 30 months. Patients receiving bevacizumab survived more than 26 months. However, patients receiving cetuximab commonly developed a skin rash, which can be a challenging side effect of this medication.

What Patients Need to Know

When added to standard treatment, both bevacizumab and cetuximab may be beneficial in extending survival for certain people with metastatic cancer of the colon or rectum. Researchers will need to conduct further clinical trials before deciding who will benefit the most from these medications and whether cetuximab is more effective than bevacizumab in this situation.

Leukemia

Researchers reported a number of important findings in leukemia treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

Imatinib continues to be an effective treatment for people with chronic myeloid leukemia (CML). After a long period of study, imatinib at standard doses is still considered safe and effective, with fewer side effects over time. Higher doses may improve tumor response over the long term (*page 25*).

Nilotinib appears to be more effective than imatinib for treating people with CML. For newly diagnosed patients, remissions (a decrease in or disappearance of the signs and symptoms of cancer) are more likely with nilotinib than imatinib. Nilotinib also reduces the chance of the cancer becoming more advanced (*page 26*).

Early results from a clinical trial showed that untreated CML responded better to ponatinib than imatinib. Ponatinib is a more potent type of targeted treatment now used to treat people whose cancer did not respond previously to other medications (*page 28*).

Ruxolitinib plus panobinostat may benefit people with myelofibrosis, a rare condition that can lead to leukemia. This combination treatment was able to help reduce symptoms and target cells that may cause the cancer, but the results are still very early (*page 29*).

The combination of ibrutinib and ofatumumab appears to be effective in stopping cancer from returning in people with chronic lymphocytic leukemia (CLL). Researchers will continue to study this combination treatment to find the most effective dose (*page 30*).

Three different clinical trials are being conducted to find out whether ABT-199 is an effective treatment for people with CLL. Researchers hope that this drug will be an important treatment for patients whose leukemia no longer responds to treatment (*page 31*).

Imatinib for CML

Two long-term clinical trials show that imatinib (Gleevec) continues to be an effective treatment for people with CML.

In the first study, more than 1,500 patients with CML received imatinib. After 10 years, the cancer was still in remission in 81 percent of patients. (Remission is a period in which there is a decrease in or disappearance of the signs and symptoms of cancer.) Seventy-four percent of patients experienced side effects such as stomach upset, rash, joint discomfort



and fatigue. Most of these side effects occurred during the first three years of treatment with imatinib and went away as treatment continued.

In the second clinical trial, more than 270 untreated patients received imatinib for CML. Approximately two-thirds of these patients received a higher dose of imatinib. The remainder received a lower dose of imatinib. After 10 years, the cancer did not come back in 77 percent of patients who received the higher dose of imatinib and 66 percent of those who received the lower dose. Both groups of people did equally well in terms of the length of survival.

Imatinib revolutionized the treatment of people with this type of leukemia. It is a type of targeted treatment that focuses on specific gene mutations (changes) that drive the growth and survival of tumor cells. (Unlike chemotherapy, targeted treatments are designed to spare healthy tissues and cause less severe side effects.)

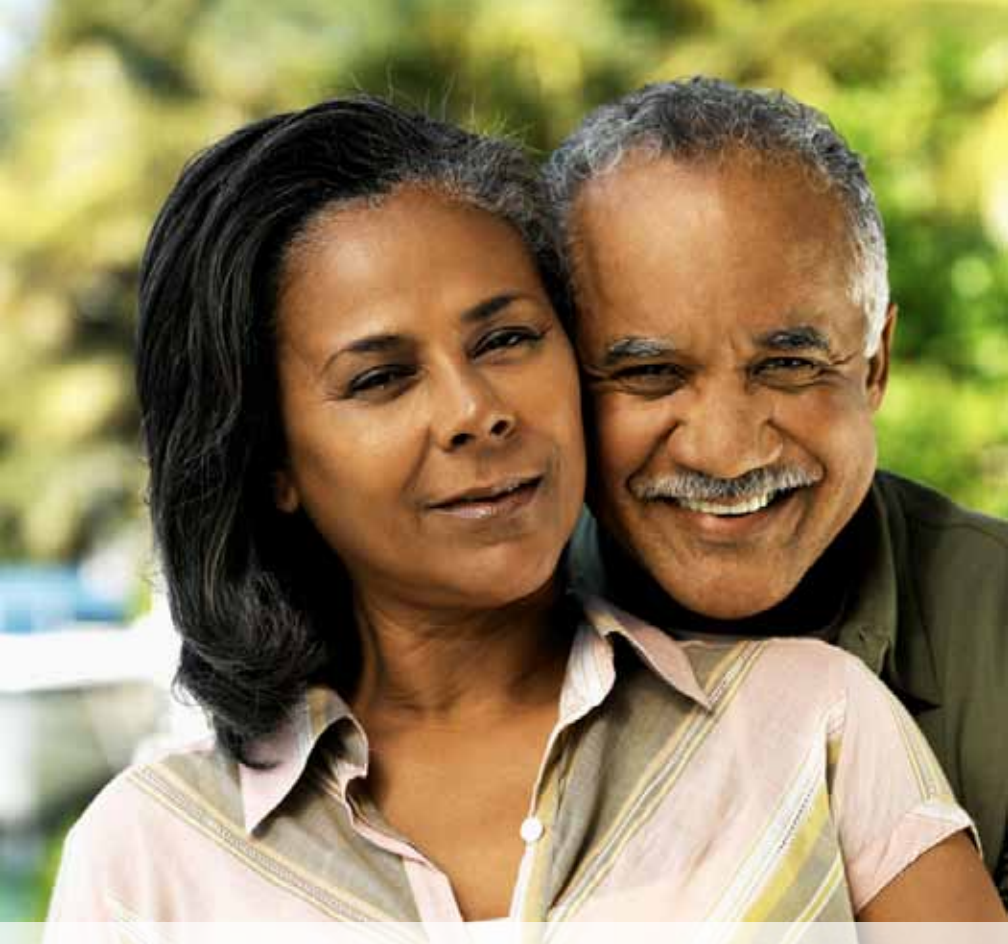
What Patients Need to Know

Imatinib continues to be an effective treatment for people with CML. It appears that the longer people receive imatinib, the more effective it is at stopping their cancer from coming back, with fewer side effects. Researchers continue to study which dose of imatinib is best for individual patients.

Nilotinib Versus Imatinib for Newly Diagnosed CML

Results from a clinical trial showed that CML responds better to nilotinib (Tasigna) than imatinib.

More than 800 patients took part in this study. One-third received a standard dose of imatinib, and the other two-thirds were split into two groups that received different doses of



nilotinib. After five years, the rates of remission (in which signs of cancer could not be detected) were higher in both nilotinib groups. The cancer did not progress to an advanced form in 98 percent of patients who received the higher dose of nilotinib and in 96 percent of those who received the lower dose of nilotinib. For the patients receiving imatinib, the cancer did not progress in 92 percent.

However, patients experienced more heart- and blood vessel-related side effects with both doses of nilotinib than with imatinib. Researchers are still trying to find out the reason for this difference.

What Patients Need to Know

Nilotinib is a newer type of targeted treatment in the same class of drugs as imatinib. In this clinical trial, nilotinib appears to be more effective than imatinib for treating people with CML. Further research is needed to show which dose of nilotinib is best over the long term and how to prevent or reduce serious side effects.

Ponatinib Versus Imatinib for CML

Early results from the EPIC clinical trial showed that untreated CML responded better to ponatinib (Iclusig) than imatinib.

More than 250 people with untreated CML took part in the EPIC study. Half of the patients received ponatinib, and the other half received imatinib. EPIC was stopped early because another clinical trial known as PACE showed that people



with treatment-resistant CML who were taking ponatinib experienced serious side effects. But the information available from the EPIC study showed that ponatinib led to remission much earlier than did imatinib and in at least twice as many patients at three, six and nine months.

However, in the patients who received ponatinib, there was an increase in heart- and blood vessel-related side effects and lowered levels of platelets (which help the blood to clot). Until more is known about the safety and ideal doses of ponatinib, researchers have stopped further study of this drug in newly diagnosed CML.

What Patients Need To Know

Ponatinib is a more potent type of targeted treatment. It is used to treat people whose cancer did not respond previously to other treatments. Early results from the EPIC trial showed that ponatinib was more effective than imatinib in previously untreated people with CML. Further research is needed to find out who would benefit most from treatment with ponatinib.

Ruxolitinib Plus Panobinostat for Myelofibrosis

The combination of ruxolitinib (Jakafi) and panobinostat (Farydak) was an effective treatment for people with myelofibrosis, according to an early clinical trial. Myelofibrosis is a rare condition that disrupts the body's normal production of blood cells. In some people it can lead to leukemia. One of the signs of myelofibrosis is enlargement of the spleen.

More than 45 people with myelofibrosis took part in the study. Patients received ruxolitinib twice a day plus panobinostat three times a week every other week. In 75 percent of those who received the combination treatment, the size of the

spleen was reduced by 50 percent. However, some patients did experience side effects, including anemia (a decrease in red blood cells), stomach pain, diarrhea and low platelet levels.

Ruxolitinib is an oral medication currently used to treat myelofibrosis. Panobinostat is still being studied as a treatment for other blood cancers, including multiple myeloma. Combining these drugs may improve the response of myelofibrosis to treatment and possibly prevent leukemia in some people with this condition.

What Patients Need to Know

Results from this clinical trial showed that the combination of ruxolitinib and panobinostat may benefit people with myelofibrosis in the future. This combination treatment was able to target cells that may cause leukemia.

Ibrutinib Plus Ofatumumab for CLL

Results from a clinical trial showed that CLL responded well to treatment with ibrutinib (Imbruvica) plus ofatumumab (Arzerra). The leukemia in these patients no longer responded to previous treatments.

More than 70 people took part in the study. All received one of three different doses of the combination treatment. After 12 months, the cancer stayed in remission in 90 percent of these patients. The most common side effect was diarrhea.

What Patients Need to Know

In this clinical trial, the combination of ibrutinib and ofatumumab appears to be effective in stopping cancer from returning in people with CLL. Researchers will continue to study this drug combination to find the most effective dose.

ABT-199 for CLL

Three different early clinical trials are being conducted to find out whether ABT-199 is effective for people with CLL that no longer responds to treatment. ABT-199 is an oral medication that specifically targets CLL cells.

In the first study, which will run until 2020, about 370 patients will take part. Half of these people will receive rituximab (Rituxan) plus ABT-199. The other half will receive rituximab plus bendamustine (Treanda). Rituximab and bendamustine are standard treatments for people with non-Hodgkin lymphoma or CLL.

In the second clinical trial, about 70 patients will take part. They will start out receiving a lower dose of ABT-199 and then receive increasingly higher doses of ABT-199.

In the third clinical trial, about 80 patients with CLL have taken part so far. (More people are expected to join the study.) Of the 80 patients who have been receiving ABT-199, the cancer responded in 79 percent. Most patients' cancer continued to respond after one year—65 percent for those with partial remission (in which some, but not all, signs and symptoms of cancer have disappeared) and 91 percent for those with complete remission (in which all signs and symptoms of cancer have disappeared, although cancer still may be in the body).

What Patients Need to Know

Researchers hope that ABT-199 will be an important treatment for people with CLL whose cancer no longer responds to other treatment. As the clinical trials proceed, scientists expect to learn more about the future role of ABT-199.

Lung Cancer

Researchers reported a number of important findings in lung cancer treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

In early clinical trials, three new medications—AZD9291, CO-1686 (rociletinib) and HM61713—appear to be promising for people with treatment-resistant non-small cell lung cancer (NSCLC). Further research is needed to learn which patients would benefit most from these drugs (*page 32*).

Combining erlotinib and bevacizumab appears to benefit people with EGFR-positive NSCLC. The results are from an early clinical trial and must be verified (*page 34*).

Ceritinib and alectinib appear to be promising treatments for a type of NSCLC called “ALK-rearranged.” These medications are being studied to treat people whose cancer did not respond well to previous treatment (*page 35*).

People who received chemotherapy for NSCLC that has spread to the brain did not receive any added benefit from having stereotactic radiosurgery. Researchers will continue to study this radiation technique in larger clinical trials to see which patients could benefit from it (*page 37*).

Early Results on New Treatments for EGFR-Positive NSCLC

In early clinical trials, three new medications—AZD9291, CO-1686 (rociletinib) and HM61713—appear to be promising for people with treatment-resistant non-small cell lung cancer (NSCLC). Doctors know that people who have a certain type of lung cancer, called EGFR-positive lung cancer, may not benefit

from standard treatments. This may be due to a mutation (change) in one of their genes, called T790M.

In the first clinical trial, researchers reported results on 199 patients with EGFR-positive NSCLC who received different oral doses of AZD9291. After about 11 months, the cancer responded to treatment in 51 percent of the study participants. However, some of the patients experienced side effects, including diarrhea, rash and nausea.

In the second clinical trial, researchers reported results on 85 patients with EGFR-positive NSCLC who were given different oral doses of a drug called CO-1686. After about 12 months, the cancer responded to treatment in 64 percent of the patients. Some of these people also experienced side effects, including nausea, fatigue and high blood sugar.

In the third clinical trial, researchers reported results on 93 patients with EGFR-positive NSCLC who received different



oral doses of HM61713. The cancer responded to treatment in 73 percent of the patients. The side effects they experienced included nausea, diarrhea, rash, reduced appetite and itching.

AZD9291, CO-1686 and HM61713 belong to a class of medications known as tyrosine kinase inhibitors. They work by blocking the function of a protein called EGFR. When there is too much EGFR, it leads to the uncontrolled growth of cancer cells. These drugs are being studied in people whose cancer does not respond to other treatments.

What Patients Need to Know

Researchers are always looking for new treatments to help people whose lung cancer no longer responds to other treatments. These trials showed that AZD9291, CO-1686 and HM61713 may be effective in people with treatment-resistant, EGFR-positive NSCLC. Further research is needed to find out which patients would benefit most from these new treatments and how well they are tolerated.

Erlotinib Plus Bevacizumab for EGFR-Positive NSCLC

Combining erlotinib (Tarceva) and bevacizumab (Avastin) appears to benefit people with EGFR-positive NSCLC, according to an early clinical trial. More than 150 patients took part in this study. None of them had previously received chemotherapy. All had EGFR-positive lung cancer.

About half of the patients received erlotinib plus bevacizumab. The rest of the patients were treated with erlotinib alone. It took longer for the lung cancer to come back in patients who received erlotinib plus bevacizumab than in those who received erlotinib alone (16 months versus 9 months). There was no difference in side effects between the two groups of patients.



What Patients Need to Know

This trial showed that erlotinib plus bevacizumab was more effective in people with EGFR-positive NSCLC compared with erlotinib alone. Further research is needed.

Ceritinib and Alectinib for ‘ALK-Rearranged’ NSCLC

Two new medications—ceritinib (Zykadia) and alectinib—appear to be promising treatments for a type of NSCLC called ALK-rearranged. The findings are from two clinical trials.

In the first study, more than 240 patients took part. About 60 percent previously had been treated with crizotinib (Xalkori). But the cancer came back in 96 percent of the people in this group. All of the patients whose cancer came back then received treatment with ceritinib. After almost seven months, the cancer did not come back in 58 percent of patients who received ceritinib. However, some of them experienced side effects, including nausea, diarrhea, vomiting and fatigue.

In the second clinical trial, more than 30 patients took part. About 67 percent had been treated before with crizotinib, and the cancer came back in about half of them. All of the patients whose cancer came back then received treatment with alectinib. Half received a lower dose of alectinib, and the other half were given a higher dose. After almost four months, the cancer did not come back in 60 percent of people who received alectinib. There was no difference in survival between people who received the higher dose and those who were given the lower dose.

ALK-rearranged NSCLC is a rare type of lung cancer in which the ALK gene is mutated (changed) and joined with another gene. The joining of the two genes shields cancer cells from crizotinib, allowing tumors to grow and spread.

Ceritinib, alectinib and crizotinib are known as ALK inhibitors. Ceritinib and alectinib are newer and more potent versions of



this type of drug. They are being studied to treat people with ALK-rearranged NSCLC whose cancer did not respond well to previous treatment.

What Patients Need to Know

Results from these two clinical trials showed that both ceritinib and alectinib were effective in people with ALK-rearranged NSCLC that resisted treatment with crizotinib. Further research is needed to find out who would benefit most from treatment with these newer drugs.

Stereotactic Radiosurgery for NSCLC

People who received chemotherapy for NSCLC that has spread to the brain did not experience any added benefit from having stereotactic radiosurgery (SRS), according to a clinical trial. SRS is a form of radiation treatment that targets tumors in the brain. Lung cancer is the most common type of cancer to spread to the brain.

More than 100 patients took part in this study. About half received treatment with SRS and chemotherapy. The other half received chemotherapy alone. People who had chemotherapy alone survived longer than those receiving SRS and chemotherapy (17 months versus 15 months).

What Patients Need to Know

Adding SRS to chemotherapy appears to be no more effective than receiving chemotherapy alone for NSCLC that has spread to the brain. Researchers will continue to study SRS in larger clinical trials to see which patients, if any, would benefit from it.

Lymphoma

Researchers reported a number of important findings in lymphoma treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

For people with newly diagnosed Hodgkin lymphoma, brentuximab vedotin may be beneficial when taken just before chemotherapy as a first treatment. However, further research is needed before doctors move away from the usual standard treatment of using chemotherapy first (*page 38*).

A new blood test may be able to identify people at risk of having their diffuse large B-cell lymphoma return or those who need to be followed more closely. Further research is needed to confirm whether this information can improve long-term survival (*page 40*).

For people with follicular lymphoma, PET-CT imaging may provide more useful information than standard CT scanning when it comes to monitoring the effectiveness of treatment and predicting long-term survival. However, further research is needed before doctors change their approach to imaging (*page 40*).

Brentuximab Vedotin for Untreated Hodgkin Lymphoma

The use of brentuximab vedotin (Adcetris) just before standard chemotherapy has been found to be safe and effective in people with untreated Hodgkin lymphoma, according to results from a recent clinical trial conducted in Italy. In this small study, 12 patients were first given brentuximab vedotin. Then they were given a standard chemotherapy treatment called ABVD, a combination

of doxorubicin (Adriamycin), bleomycin, vinblastine and dacarbazine (DTIC-Dome and others). ABVD is the usual first treatment for people with Hodgkin lymphoma.

In 11 patients, the cancer responded after two cycles of brentuximab vedotin treatment. No major unexpected side effects were reported.

What Patients Need to Know

Brentuximab vedotin is a new and important type of cancer treatment. It belongs to a class of medications called antibody-drug conjugates, which destroy cancer cells without harming surrounding healthy cells. For people with newly diagnosed Hodgkin lymphoma, brentuximab vedotin may be beneficial when taken just before chemotherapy as a first treatment. However, further research is needed before doctors move away from the standard approach of using ABVD first.



New Blood Test to Detect Traces of B-Cell Lymphoma

A new blood test may be able to detect traces of cancer in people who were previously treated for diffuse large B-cell lymphoma (DLBCL). This test could prove to be important for people with this type of cancer. If this fast-growing cancer returns and can be found quickly, treatment could begin right away.

In a clinical study, 50 patients with DLBCL were monitored for traces of the cancer in their blood, using a DNA test called Ig-HTS. (DNA contains the blueprint of genetic information for all living things, including cancer cells.) This test was able to detect evidence of tumor-specific DNA in most of the 50 patients examined.

What Patients Need to Know

The Ig-HTS blood test was able to detect tumor-specific DNA in the blood of some patients with previously treated DLBCL. Although more studies are needed before Ig-HTS becomes part of standard practice, it may be able to identify people at risk of having their cancer return or those who need to be followed more closely. Further research will confirm whether this information can improve long-term survival.

PET-CT Scans for Monitoring Follicular Lymphoma

The use of PET-CT scans in people with follicular lymphoma can help doctors monitor the effectiveness of treatment. Switching from standard CT scanning to PET-CT may improve long-term survival, according to the results of recent research.

In this study, doctors analyzed records from nearly 250 scans of people who had been treated for follicular lymphoma. Scans



to monitor their progress were made by either standard CT imaging or the newer PET-CT imaging. Over four years, PET-CT imaging results at the end of treatment provided better information on long-term survival than did the results of CT imaging.

What Patients Need to Know

PET-CT combines two scan techniques in one exam: a PET (positron emission tomography) scan and a CT (computed tomography) scan. A PET scan is an imaging test that uses a radioactive substance to look for cancer cells in the body. A CT scan creates a three-dimensional picture of the inside of the body with an x-ray machine. It shows the structure of body organs and the blood flow to and from those organs.

For people with follicular lymphoma, PET-CT imaging may provide more useful information than standard CT scanning when it comes to monitoring the effectiveness of treatment and predicting long-term survival. However, further research is needed before doctors change their approach to imaging.

Melanoma

Researchers reported a number of important findings in melanoma treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

Ipilimumab delayed the return of cancer for people with stage III melanoma. This medication may provide an alternative to interferon for people whose cancer is at high risk of coming back (*page 42*).

Combining nivolumab and ipilimumab improved survival for people with advanced melanoma. More than 60 percent of the patients in this clinical trial had BRAF-mutated melanoma; about half of all melanomas have mutations (changes) in the BRAF gene (*page 44*).

Ribociclib plus binimetinib acted against tumors in people with NRAS-mutated melanoma. NRAS mutations are found in 10 percent to 20 percent of people with melanoma (*page 44*).

A local treatment known as T-VEC benefited patients with stage IIIB/C and stage IV melanoma. T-VEC is injected directly into a melanoma tumor and helps the body's immune system fight cancer cells (*page 46*).

Ipilimumab for Stage III Melanoma

Ipilimumab (Yervoy) delayed the return of cancer in people with stage III melanoma, according to early results from a clinical trial. (In stage III, the tumor has spread to nearby lymph nodes, which are small bean-shaped organs located throughout the body that remove waste and fluids and help fight infection.)

More than 950 patients took part in this study. About half received ipilimumab. The other half received placebo (a look-

alike substance that has no active ingredients). The people who received ipilimumab survived longer without their melanoma returning than those receiving placebo (26 months versus 17 months). There were some side effects with ipilimumab treatment. They included stomach upset, rash and conditions related to the liver. Within 12 weeks, almost 40 percent of patients stopped taking ipilimumab because of side effects.

What Patients Need to Know

Ipilimumab is a type of treatment known as immunotherapy, which is designed to help the body's immune system seek out and destroy cancer cells. This medication may provide doctors with an option to treat people with advanced melanoma who are at high risk of having their melanoma return. Researchers will continue to study ipilimumab to see whether they can reduce its side effects and offer the medication as an alternative to interferon—which has its own side effects—for this group of patients.



Nivolumab Plus Ipilimumab for Advanced Melanoma

Combining nivolumab (Opdivo) and ipilimumab improved survival in people with advanced melanoma more than previously seen, according to early reports from a clinical trial. Response to this treatment appeared to occur whether or not the patients had mutations (changes) in the BRAF gene, offering hope for two major types of melanoma patients.

Over 50 people took part in this study. They received both nivolumab and ipilimumab followed by nivolumab alone. After 36 weeks, the tumor shrank in about 40 percent of patients.

What Patients Need to Know

Nivolumab is a monoclonal antibody that targets the PD1 molecule on immune cells. In some patients with melanoma, blocking PD1 with the antibody appears to alert the immune system that the cancer is present and should be destroyed.

Early results showed the combination of nivolumab and ipilimumab was beneficial for people with advanced melanoma. With the increased benefit, there also was an increase in side effects. Researchers will continue to study these medications to find out who would benefit most from them, including people with other types of cancer.

Ribociclib Plus Binimetinib for NRAS-Mutated Melanoma

Ribociclib (LEE011) plus binimetinib (MEK162) acted against tumors in people with melanoma and NRAS mutations, according to early results of a clinical trial. NRAS mutations are changes in the NRAS gene. These mutations are found in 10 percent to 20 percent of people with melanoma.



Different doses of ribociclib and binimetinib were given to 14 people with melanoma and NRAS mutations. After eight months, the tumors in almost half of these patients responded well to treatment. In some patients the tumor shrank, and in others it did not continue to grow. However, this combination treatment did have side effects, including rash, swelling, anemia (a lack of red blood cells), nausea, diarrhea and fatigue.

What Patients Need to Know

Ribociclib is a type of medication known as a cyclin-dependent kinase (CDK) inhibitor. It blocks the growth of a protein known as CDK. CDK is needed for the growth of cancer cells.

Binimetinib is a type of medication known as a mitogen-activated protein kinase (MEK) inhibitor. Like ribociclib, it also blocks the growth of a protein, this one known as MEK. MEK also is needed for the growth of cancer cells.

The combination of ribociclib and binimetinib shows promise in people with melanoma and NRAS mutations. Researchers will continue to study these medications to see who would benefit most from them.

A Local Treatment for Stage IIIB/C and Stage IV Melanoma

A cancer-destroying virus known as T-VEC showed improved outcomes in people with advanced melanoma, according to two early reports from a large clinical trial called OPTiM. More than 430 patients took part in the study.

T-VEC is injected directly into a melanoma tumor to kill the tumor cells and help the body's immune system fight the cancer cells.

In the first report, about two thirds of patients received T-VEC. The rest of the patients received a man-made substance called GM-CSF. This substance helps make infection-fighting white blood cells. After about 18 months, the cancer in almost half of the people who received T-VEC did not continue to grow. There were few side effects with T-VEC.

In this report, the patients had stage IIIB/C melanoma, in which the tumors had spread to nearby lymph nodes, or stage IV melanoma, in which the tumors had spread to distant parts of the body.

In the second report, patients receiving T-VEC went longer without their cancer coming back than patients receiving GM-CSF (23 months versus 18 months). As in the previous report, the patients had stage IIIB/C or stage IV melanoma.

What Patients Need to Know

T-VEC is an exciting new treatment for people with advanced melanoma. One of the many benefits of these types of local treatments is fewer, less severe side effects than those caused by other types of cancer medications.

Oral and Head and Neck Cancer

Researchers reported a number of important findings in oral and head and neck cancer treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

When given after standard chemotherapy, combining cetuximab or cisplatin with radiation improved survival for people with locally advanced cancer of the head and neck. Further research is needed in order for doctors to know how best to use this new treatment method (*page 48*).

People with oropharyngeal cancer caused by the human papillomavirus who have two or more other risk factors may need longer treatment. By learning which risk factors people have, doctors may be better able to predict a cancer's response to treatment (*page 49*).

People with oropharyngeal cancer caused by human papillomavirus may have better results with lower amounts of radiation treatment. Patients in this clinical trial received an advanced type of radiation treatment that targets tumors (*page 50*).

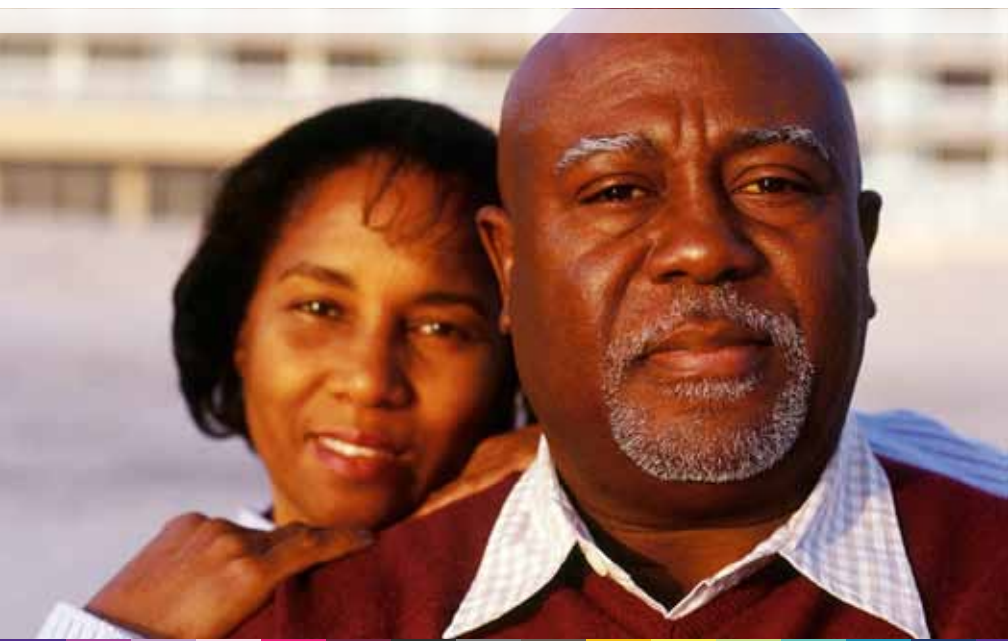
Early research from a clinical trial may prove pembrolizumab to be a safe and effective treatment for people with head and neck cancer. Pembrolizumab is a newer medication that helps the immune system destroy cancer cells (*page 51*).

For people whose thyroid cancer did not respond to standard treatment with radioactive iodine, lenvatinib improved survival. Further research is needed before doctors will know whether lenvatinib is beneficial for these patients (*page 52*).

Chemoradiation for Locally Advanced Head and Neck Cancer

When given after standard chemotherapy, chemoradiation improved survival for people with locally advanced cancer of the head and neck. Chemoradiation is a treatment that combines chemotherapy with radiation. In this clinical trial, chemoradiation consisted of either cetuximab (Erbix) plus radiation or cisplatin (Platinol and others) plus radiation. The people who took part in the study all had cancer that had spread to their lymph nodes—small bean-shaped organs located throughout the body that remove waste and fluids and help fight infection.

In the clinical trial, 415 patients were divided into two groups. Half the patients received standard chemotherapy—a combination of docetaxel (Taxotere and others), cisplatin and fluorouracil—followed by chemoradiation. The other half received standard chemotherapy and chemoradiation at the



same time. People who received standard chemotherapy followed by chemoradiation survived longer before their cancer came back than those who received chemotherapy at the same time as chemoradiation (29.7 months versus 18.5 months).

What Patients Need to Know

Giving chemoradiation to people with locally advanced head and neck cancer after they have received chemotherapy appears to help them survive longer without their cancer coming back. Further research is needed in order for doctors to know how best to use this new treatment method.

Predicting Response to Oropharyngeal Cancer Treatment

People with oropharyngeal cancer caused by the human papillomavirus (HPV) may have certain risk factors that might help doctors choose the best treatment, according to a clinical study. Oropharyngeal cancer occurs in the part of the throat at the back of the mouth, including the back of the tongue, palate and tonsils. HPV is a common sexually transmitted virus. If left untreated, some HPV infections may progress to cancer.

More than 200 people took part in this study. All of them had oropharyngeal cancers caused by HPV. About half of the patients received chemotherapy: cisplatin and fluorouracil, cisplatin alone or cetuximab. The rest received radiation.

Researchers wanted to know whether these patients had any risk factors—other than being infected by HPV—that might make their cancer less likely to respond to treatment. The risk factors included a history of smoking, locally advanced cancer and cancer that has spread to nearby lymph nodes. After about 40 months, people with one or none of these risk factors were more likely to survive longer than people with two or more of these risk factors.



What Patients Need to Know

By learning which risk factors people with oropharyngeal cancer have, doctors may be better able to predict the cancer's response to treatment. In this study, researchers learned that people with oropharyngeal cancer and certain risk factors should continue treatment until their doctors think it is time for them to stop.

Less Radiation for Oropharyngeal Cancer Caused by HPV

People with advanced oropharyngeal cancer caused by HPV may need less radiation, according to a clinical trial. People in this study received intensity modulated radiation therapy (IMRT), an advanced type of radiation treatment that targets tumors.

More than 75 patients took part in this trial. All had oropharyngeal cancer caused by HPV. About 95 percent of patients received chemotherapy: cisplatin, paclitaxel and

cetuximab. About 75 percent of these patients also received IMRT. Of the patients receiving IMRT, 80 percent received a reduced dose and the rest received the standard dose. After almost two years, more patients on the reduced dose of IMRT survived than patients on the standard dose (84 percent versus 64 percent).

What Patients Need to Know

Researchers learned that people may have better results with lower amounts of IMRT than with higher amounts. Doctors will be pleased to know that in the future people may not need to be exposed to unnecessary radiation and its side effects. However, further studies are needed before doctors are able to know whether lowering the dose is right for every patient with oropharyngeal cancer.

Pembrolizumab for Head and Neck Cancer

Early research from a clinical trial may prove pembrolizumab (Keytruda) to be a safe treatment for people with head and neck cancer. About 40 percent of the people in this study had head and neck cancer caused by HPV; the others had head and neck cancer not caused by HPV. Researchers wanted to find out whether pembrolizumab is safe and effective in both groups of people.

So far, more than 55 patients have taken part in this trial. Early results showed that about 47 percent of patients had at least one side effect from taking pembrolizumab. The most common side effects included itching, fatigue, rash and diarrhea.

Pembrolizumab is a newer medication that helps the immune system destroy cancer cells. It is currently approved by the U.S. Food and Drug Administration (FDA) for treating people with melanoma.

What Patients Need to Know

Researchers are pleased with the early results of this study. They hope that pembrolizumab will benefit patients with head and neck cancer. Further results of this trial are pending.

Lenvatinib for Thyroid Cancer

For people whose thyroid cancer did not respond to standard treatment with radioactive iodine, treatment with lenvatinib (Lenvima) improved survival, according to a clinical trial.

More than 385 patients took part in this study. All had the most common type of thyroid tumor, known as differentiated thyroid cancer. Approximately two thirds of patients received lenvatinib. The rest of the patients received a placebo (a look-alike pill that does not contain any active ingredients). After 13 months, patients receiving lenvatinib survived longer than patients receiving placebo (18 months versus 3 months). However, some patients experienced side effects, including high blood pressure, diarrhea, reduced appetite, weight loss and nausea.

Lenvatinib is a type of medication known as a tyrosine kinase inhibitor. It blocks proteins such as VEGF, FGF and KIT from helping cancer cells to grow.

What Patients Need to Know

Lenvatinib shows promise in treating people whose differentiated thyroid cancer does not respond to standard treatment with radioactive iodine. The drug was approved by the FDA in February 2015 for treating differentiated thyroid cancer that has either come back after other treatment or spread to other parts of the body.

Ovarian Cancer

Researchers reported a number of important findings in ovarian cancer treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

Six clinical trials on new medications for a specific type of ovarian cancer have shown improved survival. The women who took part in these studies had platinum-sensitive ovarian cancer that had resisted previous treatments (*page 54*).

Using a process called molecular profiling may help doctors choose the best treatment for women with clear cell ovarian cancer. Molecular profiling was used to learn which gene mutations (changes) were found in the tumor samples of these patients (*page 57*).

Two studies show that bevacizumab may benefit women with certain subtypes of ovarian cancer. By identifying the subtype, doctors hope to be better able to provide patients with the most effective treatment (*page 58*).

Treating women with advanced ovarian cancer using a new vaccine may be of benefit. This type of treatment, which helps the body's immune system recognize and destroy cancer cells, needs more research (*page 59*).

A new drug called CRLX101 may extend survival in women with treatment-resistant ovarian cancer. CRLX101 is a new formulation (the way a medication is given) of an older drug called camptothecin (*page 60*).

Adding defactinib to paclitaxel may extend survival in women with advanced ovarian cancer. More research and further testing are needed before doctors can know which women should receive defactinib (*page 62*).

New Medications for Women With Advanced Ovarian Cancer

Six clinical trials on new medications for a specific type of ovarian cancer have shown improved survival. The women who took part in these studies had platinum-sensitive ovarian cancer (PSOC). PSOC is ovarian cancer that reappears more than six months after completing treatment with a platinum-based medication, such as cisplatin, carboplatin or oxaliplatin (Eloxatin and others).

More than 55 women took part in the first study. About half of the patients received a newer medication called trabectedin (Yondelis) plus pegylated liposomal doxorubicin (Doxil and others). The rest of the patients received pegylated liposomal doxorubicin alone. It took longer for the cancer to come back in women who received the combination treatment than in



those who did not, but the difference was small (4.5 months versus 4.2 months).

Trabectedin blocks the growth of cancer cells. It is a manmade chemical that originally was discovered in a primitive marine animal known as a sea squirt.

So far, more than 75 women have taken part in the second clinical trial. In the first stage of this trial, 22 patients received lurbinectedin. In the second stage of the trial, half of the patients received lurbinectedin and the rest received topotecan (Hycamtin and others). After about 10 months, it took longer for the cancer to come back in those who continued to receive lurbinectedin than in those who were switched to topotecan (4 months versus 2 months). However, patients who continued to receive lurbinectedin did experience side effects, including nausea and vomiting, neutropenia (a low level of white blood cells) and fatigue. White blood cells help fight off infection.

Lurbinectedin also is derived from the sea squirt and blocks the growth of cancer cells.

So far, more than 70 women have taken part in the third clinical trial. About half of these patients received pazopanib (Votrient) plus paclitaxel (Taxol and others). The rest of the patients received paclitaxel alone. After about one year, it took longer for the cancer to come back in women who received the combination treatment than in those who did not (6 months versus 3 months). Patients who received the combination treatment did experience a greater number of side effects, including neutropenia, diarrhea and high blood pressure.

Pazopanib is a newer type of medication known as a tyrosine kinase inhibitor. It helps stop the growth of a protein that fuels the growth of cancer cells.

More than 80 patients took part in the fourth trial. About half of the women received cediranib (Recentin) plus olaparib (Lynparza). The rest of the women received olaparib alone. It took longer for cancer to come back in patients who received the combination treatment than in those who did not (17 months versus 9 months). However, patients who received the combination treatment experienced a greater number of side effects, including fatigue, diarrhea and high blood pressure.

Cediranib and olaparib help stop the production of enzymes that fuel the growth of cancer cells.

More than 12 women have taken part so far in the fifth trial. About two-thirds of them received a low dose of nivolumab (Opdivo), and the rest received the standard dose of nivolumab, which is three times higher. After about 10 months, the cancer in one-third of all the patients, regardless of the dose, responded to treatment with nivolumab.

Nivolumab is a newer type of medication that attaches to a part of a cancer cell that's necessary for growth. This drug helps a person's own immune system fight off cancer.

Eleven patients have taken part so far in the sixth trial. The women received three different doses of nintedanib (Ofev) along with pegylated liposomal doxorubicin. Nintedanib was given by mouth and pegylated liposomal doxorubicin through a vein (intravenously). Researchers were trying to find out which dose level of nintedanib caused the lowest levels of side effects. These side effects included neutropenia, diarrhea, fatigue, vomiting, headache and mouth pain. So far, the lowest dose of nintedanib has been found to be the safest. However, researchers need to conduct further studies to find out which dose is the most effective.

Nintedanib is a newer type of oral medication that blocks three different proteins. These proteins fuel the growth of cancer cells.

What Patients Need to Know

The exciting news for both doctors and their patients is that many new medications are being studied for the treatment of PSOC. These drugs may offer more ways to get ovarian cancer under control.

Personalizing Treatment of Clear Cell Ovarian Cancer

Using a process called molecular profiling may help doctors choose the best treatment for women with clear cell ovarian cancer (CCOC), according to results from a study. About five percent of all women with ovarian cancer have CCOC.

Tumor samples from more than 430 women with CCOC were used as the basis for this study. The tumor samples were divided into two groups according to the type of CCOC the women had. About two-thirds of the women had “pure CCOC” and the rest had “mixed CCOC.”

Molecular profiling was used to learn which gene mutations (changes) were found in the tumor samples. Some of the gene mutations were more common in pure CCOC tumors and other gene mutations were more common in mixed CCOC tumors. The researchers were hopeful that this knowledge could help doctors choose the best treatment for women with pure or mixed CCOC ovarian tumors.

What Patients Need to Know

Medical profiling may be of benefit in targeting treatment in women with certain types of ovarian cancer, such as CCOC.



The hope is that the more researchers and doctors can learn about the molecular makeup of a certain type of tumor, the more effectively they will be able to treat it. It still remains to be seen whether treatments aimed at ovarian cancer gene mutations will prove to be effective and will lengthen survival.

Bevacizumab for Ovarian Cancer

According to two studies, bevacizumab (Avastin) may be of particular benefit for women with a certain ovarian cancer cell makeup (molecular subtype).

Tumor samples from more than 400 patients were used as the basis for the first study. These tumor samples came from women with one of four molecular subtypes of ovarian cancer. All of the patients had first received carboplatin and paclitaxel. Then half of the women received bevacizumab and the other half did not. Women who received bevacizumab survived longer without their cancer coming back than the women who did not receive bevacizumab (19 months versus 12 months).

One particular type of molecular subtype called mesenchymal responded better to bevacizumab.

In the second study, more than 260 tumor samples were used. These samples came from women with one of three molecular subtypes of ovarian cancer. All of these patients had first received carboplatin and paclitaxel. Then half of these women received bevacizumab and the other half did not. Researchers found that women who received bevacizumab survived longer without their cancer coming back than those who did not receive bevacizumab (17 months versus 12 months). One particular molecular ovarian cancer subtype called angiogenic responded better to bevacizumab treatment.

What Patients Need to Know

Today, researchers know that no two patients' tumors are exactly the same. In some cases, doctors can use information about a patient's tumor to help them decide whether one treatment is more likely than another to work.

These studies brought out two positive results. First, the addition of bevacizumab to standard chemotherapy is beneficial for women with advanced ovarian cancer. This is especially true in certain tumor subtypes such as mesenchymal and angiogenic. Second, by identifying the molecular subtype of a tumor, doctors will be better able to provide patients with the most effective treatment.

Use of a Vaccine in the Treatment of Ovarian Cancer

Treating women with advanced ovarian cancer using a new vaccine may be of benefit, according to early results from a clinical trial. This new medication is known as ONT-10. It helps the body's immune system recognize and destroy cancer cells.

More than 40 patients have taken part in this study. All had MUC1 expression (a protein seen in certain types of tumors). Besides ovarian cancer, patients in this trial also were treated for other cancers. They included breast, colorectal, pancreatic and lung cancer. Almost one-third of the patients in this clinical trial had ovarian cancer.

All the patients in this study received chemotherapy with cyclophosphamide followed by treatment with ONT-10. After six months, the cancer in about one-third of all patients (not just those with ovarian cancer) did not come back. After 34 weeks, the size of the tumors in two of the 13 patients with ovarian cancer had shrunk by almost 50 percent. Side effects of the vaccine included fatigue and skin reactions at the site of the vaccine injection.

What Patients Need to Know

Vaccines may be a useful addition to ovarian cancer treatment—but much more research is needed. Their use alone or in combination with other standard treatments seems promising. Even though this trial is at a very early stage, the results deserve further follow-up

CRLX101 for Treatment-Resistant Ovarian Cancer

CRLX101 may extend survival in women with treatment-resistant ovarian cancer, according to a clinical trial.

More than 25 patients with resistant ovarian cancer took part in this study. All had received standard chemotherapy. Patients received treatment with CRLX101 for 14 of 24 days. After almost six months, the cancer did not come back in about one-fourth of the patients. However, women who received CRLX101 did experience side effects, including

pneumonia and pulmonary embolism, which is a blockage in a lung artery.

CRLX101 is a new formulation (the way a medication is given) of an older drug called camptothecin. It is used to treat ovarian cancer by blocking an enzyme needed for the growth of cancer cells. The new formulation of CRLX101 uses nanoparticles—much smaller drug particles that are able to get into cells within the body.

What Patients Need to Know

Researchers are looking at older medications such as camptothecin and changing the way they are delivered to people. Upgrading the way these medications can be placed into the body may help people whose cancer is no longer responding to treatment.



Defactinib for Advanced Ovarian Cancer

Adding defactinib to paclitaxel may extend survival in women with advanced ovarian cancer, according to an early-stage clinical trial.

Eighteen women with advanced ovarian cancer participated in this study. Six women were involved in the first part of the trial. Three of the women received a low dose of defactinib plus paclitaxel and three received a higher dose of defactinib plus paclitaxel. In the second part of the trial, 12 additional women received the higher dose of defactinib plus paclitaxel.

After almost six months, the cancer did not come back in two of the 18 women. However, they did experience side effects, including neutropenia, anemia, nausea and vomiting.

Defactinib is a new oral medication that blocks a protein needed for the growth of cancer cells.

What Patients Need to Know

Combining defactinib with standard treatment such as paclitaxel may benefit women with advanced ovarian cancer in the future. More research is needed before doctors can know which women should receive defactinib.

Pancreatic Cancer

Researchers reported a number of important findings in pancreatic cancer treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

Combining radiation with chemotherapy delayed the return of cancer in people with locally advanced pancreatic cancer.

The findings from this study may improve the quality of life for people with this stage of pancreatic cancer (*page 64*).

People with advanced pancreatic cancer who received a combination of chemotherapy drugs called FOLFIRINOX survived longer without their cancer growing compared with people receiving gemcitabine alone. The results are from a large patient database (*page 64*).

A select group of people with metastatic pancreatic cancer who had ruxolitinib added to their treatment survived longer without their cancer growing. More studies are needed before ruxolitinib becomes part of standard treatment for people with pancreatic cancer that has spread to other parts of the body (*page 66*).

In one clinical trial, adding oxaliplatin to standard treatment does not appear to benefit people with advanced pancreatic cancer. However, the results of a previous study suggest that adding oxaliplatin to chemotherapy for people with early-stage pancreatic cancer may be beneficial (*page 66*).

Adding MM-398 to fluorouracil and leucovorin treatment for people with metastatic pancreatic cancer improved survival. MM-398 is a new form of irinotecan that allows the medication to work in the body for a longer period (*page 68*).

Chemoradiotherapy in Locally Advanced Pancreatic Cancer

Adding radiation to chemotherapy delayed the return of cancer in people with locally advanced pancreatic cancer (LAPC), according to a clinical trial. The combination of chemotherapy with radiation is called chemoradiotherapy (CRT).

More than 440 people with LAPC took part in this study. After four months of receiving chemotherapy alone, the cancer had stopped growing in nearly 270 of the patients. These patients were then divided into two treatment groups: about half received CRT and the other half continued receiving chemotherapy. After six months, more patients receiving CRT survived longer without their cancer coming back than did the patients receiving chemotherapy (159 days versus 96 days).

All the patients who took part in the clinical trial had previously received either gemcitabine (Gemzar and others) or gemcitabine plus erlotinib (Tarceva and others).

What Patients Need to Know

Adding radiation to chemotherapy may help stop LAPC from returning in a select group of people. The findings from this study may improve the quality of life for people with LAPC whose cancer responds to chemotherapy. More research is needed to learn which patients may benefit the most.

FOLFIRINOX and Gemcitabine for Advanced Pancreatic Cancer

People with advanced pancreatic cancer who received FOLFIRINOX survived longer without their cancer growing than people receiving gemcitabine-based treatment, according to an updated analysis of a large patient database. FOLFIRINOX is a combination of **f**olic acid (leucovorin), **f**luorouracil,



irinotecan (Camptosar and others) and **oxaliplatin** (Eloxatin and others). Gemcitabine-based treatment consisted of gemcitabine and nab-paclitaxel (Abraxane).

More than 2,400 patients with advanced pancreatic cancer took part in this study. Almost three-fourths of these patients received gemcitabine-based treatment; the others received FOLFIRINOX. After about three years, patients with good performance status who received FOLFIRINOX survived longer without their cancer growing than patients who received gemcitabine alone (11 months versus 7 months). Those who received gemcitabine plus nab-paclitaxel survived a little over 10 months. Good performance status means patients are generally in good health and can care for themselves despite having cancer.

What Patients Need to Know

Ongoing results from this large clinical trial show that both FOLFIRINOX and gemcitabine-based treatment increased survival in people with advanced pancreatic cancer who had good performance status. However, people who receive FOLFIRINOX appear to survive longer without their cancer

coming back than those who receive gemcitabine alone. Gemcitabine plus nab-paclitaxel also proved beneficial.

Ruxolitinib for Metastatic Pancreatic Cancer

People with metastatic pancreatic cancer who had ruxolitinib (Jakafi) added to their treatment survived longer without their cancer growing, according to a clinical trial. Ruxolitinib is an oral medication known as a JAK inhibitor. JAK is a gene that plays a role in the growth of cancer cells. A JAK inhibitor stops the growth of cancer cells. Metastatic pancreatic cancer has spread beyond the pancreas to other parts of the body.

More than 120 patients with metastatic pancreatic cancer took part in this study. They had all been treated with gemcitabine and had inflammation related to their cancer, measured by a blood test called CRP, or C-reactive protein. Half of these patients then received capecitabine plus ruxolitinib. The other half received capecitabine plus placebo (a look-alike pill with no active ingredient). After six months, more patients who received ruxolitinib as part of their treatment lived longer without their cancer growing than those who received no ruxolitinib (42 percent versus 11 percent).

What Patients Need to Know

Ruxolitinib added to standard treatment appears to benefit people with metastatic pancreatic cancer who have inflammation related to their cancer. More studies are needed before ruxolitinib becomes part of standard treatment.

Oxaliplatin for Advanced Pancreatic Cancer

Adding oxaliplatin to standard treatment for people with advanced pancreatic cancer did not improve survival, according to a clinical trial called PANCREOX. Researchers were trying to find out whether adding oxaliplatin to fluorouracil and leucovorin would stop the cancer from coming back.

More than 100 patients with advanced pancreatic cancer took part in this study. They had been all treated with gemcitabine-based treatment and had good performance status. Half of these patients then received fluorouracil and leucovorin plus oxaliplatin. The rest of the patients received fluorouracil and leucovorin only.

Those who received fluorouracil and leucovorin plus oxaliplatin survived slightly longer without their cancer coming back than patients who did not receive this combination (3.1 months versus 2.9 months). However, overall survival was shorter in patients who received fluorouracil and leucovorin plus oxaliplatin than in patients who received fluorouracil and leucovorin without oxaliplatin (6.1 months versus 9.9 months). A previously reported trial that studied a similar combination in people with early-stage pancreatic cancer showed that oxaliplatin plus fluorouracil was more beneficial than fluorouracil alone.



What Patients Need to Know

Adding oxaliplatin to standard treatment does not appear to benefit people with advanced pancreatic cancer. But it may extend survival in those with early-stage cancer. It is important to have this information in order to choose the best possible treatment for the right patient.

MM-398 in Metastatic Pancreatic Cancer

Adding MM-398 to fluorouracil and leucovorin improved survival for people with metastatic pancreatic cancer, according to a clinical trial called NAPOLI-1. MM-398 is a new form of irinotecan that allows the medication to work in the body for a longer period.

More than 400 patients with metastatic pancreatic cancer took part in this study. They had been treated with gemcitabine-based treatment but their cancer came back. Half of these patients received MM-398 plus fluorouracil and leucovorin. The rest received fluorouracil and leucovorin only. Patients who received MM-398 plus fluorouracil and leucovorin survived longer without their cancer coming back than patients who did not (3.1 months versus 1.5 months).

However, patients receiving MM-398 plus fluorouracil and leucovorin did experience side effects from the MM-398, including diarrhea, vomiting, neutropenia (lowered levels of infection-fighting white blood cells) and fatigue.

What Patients Need to Know

Adding MM-398 to fluorouracil and leucovorin appears to benefit people with metastatic pancreatic cancer. Researchers are continuing to find new forms of standard chemotherapies, such as irinotecan, to make them more effective. Further study is needed before MM-398 can become part of standard treatment.

Prostate Cancer

Researchers reported an important finding in prostate cancer treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

When docetaxel plus standard hormone therapy is given early in the course of treating metastatic prostate cancer, the combination can increase men's survival. This finding may change the way doctors treat prostate cancer in the future.

Docetaxel and Standard Hormone Treatment for Metastatic Prostate Cancer

Adding docetaxel (Taxotere and others) to standard hormone treatment increases survival in men with metastatic prostate cancer, according to a recent clinical trial. (Cancer that is metastatic has spread from its original tumor site to other parts of the body.) Docetaxel belongs to a group of cancer-fighting medications known as taxanes. These chemotherapy drugs work by blocking the ability of cancer cells to grow and reproduce.

Nearly 800 men with metastatic prostate cancer took part in a study conducted by the Eastern Cooperative Oncology Group (ECOG), one of the largest clinical cancer research organizations in the United States. The men were divided into two treatment groups. One group received standard hormone treatment plus docetaxel. The other group received standard hormone treatment only. Hormone treatment lowers the levels of androgens (male hormones) in the body, which helps to slow or stop cancer growth. These hormones are known to fuel the growth of prostate cancer.

The men who received standard hormone treatment plus docetaxel survived about 14 months longer than those who received hormone treatment alone. In addition, the earlier in the course of their prostate cancer the men received



docetaxel, the longer they survived before their cancer continued to grow. It is important to note that the men who benefited most from this chemotherapy-plus-hormone treatment had four or more metastatic tumors in the bone.

What Patients Need to Know

When docetaxel plus standard hormone therapy is given early in the course of treating metastatic prostate cancer, the combination can increase men's survival. This finding may change the way doctors treat prostate cancer in the future. In the standard treatment, a medication such as docetaxel is usually not given to patients unless hormone treatment stopped working. Based on the results of this clinical trial, doctors may start patients on medications such as docetaxel at the beginning of treatment to improve survival.

Because men with four or more metastatic tumors in the bone were the ones to benefit most from this chemotherapy-plus-hormone treatment, patients should discuss this treatment with their doctors to be sure they need this combination of medications.

Sarcoma

Researchers reported a number of important findings in sarcoma treatment at the 2014 Annual Meeting of the American Society of Clinical Oncology:

A new medication, adoxorubicin, may benefit people with advanced soft tissue sarcoma. This drug appears to help delay the return of cancer; more detailed studies are underway (*page 72*).

Combining paclitaxel and bevacizumab did not provide any greater benefit than paclitaxel alone for people with advanced angiosarcoma. Paclitaxel, the standard treatment, is still considered to be useful, even as scientists search for more effective medications (*page 73*).

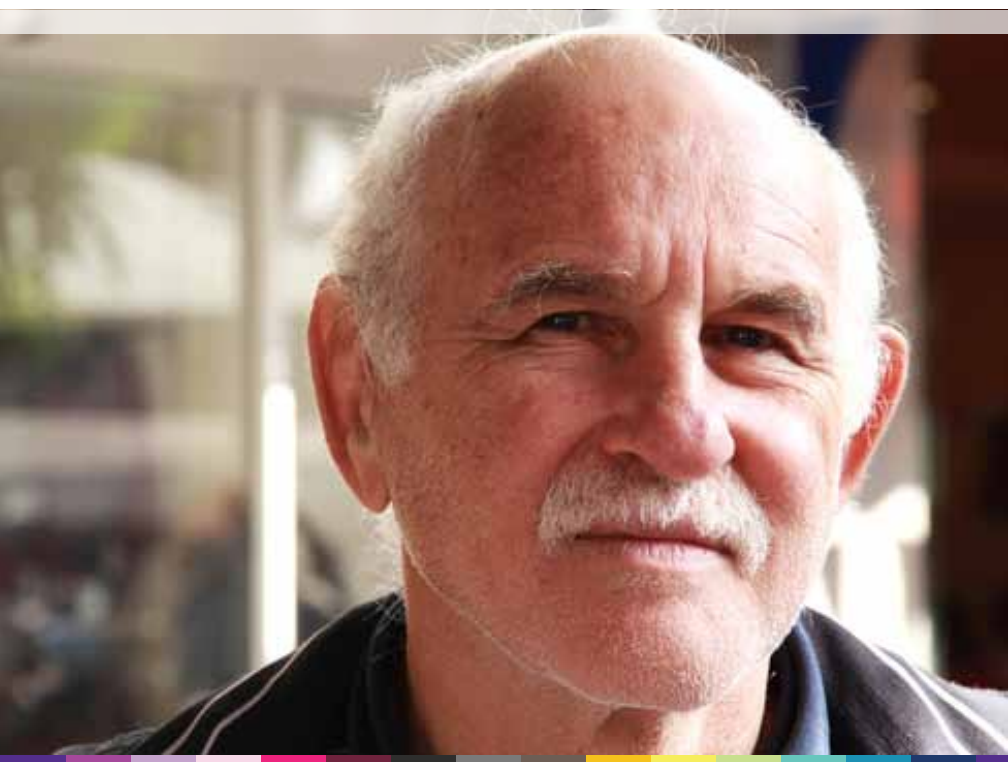
Ponatinib appears to benefit people with advanced gastrointestinal stromal tumors whose cancer contains a mutation (change) in the KIT gene. Researchers will continue to study ponatinib to see in which patients it will be most useful (*page 74*).

RG7155 and PLX3397 appear to have benefited people with pigmented villonodular synovitis, a condition that causes the tissue lining the joints and tendons to thicken and grow. Tumors that result from this overgrowth are not cancerous, but pigmented villonodular synovitis can lead to bone damage and arthritis if left untreated (*page 75*).

Aldoxorubicin for Advanced Soft Tissue Sarcoma

A new medication, aldoxorubicin, may benefit people with advanced soft tissue sarcoma (ASTS), according to a clinical trial. Soft tissue sarcoma is a type of cancer that begins in the soft tissues of the body. Soft tissues connect, support and surround other body structures. The soft tissues include muscle, fat, blood vessels, nerves, tendons and the lining of the joints.

More than 120 patients with ASTS took part in this study. Two-thirds received aldoxorubicin. The remaining patients received doxorubicin, which is considered standard treatment for soft tissue sarcoma. For patients who received aldoxorubicin,



it took longer for their cancer to come back than it did in patients who received doxorubicin (5.7 months versus 2.8 months). However, patients receiving aldoxorubicin did experience more side effects, including neutropenia (lowered levels of a type of infection-fighting white blood cells), nausea, vomiting, fatigue and loss of appetite.

What Patients Need to Know

Aldoxorubicin appears to help delay the return of cancer in people with ASTS. Researchers will study aldoxorubicin further to confirm these results.

Paclitaxel Plus Bevacizumab for Advanced Angiosarcoma

Combining paclitaxel (Taxol and others) and bevacizumab (Avastin) did not provide any greater benefit than paclitaxel alone for people with advanced angiosarcoma, according to a clinical trial. Angiosarcoma is an uncommon type of cancer that appears in blood vessels and the lining of the joints. Advanced angiosarcoma has spread to the skin, bones or other parts of the body.

More than 50 patients with advanced angiosarcoma took part in this study. One half received paclitaxel. The other half received paclitaxel plus bevacizumab. Paclitaxel is considered standard treatment for advanced angiosarcoma. After about 14 months, in people who received paclitaxel plus bevacizumab, the cancer came back in 6.9 months. In those who received paclitaxel alone, the cancer returned in 6.8 months. There was a higher risk of serious side effects for patients receiving the combination treatment.

What Patients Need to Know

Adding bevacizumab to paclitaxel did not appear to provide any additional benefit for people with advanced angiosarcoma. Paclitaxel remains the standard treatment for angiosarcoma. Researchers will continue to use clinical trials to improve treatments for people with angiosarcomas.

Ponatinib for Advanced Gastrointestinal Stromal Tumors

Ponatinib (Iclusig) appears to benefit people with advanced gastrointestinal stromal tumors (GISTs), according to early results from a clinical trial. GISTs are uncommon tumors of the gastrointestinal tract.

More than half of GISTs start in the stomach. Most of the others start in the small intestine. GISTs are different from other gastrointestinal tract cancers such as cancer of the colon or the esophagus. They start in different types of cells and need different types of treatment.

Results were reported on 35 patients with advanced GIST who took part in this study. Their cancer cells had become resistant to previous treatments. All people in the clinical trial received ponatinib. The patients were separated into two groups. About two-thirds of the patients had a mutation (change) in the KIT gene. The others did not. Researchers wanted to know whether the presence or absence of this mutation had an effect on treatment.

About 40 percent of patients in the study had no significant tumor growth after 16 weeks of treatment. Ponatinib was of most benefit for people with KIT mutations. However, the



drug did lead to side effects, including rash, fatigue, dry skin, headache, abdominal pain and constipation.

What Patients Need to Know

Early results from this trial show that ponatinib may benefit people with GIST whose cancer did not respond to earlier treatment. Researchers will continue to study ponatinib to see in which patients it will be most useful.

RG7155 and PLX3397 for Pigmented Villonodular Synovitis

Two new medications, RG7155 and PLX3397, appear to have benefited people with pigmented villonodular synovitis (PVNS), according to two early-stage clinical trials. PVNS is a condition that causes the synovium (the tissue lining the joints and tendons) to thicken and grow. The tumor that results from

this overgrowth is not cancerous, but PVNS can lead to bone damage and arthritis if it is not treated.

More than 10 patients with locally advanced PVNS took part in the first study. In some of the people, the PVNS had resisted previous chemotherapy. Some patients had previous surgery that did not provide a cure. All patients received RG7155. After almost 16 months, the tumor did not come back in about 90 percent of these patients.

More than 15 patients with locally advanced PVNS took part in the second clinical trial. All patients received PLX3397. After almost 16 months, there was a decrease in the size of the tumor in about 64 percent of these patients.

What Patients Need to Know

RG7155 is an injectable drug that stops the growth of cells responsible for PVNS. PLX3397 is an oral drug that blocks a substance called colony stimulating factor 1, a driving force in the development of PVNS.

Both RG7155 and PLX3397 appeared to benefit people with advanced PVNS. Researchers will continue to study these medications in larger clinical trials to learn which patients will benefit most.

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