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Your Guide to the Latest Cancer Research and Treatments

*Highlights from the
2010 Annual Meeting of the
American Society of Clinical Oncology*

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- Recent news on various cancers
- Promising new treatments
- Clinical trials
- Managing side effects



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Your Guide to the Latest Cancer Research and Treatments

Highlights from the 2010 Annual Meeting of the American Society of Clinical Oncology

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About This Guide

The American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing doctors who treat people with cancer. Each year, more than 30,000 cancer researchers and oncologists from around the world gather in the United States for ASCO's Annual Meeting.

The ASCO Annual Meeting is an international conference in which presentations are given on the most cutting-edge findings in cancer treatment and care. At the meeting, cancer care professionals have the opportunity to listen to, learn from, and discuss scientific papers that point the way to improved treatment.

This guide, produced by CancerCare®, covers key research findings presented on 12 different cancer types. It also includes a chapter on advances in managing side effects. Each chapter was edited by an expert in the field, who ensured the accuracy of the information presented. Their names and titles are listed on pages 6 to 8.

We hope you find this guide helpful in your search for the latest cancer information. For more information on other CancerCare publications, or to learn how our oncology social workers can help you cope with cancer, visit us at www.cancercares.org or call **1-800-813-HOPE (4673)**.

How Clinical Trials Contribute to Treatment Options

This CancerCare Connect® booklet focuses on recent advances in the treatment of various cancer types—advances made possible only through the process of clinical trials. Clinical trials are studies that proceed in phases and test new drugs, treatments, or other interventions with the goal of improving the survival and quality of life of people with cancer.

Phase I trials test, for the first time, the safety of a new drug or dosage in a relatively small group of people. Phase II trials test the treatment in a larger group of people to see whether it is in fact effective. In phase III trials, the new treatment is given to a larger group of patients and compared head-to-head with the current standard of care. If it is found to be more effective, it may change the way patients with that diagnosis are treated in the future.

There are many reasons to consider joining a clinical trial. For example, in later-stage trials, the treatments being tested have already shown promise of being just as effective or possibly better than the current standard of care. On the other hand, earlier-stage trials may offer additional treatment options for individuals who have already tried the standard of care or various other treatments.

If you are interested in joining a clinical trial, speak with your oncologist. He or she is most familiar with your case and can tell you whether any of the trials discussed in this booklet, or others in progress, may be right for you. You can also find listings of clinical trials through the Web resources listed on page 68 of this booklet.

About the Editors

CancerCare® is a national nonprofit organization that provides free professional support to anyone affected by cancer. Our services are provided by oncology social workers and include individual counseling, support groups, education, financial assistance, and referrals to resources.

Each year, the CancerCare Connect® booklet series publishes a special edition that presents research highlights from the Annual Meeting of the American Society of Clinical Oncology (ASCO). For this 2010 report, we are indebted to the following medical experts, who ensured the accuracy of the information discussed in this publication.



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Bladder Cancer

Bladder cancer continues to pose many challenges, especially when it comes to treating people whose cancer has invaded the muscle wall of the bladder. The hope is that combining surgery, radiation, chemotherapy, and newer cancer-fighting drugs will lead to improved survival for these patients. The studies discussed here from ASCO's Annual Meeting are important steps toward that goal.

Judd W. Moul, MD
Duke University Medical Center

Chemoradiotherapy for Bladder Cancer

In a recent clinical trial, people with bladder cancer that had spread to the muscle who were treated with a combination of chemotherapy and radiation (chemoradiotherapy) lived longer than those treated with radiation alone. Five years after treatment, 50 percent of the patients who received chemoradiotherapy were alive, compared with 33 percent of those who received radiation alone. Chemotherapies used in this study included fluorouracil and mitomycin (Mutamycin and others). Chemoradiotherapy helped stop bladder cancer from returning, and there was no increase in side effects with this treatment.



WHAT PATIENTS NEED TO KNOW

This study is only the second late-stage clinical trial to show that radiation is more beneficial when given with

chemotherapy than when it is given by itself. But it is the largest study ever conducted with people who have bladder cancer that has spread to the muscle, and researchers are pleased with the results. They hope that with further follow-up, the treatment will show an increase in survival.

Triple Chemotherapy Treatment for Bladder Cancer After Surgery

Combining three chemotherapy drugs—paclitaxel (Taxol and others), gemcitabine (Gemzar), and cisplatin (Platinol and others)—may prove to be an effective way to extend the lives of people with invasive bladder cancer (cancer that is growing into surrounding healthy tissues). Patients who had surgery to remove their bladder tumors took part in a clinical trial to study the effectiveness of the three drugs. After five years, 60 percent of those who received these three drugs were still alive, compared with 31 percent of those who did not receive the drugs. This new treatment, called the PGC triplet, lengthened the time it took for the cancer to start growing again after surgery. The treatment also increased the amount of time that patients remained free of cancer after surgery.

WHAT PATIENTS NEED TO KNOW

Approximately half of people with invasive bladder cancer experience a relapse (return of cancer symptoms after a period of improvement) within the first three years after surgery. So researchers were pleased with the early results of this PGC triplet and hope to confirm these benefits in future clinical trials.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Blood and Lymph Cancers

This is a time of unprecedented progress in leukemia and lymphoma treatment. For the first time, novel drugs such as lenalidomide (Revlimid) can be used not only to treat newly diagnosed or relapsed myeloma but also as maintenance therapies to extend the response to treatment. New medications are also clearly changing the treatment outcome in myeloma, increasing both quality and length of life.

Kenneth C. Anderson, MD
Harvard Medical School and
Dana-Farber Cancer Institute

Alternatives to Standard Treatment of Chronic Myelogenous Leukemia

When imatinib (Gleevec) was introduced in 2001, it revolutionized the treatment of chronic myelogenous leukemia (CML). Now, two newer medications appear to be even more effective than imatinib and could become the new standard of care for people with newly diagnosed CML.



A clinical trial known as the ENESTnd study compared imatinib and nilotinib (Tasigna). After 12 months of treatment, the bone marrow, which produces blood cells, had begun to work properly in twice as many patients who received nilotinib as those who received

imatinib (44 percent versus 22 percent). In 80 percent of the people who took nilotinib, there was no longer any evidence of cancer in their bone marrow. In those who took imatinib, 65 percent had no evidence of cancer in the bone marrow.

Another clinical trial, called DASISION, compared imatinib with another newer drug, called dasatinib (Sprycel). In the DASISION study, the bone marrow had begun to produce normal cells and, at least to some extent, started working properly in more patients who received dasatinib than imatinib (77 percent versus 66 percent). Also, dasatinib acted more quickly than imatinib: the time it took to see these improvements was 6.3 months for dasatinib compared with 9.2 months for imatinib.

WHAT PATIENTS NEED TO KNOW

Nilotinib has been approved by the U.S. Food and Drug Administration (FDA) as a first-line (first-time) treatment for CML. Approval of dasatinib as a first-line treatment for CML is expected soon. As researchers understand more about how leukemia cells resist treatment, they should be able to learn how best to use imatinib, nilotinib, and dasatinib to treat people with CML. All of these medications are targeted treatments. They work by blocking a substance that encourages the growth of cancer cells.

Bosutinib for Resistant Chronic Myelogenous Leukemia

A new drug called bosutinib may prove to be an effective second-line treatment for people who have CML that does not respond or no longer responds to the standard treatment, imatinib. More than one year after treatment in a clinical trial, cancer cells had completely disappeared in about 50 percent of patients who received bosutinib, and their bone marrow had started to work properly.

WHAT PATIENTS NEED TO KNOW

These results are from a fairly early stage of clinical research and need to be confirmed in further studies. A later-stage clinical trial is currently comparing bosutinib and imatinib

in patients with newly diagnosed CML, and results are expected later this year. Researchers hope to learn whether bosutinib can also extend the lives of people with CML.

Combination Treatment With Stem Cell Transplant for Acute Lymphoblastic Leukemia

A small, early-stage clinical trial found that a combination of chemotherapy and targeted treatments along with stem cell transplantation may extend the lives of people who have Ph+ (Philadelphia chromosome-positive) acute lymphoblastic leukemia (ALL). The Philadelphia chromosome carries a genetic change that causes leukemia cells to grow uncontrollably.

In the trial, 90 percent of younger patients (below age 40) with Ph+ ALL who were treated with both the combination treatment and a transplant were still alive three years later, compared



with 33 percent of those who did not receive a transplant. The medications given were imatinib plus hyperCVAD, a group of anti-cancer drugs that includes cyclophosphamide (Cytoxan and others), vincristine (Oncovin and others), doxorubicin (Adriamycin and others), and dexamethasone. HyperCVAD is given in small doses to reduce side effects.

WHAT PATIENTS NEED TO KNOW

The results of this small study support those of other recent clinical trials that showed the advantage of using stem cell transplant to treat leukemia. Although targeted treatments such as imatinib are changing the way several

types of leukemia are being treated, this clinical trial indicates that stem cell transplant may still be important for people with ALL.

A New Form of Vincristine for Resistant ALL

A recent clinical trial found that a new form of the chemotherapy vincristine appears to be a promising way to stop ALL from growing and may be able to extend the lives of people with resistant ALL. In the new form of the drug, called vincristine sulfate injection (Marqibo), the medication is placed inside oil droplets called liposomes. This allows vincristine to be released slowly and steadily so that it continuously attacks cancer cells.

Researchers have found that this treatment seems to be more beneficial for people who have Ph⁻ (Philadelphia chromosome-negative) ALL than for those who have Ph⁺ ALL. Patients in the clinical trial who received the new form of vincristine lived for an average of 4.6 months after treatment. Also, the tumor

shrank or completely disappeared in more than 35 percent of people who had Ph⁻ ALL that did not respond or no longer responded to other treatments. This group of patients lived an average of 7.3 months after treatment.



WHAT PATIENTS NEED TO KNOW

Over time, ALL tends to resist treatment. So researchers are pleased with the early results of the new vincristine sulfate injection, which may be an effective way to treat people whose cancer no longer responds to previous treatments. Further studies are needed to confirm these benefits.

Rituximab Maintenance Treatment for Follicular Lymphoma

In a large late-stage clinical trial, two years of maintenance therapy with rituximab (Rituxan) after first-time combination chemotherapy decreased the risk of the return of follicular lymphoma (FL) by 50 percent. Maintenance therapy is treatment given, perhaps for a long time, to keep cancer from coming back after successful first-time treatment. The clinical trial also showed that the tumor had stopped growing in 82 percent of patients who received rituximab maintenance therapy, compared with 66 percent of those who did not receive the additional rituximab treatment. More than 1,000 people with FL from more than 25 countries took part in this clinical trial.

WHAT PATIENTS NEED TO KNOW

Researchers are so impressed with the results of this trial that they believe rituximab maintenance treatment after first-time chemotherapy containing rituximab should now be considered the standard of care for first-time treatment of people with FL. However, the patients in this study will continue to be evaluated to learn whether the extra treatment with rituximab can help them live longer. Rituximab belongs to a class of drugs called monoclonal antibodies, which zero in on cancer cells to destroy them. This medication is approved for treating chronic lymphocytic leukemia and certain types of non-Hodgkin lymphomas (NHLs).

Delaying the Growth of Follicular Lymphoma

In another clinical trial, rituximab also benefited people with resistant FL. In this study, the drug was given to patients before stem cell transplantation in a procedure called purging. Rituximab was then given as maintenance treatment after

transplantation. Five years after treatment, the tumor had not continued growing in 63 percent of patients who received rituximab before and after transplantation, compared with 38 percent of those who did not.

WHAT PATIENTS NEED TO KNOW

Based on these encouraging results, many researchers now believe that rituximab maintenance may be effective for all people with FL who are eligible for transplantation and have already responded to rituximab. However, the early benefits with this new treatment approach do not appear to prolong the lives of these people. Thus, further studies are needed to learn how best to use rituximab maintenance for people with FL.

Chemotherapy and Radiation for Diffuse Large B-Cell Lymphoma

A recent clinical trial showed that, when used along with standard chemotherapy, two different types of radiation treatment appear to be equally safe and effective in stopping the growth of cancer and extending the lives of people with early-stage diffuse large B-cell lymphoma (DLBCL).

The standard approach, called involved-field radiotherapy, delivers radiation to those areas involved in the lymphoma (such as the neck or underarm). The newer approach, which is known as involved nodal radiotherapy, delivers radiation to the smaller, more targeted area of the lymph nodes (less than or equal to about two inches) in the region affected by lymphoma.



Five years after treatment with chemotherapy and radiation, the tumor had not grown in more than 80 percent of the patients in a clinical trial. Also, more than 80 percent of the patients were still alive, regardless of the type of radiation therapy used.

WHAT PATIENTS NEED TO KNOW

People who have early-stage DLBCL, the most common type of NHL, are often treated with a combination of chemotherapy and radiation. Researchers were pleased to find out that it may be possible to use more targeted radiation and still effectively treat the cancer. This approach would reduce the amount of radiation given to these people, which should in turn limit its side effects. Thirteen years after treatment, the cancer returned in only two patients who took part in the clinical trial.

Denileukin Diftitox Plus Chemotherapy for Peripheral T-Cell Lymphoma

A small, early-stage clinical trial found that combining standard chemotherapy and a drug called denileukin diftiox (Ontak) may be an effective way to shrink tumors in people who have newly diagnosed peripheral T-cell lymphoma (PTCL). PTCL is a rare type of lymphoma. In the trial, the tumor shrank or disappeared in approximately 65 percent of patients who received the new combination treatment. This response lasted for more than two years.

WHAT PATIENTS NEED TO KNOW

Denileukin diftiox works by latching on to cancer cells with a specific target and introducing the diphtheria toxin to kill the cells. Doctors already knew that denileukin diftiox was an effective way to treat PTCL when it does not respond to other treatments. Now, they are pleased to discover that the

benefits of this drug may also extend to people with newly diagnosed PTCL. A large clinical trial, which will compare this new combination treatment with chemotherapy alone in people with PTCL, is being planned.

Panobinostat After Stem Cell Transplant for Hodgkin Lymphoma

According to an early-stage, international clinical trial, a new drug called panobinostat is a promising treatment option



for people whose Hodgkin lymphoma (HL) returns after stem cell transplant. In the trial, the tumor shrank or disappeared in one-fourth of the patients treated with panobinostat. Furthermore, the tumor neither shrank nor grew in 60 percent of treated patients. All of the

people in this study had already received an average of four treatments for their HL.

WHAT PATIENTS NEED TO KNOW

Currently, there is no standard treatment for people whose HL returns after a stem cell transplant. Thus, researchers are excited by these early results with panobinostat. However, this new treatment will be studied further to learn whether it is more effective if given alone or in combination with other treatments.

Lenalidomide Combinations for Multiple Myeloma

New combinations of treatment with lenalidomide (Revlimid) are proving to be at least as effective as, and perhaps better than, stem cell transplant for people with newly diagnosed

multiple myeloma. In one early-stage clinical trial, tumors shrank or disappeared in 100 percent of patients treated with the combination of lenalidomide, bortezomib (Velcade), and dexamethasone without stem cell transplant. This is the first time that such a response rate has been seen in people with previously untreated multiple myeloma.

In another later-stage clinical trial, combination treatment with lenalidomide, prednisone, and melphalan (Alkeran) appeared to be equally effective as stem cell transplant in people with newly diagnosed multiple myeloma. One year after treatment, the tumor had not continued to grow in more than 90 percent of patients in both groups. Also, between 97 and 98 percent of patients in both groups were still alive one year after treatment.

WHAT PATIENTS NEED TO KNOW

Researchers are so impressed with these unprecedented results on lenalidomide in combination treatment that many of them now question whether stem cell transplantation should still be used to treat people with newly diagnosed multiple myeloma. In the future, stem cell transplant may be delayed (or perhaps avoided altogether) in certain people with multiple myeloma. Larger studies are still needed to confirm these results.



Lenalidomide Maintenance Therapy After Stem Cell Transplant for Multiple Myeloma

Recently, clinical trials have found and confirmed that extended treatment with lenalidomide after a stem cell

transplant, also referred to as maintenance therapy, lengthened the time it took for the cancer to continue growing in people with multiple myeloma. Three years after stem cell transplantation, the tumor had not continued to grow in nearly 70 percent of patients who received lenalidomide maintenance therapy. In those who did not receive maintenance therapy, that number was less than 35 percent.



WHAT PATIENTS NEED TO KNOW

Considered a breakthrough medication for multiple myeloma, lenalidomide seems to work in a number of ways, including helping a person's immune system fight the growth of cancer. The progress of the patients in this clinical trial will continue to be followed. Researchers are impressed with these results on lenalidomide maintenance treatment; over time, they hope to see improved survival for these patients.

Lenalidomide was not associated with any serious side effects.

Zoledronic Acid for Multiple Myeloma

In a clinical trial, almost 2,000 patients with newly diagnosed multiple myeloma were treated with one of two bone-strengthening drugs, zoledronic acid (Zometa) or clodronate (Bonefos), in addition to traditional treatment for multiple myeloma. It took longer for the cancer to continue growing in the people who were treated with zoledronic acid than in those who were treated with clodronate (19.5 months versus 17.5 months). Also, those who received zoledronic acid lived an average of 5.5 months longer than those who received clodronate (50 months versus 44.5 months).

WHAT PATIENTS NEED TO KNOW

Zoledronic acid and clodronate belong to a class of drugs known as bisphosphonates, which help prevent the loss of calcium from bone, reduce bone pain, and decrease the risk of bone fractures (breaks). Some bisphosphonates, including zoledronic acid, are approved for treating and reducing the risk of bone metastases (cancer that has spread to the bone) and bone loss in people with cancer. Recently, some bisphosphonates have shown some promise in fighting cancer directly. Further studies are needed to confirm these early, yet encouraging results.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Brain Cancer

The following are just some of the many clinical trial results reported at this year's ASCO Annual Meeting. Although the standard of care for newly diagnosed glioblastoma remains surgery, radiation, and temozolomide (Temodar) followed by more temozolomide, we are hopeful that adding bevacizumab (Avastin), and possibly tumor treatment fields (described below), will prove effective. It is clear that newer strategies are needed for patients with malignant brain tumors. The next several years will give us more information on the role of these treatments.

Henry S. Friedman, MD
Duke University Medical Center

An Alternative to Chemotherapy for Glioblastoma

A recent clinical trial found that a new treatment that delivers electricity to the brain through electrodes temporarily placed on the head may be an effective way to stop glioblastoma from returning. Known as TTF (tumor treatment fields), this potential alternative to chemotherapy has fewer side effects.



WHAT PATIENTS NEED TO KNOW

This is the first time that TTF has been tested in such a late-stage clinical trial. Doctors are intrigued with it, but further studies are needed to confirm these early results and

to learn whether TTF can lengthen the lives of people with glioblastoma. This type of research is important because for

many people with this type of quickly growing brain cancer, standard chemotherapy either does not work or stops working after a while.

Combining Bevacizumab, Chemotherapy, and Radiation for Brain Cancer

In another clinical trial, a new combination treatment doubled the time it took for the brain cancer glioblastoma to continue growing, compared with standard treatment (14.2 months versus 6.9 months). The combination also helped these people live longer—nearly half of the patients studied in this clinical trial were alive two years after treatment. The new treatment first uses the targeted treatment bevacizumab (Avastin) with temozolomide (Temodar) and radiation, and then uses bevacizumab, temozolomide, and irinotecan (Camptosar and others).



WHAT PATIENTS NEED TO KNOW

Combining several treatments together is often more effective than using them individually. Although this new combination treatment must be studied further, some doctors believe it may change the way people with glioblastoma are treated in the future.

Bevacizumab, Alone or in Combination With Irinotecan

In another study, bevacizumab—used alone or in combination with the drug irinotecan—helped people with

resistant glioblastoma live longer than other drugs used to treat this type of brain cancer, such as temozolomide or lomustine (CeeNU). Thirty-eight percent of those who received bevacizumab were still alive 12 months after treatment, compared with between 14 percent and 27 percent of those who received other drugs. Thirty months after treatment with bevacizumab, up to 16 percent of patients were still alive.

WHAT PATIENTS NEED TO KNOW

Many people with glioblastoma are treated first with radiation therapy and temozolomide. However, sometimes these treatments stop working, and the cancer continues to grow. Researchers were pleased with the early results of this clinical trial with bevacizumab and hope to confirm the benefits in a later-stage study.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Breast Cancer

This year, we saw a number of promising new options for treating breast cancer, as illustrated by the studies highlighted in this chapter. For example, the class of drugs called bisphosphonates, used primarily for bone health, represents an exciting avenue of research for women with early-stage breast cancer. Also, the new drug eribulin (Halaven) may offer another option for patients whose cancer continues to grow after receiving standard treatments. And researchers are developing several different kinds of “PARP inhibitors,” a type of targeted treatment that may offer a new way to treat women with triple-negative breast cancer and/or those with *BRCA1* gene mutations. In addition, combining T-DM1 and pertuzumab may expand the options for patients with HER2-positive breast cancer who no longer benefit from current treatments. Also encouraging are results from studies that point toward ways to improve quality of life for women with breast cancer by avoiding unnecessary radiation treatment and removal of underarm lymph nodes.

William J. Gradishar, MD
Northwestern University
Feinberg School of Medicine

Benefits of Hormone Therapy Before Surgery for Early-Stage Breast Cancer

According to a clinical trial known as ACOSOG Z1031, neoadjuvant hormone therapy may be an extremely effective way to shrink tumors in postmenopausal women with early estrogen receptor-positive (ER+) breast cancer. Neoadjuvant therapy is treatment that is given as a first step to shrink tumors before the main treatment, in this case, surgery.

In this clinical trial, tumors shrank significantly in 79 percent of women who received letrozole (Femara and others), 77 percent of women who received anastrozole (Arimidex and others), and 69 percent of women who received exemestane (Aromasin). All of these drugs belong to a class of medications called aromatase inhibitors, which block production of the hormone estrogen. Perhaps even more impressive is that half of the women who would have initially been treated with mastectomy (surgery to remove the breast) were able to receive breast-conserving surgery as a result of the benefits of this hormone therapy.

WHAT PATIENTS NEED TO KNOW

Researchers are calling these results “hugely encouraging” for women with early ER+ breast cancer. This is the first large study of the use of these drugs before surgery in the United States.

The benefits of these medications in shrinking breast cancer tumors may enable women with this type and stage of cancer to have less aggressive surgery. Furthermore,

the drugs may make it possible for women with inoperable breast tumors to have surgery. This was the case for all of the women with inoperable tumors in the ACOSOG Z1031 study.



Is Radiation Necessary for Older Women With Early-Stage Breast Cancer?

According to the long-term results of a recent clinical trial, it may be safe for women with early-stage breast cancer who are older than age 70 to not have radiation treatment. In

this study, older women with early-stage ER+ breast cancer received the cancer drug tamoxifen (Nolvadex and others) plus radiation or tamoxifen alone. (All of the women first had lumpectomy—breast-sparing surgery that removes only the tumor and very little healthy tissue). Twelve years after treatment, mastectomy had not been required and cancer had not spread to other parts of the body in more than 95 percent of women in both groups. Also, nearly 70 percent of women in both groups were still alive 12 years after treatment.

WHAT PATIENTS NEED TO KNOW

Tamoxifen is a standard treatment after surgery for women who have hormone receptor-positive tumors. Many researchers now believe that older women with small ER+ breast tumors may use tamoxifen alone and safely avoid radiation. These very positive results with lumpectomy and tamoxifen may indeed change the way in which these older women are treated in the future.

Axillary Lymph Node Dissection for Early-Stage Breast Cancer

A surgical procedure known as axillary lymph node dissection (ALND) appears to offer no survival benefit to women who have breast cancer that has spread to the sentinel lymph node (the first lymph node to which breast cancer is likely to spread). More than 800 women with early-stage breast cancer and positive sentinel lymph nodes took part in a late-stage clinical trial. All of the women had previously had a lumpectomy.

About 90 percent of those who had ALND and 90 percent of those who did not have the procedure were still alive five years after treatment. Until now, ALND, which removes all of the lymph nodes found in and around the underarm, had been commonly used in the hope of extending the lives of women with early-stage breast cancer.

WHAT PATIENTS NEED TO KNOW

This study is the largest late-stage trial of ALND in women with cancer in their sentinel lymph nodes. Based on these results, the way women with newly diagnosed early-stage breast cancer and positive sentinel lymph nodes are treated should change in the near future. With no differences found in survival between those who had ALND and those who did not, many of these women can be safely spared the surgical procedure. As a result, they may also be spared developing lymphedema, an uncomfortable swelling of the arm that often results from ALND. However, researchers cautioned that ALND may still be beneficial for certain women with breast cancer, such as younger women with many more microscopic cancer cells that have spread to other parts of the body.

New Diagnostic Technique Proves to Be Not Beneficial for Women With Early-Stage Breast Cancer

A related study focused on the role of routinely evaluating sentinel lymph nodes with a sophisticated technique called immunohistochemistry (IHC). With such a technique, doctors can find microscopic signs of cancer that may not be noticed on standard diagnostic tests.

In this clinical trial, IHC was used to look for hidden cancer cells in the sentinel lymph nodes of women with early-stage breast cancer. The standard tests had not found any cancer cells. But researchers found that performing IHC on sentinel lymph nodes and identifying a few cancer cells did not appear to help these women to live any longer. For both groups of patients—those who had cancer cells detected in a sentinel lymph node by IHC and those who did not—95 percent of the women were still alive five years after their diagnosis.

WHAT PATIENTS NEED TO KNOW

Although IHC may be worthwhile for certain women with early-stage breast cancer, routine examination of the sentinel nodes by IHC is probably not necessary in this group of women.

Zoledronic Acid for Early-Stage Breast Cancer

The bone-strengthening drug zoledronic acid (Zometa) may be a promising way to stop breast cancer from recurring (coming back after a period of improvement in symptoms of cancer). In a small initial clinical trial, women who had received chemotherapy for early-stage breast cancer were treated with zoledronic acid. Two years later, the number of tumor cells found in the bone marrow of these women was significantly reduced. (Bone marrow is the soft, spongy tissue in the center of most bones that produces blood cells.)



WHAT PATIENTS NEED TO KNOW

Women treated for early-stage breast cancer who have high numbers of tumor cells in their bone marrow are more likely to have a cancer recurrence somewhere else in their bodies than women who don't. Thus, researchers are encouraged to learn that zoledronic acid may prove to be an effective way to decrease the number of these tumor cells and prevent the return of cancer, but more research is needed. Zoledronic acid belongs to a group of drugs known as bisphosphonates, which help prevent the loss of calcium from bone and reduce the risk of bone fractures (breaks).

Some bisphosphonates, including zoledronic acid, are also approved for treating bone metastases (cancer that has spread to the bone) and bone loss in people with cancer.

Eribulin for Drug-Resistant Metastatic Breast Cancer

A new drug called eribulin (Halaven) may prove to be an effective way to extend the lives of women with metastatic breast cancer that no longer responds to initial chemotherapy. In a late-stage clinical trial, women who received eribulin lived for an average of 13.2 months, whereas women who did not receive eribulin lived for an average of 10.7 months. All of the patients in this clinical trial had already received between two and five different types of chemotherapy for their resistant breast cancer.

WHAT PATIENTS NEED TO KNOW

When breast cancer no longer responds to other treatments, it becomes more difficult to treat. This is the first time in a late stage of clinical research that a single drug has extended the lives of women with highly resistant breast cancer. Based largely on the results of this clinical trial, the U.S. Food and Drug Administration recently approved eribulin for the treatment of metastatic breast cancer that has failed to respond to at least two prior forms of chemotherapy for advanced cancer. Many researchers believe that eribulin would be a welcome addition to their treatment options for women with resistant breast cancer.

Combining PARP Inhibitors With Other Treatments for Metastatic Breast Cancer

Veliparib and olaparib—two drugs that belong to an exciting new class of targeted treatments called PARP inhibitors—are

showing encouraging results in early-stage clinical trials for women with metastatic breast cancer. In one clinical trial, tumors shrank or did not continue growing in nearly half of women with metastatic breast cancer who received the combination of veliparib and a drug used to treat certain types of brain tumors called temozolomide (Temodar). In another trial, breast tumors shrank by at least 50 percent in about half of women with metastatic triple-negative breast cancer who received the combination of olaparib and the standard anti-cancer drug paclitaxel (Taxol and others).



WHAT PATIENTS NEED TO KNOW

Although researchers are pleased with the early results on these PARP inhibitor combination treatments, it is important to remember that these studies are at a very early stage of clinical research. Additional studies in larger groups of women with metastatic breast cancer are needed to confirm the effectiveness of these drugs and to determine the proper doses and schedules for treatment with these combinations. PARP is short for “poly(ADP-ribose) polymerase.”

PARP inhibitors block a cancer cell’s ability to repair itself when damaged by radiation or chemotherapy, for example. These drugs may improve the effectiveness of other treatments.

Combination Treatment With Pertuzumab and Trastuzumab-DM1 for Metastatic Breast Cancer

An early-stage clinical trial showed that a new treatment combining pertuzumab and T-DM1 is a promising way

to treat women who have HER2-positive locally advanced or metastatic breast cancer. T-DM1 is a drug made up of trastuzumab (Herceptin), which specifically targets HER2-positive breast cancer cells, and DM1, which kills them.

In the trial, tumors shrank by at least 50 percent in nearly half of the women who received this new combination treatment. All of these patients had already received at least four different chemotherapy treatments for their breast cancer.

WHAT PATIENTS NEED TO KNOW

These encouraging results with T-DM1 and pertuzumab are from a very small clinical trial. How well this combination



treatment actually fights cancer will be discovered in later stages of clinical study. Researchers hope that this new combination will become a safe and effective alternative for women with HER2-positive locally advanced or

metastatic breast cancer. Both trastuzumab and pertuzumab are monoclonal antibodies. These drugs zero in on cancer cells and target specific cell mechanisms that encourage the growth of cancer. By linking DM1 with trastuzumab, T-DM1 delivers the cell-killing activity of DM1 directly to breast cancer cells with less risk of damaging normal cells and potentially fewer side effects.

Please note: Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.

Colorectal Cancer

The following studies presented at the ASCO Annual Meeting demonstrate the expanding number of treatment options for people with colorectal cancer. They also emphasize the need for continued follow-up to learn more about the long-term benefits of various treatments. In a couple of the studies, researchers found that some treatments possibly cause more side effects than other equally effective treatments. This is also important information for doctors and patients to know.

Stuart M. Lichtman, MD
Memorial Sloan-Kettering Cancer Center

Combined Treatments for Early-Stage Rectal Cancer

Combination treatment with chemotherapy and radiation may allow people with early-stage rectal cancer to safely have surgery. In a recent clinical trial, patients received the chemotherapies capecitabine (Xeloda) and oxaliplatin (Eloxatin and others) plus radiation around the hip. About four to eight weeks later, they had surgery to remove the tumor. The tumor was completely gone in almost half of the people who received chemotherapy plus radiation before having the less aggressive surgery.



WHAT PATIENTS NEED TO KNOW

Many people who have early-stage rectal cancer are treated with aggressive surgery, which may require the removal

of the rectum and is often associated with complications. Based on the results of this clinical trial, patients may be offered a less-involved yet effective type of surgery in the future. Researchers plan to follow these people closely to see whether the benefits last long term and whether the cancer returns.

Bevacizumab for Metastatic Colorectal Cancer

For people with metastatic colorectal cancer, bevacizumab (Avastin) alone may become an effective treatment option after initial treatment with the standard chemotherapy XELOX (capecitabine and oxaliplatin) plus bevacizumab. In a clinical trial, all the patients received XELOX plus bevacizumab for their initial treatment. Then they were divided into two groups: one group received more XELOX plus bevacizumab; the other group received bevacizumab alone.

There were no major differences in how long it took tumors to continue growing and in how long patients lived after treatment with XELOX plus bevacizumab versus bevacizumab alone. However, more people treated with XELOX plus bevacizumab experienced a severe side effect called sensory neuropathy than did those treated with bevacizumab alone (25 percent versus 18 percent). Sensory neuropathy is damage to nerves that may cause numbness, tingling, or pain in the arms or legs.



WHAT PATIENTS NEED TO KNOW

Although researchers hope to find improved treatments through clinical trials, it's also important to find out that

some medications are equally good but better tolerated. That was the case in this clinical trial. Further studies are under way to evaluate bevacizumab after standard chemotherapy for people with metastatic colorectal cancer.

Bevacizumab Use After Metastatic Colorectal Cancer Continues Growing

An evaluation of patients from the ongoing ARIES study included more than 1,000 people with metastatic colorectal cancer who originally received bevacizumab plus chemotherapy. The people who continued receiving bevacizumab after their tumor grew or spread lived longer (16.3 months) than people who did not (8.5 months for those receiving another type of treatment and 5.2 months for those who stopped treatment altogether).

WHAT PATIENTS NEED TO KNOW

Researchers believe they are on the right track for improving the outcomes of people with metastatic colorectal cancer. To confirm these results, a later-stage clinical trial is now evaluating the continued use of bevacizumab versus

chemotherapy alone as secondary treatment after colorectal cancer has returned.



Cetuximab With Chemotherapy for Metastatic Colorectal Cancer

A recent clinical trial compared cetuximab (Erbix) plus chemotherapy with chemotherapy alone in people with

metastatic colorectal cancer. All the patients in the study had the normal form of the *KRAS* gene. (*KRAS* is a gene involved in the growth of cancer cells, and researchers have found that people who have a change, or mutation, in the *KRAS* gene do not seem to benefit from combination treatment with cetuximab and chemotherapy.) Patients who were treated with cetuximab and chemotherapy lived longer than those who were treated with chemotherapy alone (23.5 months versus 19.5 months).

WHAT PATIENTS NEED TO KNOW

Testing for the *KRAS* gene has revolutionized the treatment of metastatic colorectal cancer. It has helped doctors select those people who have the best chance of responding to treatment with cetuximab and standard chemotherapy. At the moment, *KRAS* status is the only way to predict which people will benefit from cetuximab.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Esophageal Cancer

This year at the ASCO Annual Meeting we learned about a number of important advances in treating esophageal cancer. We now have the strongest evidence yet that chemotherapy and radiation should be given before surgery for esophageal cancer. And evidence is emerging that adding targeted treatments to chemotherapy may offer an important way to treat esophageal cancer that has spread.

Malcolm J. Moore, MD
Princess Margaret Hospital

Chemoradiotherapy Before Surgery for Esophageal Cancer

In a recent clinical trial, people with esophageal cancer who were treated with chemoradiotherapy before surgery lived longer than those who were treated with surgery alone. (Chemoradiotherapy is treatment that combines chemotherapy with radiation.) The chemotherapies used in the study included paclitaxel (Taxol and others) and carboplatin. One year after treatment, 82 percent of those who received chemoradiotherapy had survived, compared with 70 percent of those who did not. These benefits lasted two and three years after treatment.



WHAT PATIENTS NEED TO KNOW

This late-stage clinical trial is the largest study ever on chemoradiotherapy before surgery. The positive results of this study now confirm the results seen in earlier clinical

trials in which chemoradiotherapy before surgery benefitted people with esophageal cancer. This treatment may become the standard of care in the future for people facing surgery for esophageal cancer.

Combination Chemotherapy With Cetuximab for Metastatic Esophageal Cancer

Adding the targeted treatment cetuximab (Erbix) to standard chemotherapy appears to be a promising treatment for people with metastatic esophageal cancer. In a recent clinical trial, the cancer shrank or disappeared in more than 50 percent of patients treated with both cetuximab and FOLFOX (oxaliplatin [Eloxatin and others], leucovorin, and fluorouracil).

WHAT PATIENTS NEED TO KNOW

Cetuximab belongs to a newer class of drugs called monoclonal antibodies. These medications zero in on a “target molecule” on cancer cells, in this case the epidermal growth factor receptor (EGFR). EGFR is found in three-fourths of people with esophageal cancer, so researchers are very interested in drugs like cetuximab. However, these results are from an early stage of clinical research, and so further studies are needed to confirm whether this type of drug is effective for these patients.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Head and Neck Cancers

This is a time of unprecedented progress in understanding and treating head and neck cancers. As described below, human papillomavirus status will help doctors craft better, more specific treatments for their patients. This is the first time that such treatments are available for head and neck cancer patients. Other new treatments are expected to improve outcomes by increasing life expectancy and quality of life. It is not often that so many significant findings are reported in a single meeting, and the next two years look promising as well.

Marshall R. Posner, MD
Mount Sinai School of Medicine

HPV Status and Oropharyngeal Cancer

In a recent clinical trial, oropharyngeal cancer patients whose tumors tested positive for the human papillomavirus (HPV+) survived longer than those who tested negative for HPV (HPV-). Eighty-two percent of HPV+ patients were still alive five years after treatment, compared with 35 percent of HPV- patients.



WHAT PATIENTS NEED TO KNOW

Doctors now believe that people with this type of head and neck cancer whose tumors are HPV+ may do better with less aggressive treatment; those who are HPV- may need more aggressive treatment. HPV is a virus that has been associated with several different cancers, including cervical and head and neck cancers. It now seems clear that HPV+ and HPV- are two different diseases requiring different treatment approaches.

Zalutumumab for Resistant Head and Neck Cancers

In a recent clinical trial, a new drug called zalutumumab prolonged the time it took for cancer to continue growing in people whose head and neck cancer no longer responded to standard chemotherapy. More than six months after treatment, the cancer had not continued to grow in 20 percent of patients who received zalutumumab. In those who were not treated with the new drug but instead received “best supportive care” (the management of symptoms when anti-cancer treatment is no longer thought to be able to cure the cancer), the cancer did not continue to grow in only seven percent. However, there was no significant improvement in survival seen with zalutumumab.



WHAT PATIENTS NEED TO KNOW

Although zalutumumab did not extend the lives of people with head and neck cancer as was hoped, researchers were pleased to see that it was able to delay the time it took for the cancer to continue growing. Zalutumumab belongs to a class of drugs that targets the epidermal growth factor receptor, which is found in excess amounts on many cancer cells. This is the first study to show such a benefit with this type of drug alone in people whose cancer returned after chemotherapy.

BIBW 2992 for Advanced Head and Neck Cancers

Results from a recent clinical trial show that a new medication referred to as BIBW 2992 seems to be at least as effective as cetuximab (Erbix) in shrinking recurrent

or metastatic head and neck cancers. (Recurrent cancer is cancer that has come back, and metastatic cancer is cancer that has spread from where it started to other places in the body.) In this study, the tumor shrank to at least half its original size in 22 percent of patients who received BIBW 2992 but in only 13 percent of those who received cetuximab. The time it took for the cancer to start growing again was similar with both drugs.

WHAT PATIENTS NEED TO KNOW

Cetuximab has been approved by the U.S. Food and Drug Administration for the treatment of head and neck cancer. BIBW 2992, which is also being studied in people who have lung or breast cancer, belongs to a class of drugs known as tyrosine kinase inhibitors (TKIs). These drugs interfere with the communication and growth of cancer cells. This is the first time that a TKI has successfully challenged cetuximab in treating recurrent or metastatic head and neck cancers.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Lung Cancer

This year, researchers at the ASCO Annual Meeting reported on several promising new drugs for lung cancer treatment, with hopeful early results that we will follow closely and continue to study. For example, nab-paclitaxel (Abraxane) has shown advantages over standard paclitaxel (Taxol and others) in treating advanced non-small cell lung cancer (NSCLC). And early results with several different pemetrexed (Alimta) combinations along with radiation are encouraging for people with a type of lung cancer called adenocarcinoma. In addition, early results with two new agents, PF299804 and ARQ197, show promise. We also learned about a new drug in clinical trials that targets lung tumors in a small population of people with NSCLC who have a specific gene. This medication, crizotinib, has the potential to become a new standard of care for these patients. Presentations at this year's ASCO meeting also indicated that older patients with advanced NSCLC can be safely and effectively treated with more aggressive chemotherapy. And in another positive finding, researchers reported that supportive care not only improves the quality of life for people with metastatic lung cancer but also extends their lives.

Roy S. Herbst, MD, PhD
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MD Anderson Cancer Center

Chemotherapy Before Surgery for Early-Stage NSCLC

A recent follow-up of patients with non-small cell lung cancer (NSCLC) who were enrolled in a decade-old clinical trial showed that chemotherapy given before surgery significantly

extended the lives of those who had a relatively early stage of lung cancer at the time of surgery. Ten years after surgery, 38% of those who had stage I or stage II NSCLC and received chemotherapy before surgery were still alive, compared with 23% of those who received surgery alone. Having chemotherapy before surgery did not appear to make much of a difference in survival among patients who had a more advanced stage of lung cancer at the time they underwent surgery. However, 10 years after treatment, significantly more people with all stages of lung cancer who received chemotherapy before surgery remained free of cancer, compared with those who had surgery alone (55 percent versus 38 percent). The chemotherapies used in this trial were mitomycin (Mutamycin and others), ifosfamide (Ifex and others), and cisplatin (Platinol and others).

WHAT PATIENTS NEED TO KNOW

Chemotherapy is often given before surgery for NSCLC to shrink the tumor before it is removed surgically, in the hope that surgery—the first line of treatment for lung cancer—will be curative. This study confirmed the belief that having chemotherapy before surgery will prolong the patient's life, especially if the tumor is still small and hasn't spread far before it is removed by surgery. Even with more advanced tumors, the benefits of chemotherapy before surgery appear to extend 10 or more years beyond surgery, in terms of prolonging the time before the cancer continued to grow in a significant proportion of patients.



Combination Chemotherapy for Older Adults With Advanced NSCLC

Combination chemotherapy with carboplatin plus paclitaxel (Taxol and others) may stop cancer from growing and

extend the lives of older people with advanced NSCLC. In a late-stage clinical trial, combination chemotherapy was compared with a single chemotherapy drug—either vinorelbine (Navelbine and others) or gemcitabine (Gemzar). Older adults, whose average age was 77, took part in this clinical trial. They all had advanced lung cancer.

Patients who received the combination chemotherapy lived longer than those who received just one drug (10.3 months versus 6.2 months). Also, one year after treatment, 45 percent of those who received both carboplatin and paclitaxel were alive, compared with 27 percent of those who did not take these drugs. In addition, patients who received the combination chemotherapy went longer before their cancer continued to grow than did patients who received the single drug (6 months versus 3 months).

WHAT PATIENTS NEED TO KNOW

This study showed that older patients with advanced NSCLC can be safely and effectively treated with more aggressive chemotherapy. This is the first late-stage clinical trial to compare single-drug and double-drug treatments in people older than age 70 with advanced NSCLC. The results may change the way in which older adults with lung cancer are treated in the future.

Nab-Paclitaxel Plus Carboplatin for Advanced NSCLC

Combining carboplatin with a newer form of paclitaxel may prove to be a more effective treatment of advanced NSCLC than carboplatin plus standard paclitaxel. This newer form of paclitaxel, called nab-paclitaxel (Abraxane), is used to treat cancer that has spread or come back after chemotherapy. In a late-stage clinical trial of more than 1,000 patients with advanced NSCLC, the tumor disappeared or shrank in 33 percent of those who received nab-paclitaxel, compared

with 25 percent of those who received standard paclitaxel. The results were even more positive in people who had a certain type of lung cancer known as squamous cell cancer (41 percent versus 24 percent).

WHAT PATIENTS NEED TO KNOW

Researchers are encouraged by these early results with nab-paclitaxel. Later this year, they expect to learn whether, in addition to shrinking tumors, this new treatment can extend the lives of these patients and increase the time it takes for their cancer to continue to grow. Two other advantages of nab-paclitaxel over standard paclitaxel are that it takes less time to give the newer drug than the standard one (30 minutes versus three hours) and no special medication before treatment is needed with the newer drug, as it is with the older drug.

Pemetrexed Combinations for Locally Advanced NSCLC

Early-stage clinical research suggests that pemetrexed (Alimta) in combination with either carboplatin or cisplatin may prove to be an effective treatment for people with locally advanced NSCLC that cannot be treated effectively with surgery. Very early results show that the tumor disappeared or shrank by at least half in 47 percent of patients who received pemetrexed and carboplatin and in 60 percent of patients who received pemetrexed and cisplatin. All of the patients in both groups also received radiation therapy as part of their treatment.

WHAT PATIENTS NEED TO KNOW

Doctors are not certain which chemotherapy drugs are the best for treating people whose locally advanced NSCLC cannot be treated effectively with surgery. So these early results with different pemetrexed combinations along with radiation are encouraging. Pemetrexed has already been

approved by the U.S. Food and Drug Administration as maintenance therapy for people who have advanced NSCLC. Maintenance therapy is treatment that is given, perhaps for a long time, to keep cancer from coming back after it has disappeared following first-time treatment.

Supportive Care for People With Metastatic Lung Cancer

In a late-stage clinical trial, people who received supportive care within eight weeks of being diagnosed with metastatic lung cancer lived longer than those who received standard care (11.6 months versus 8.9 months). Supportive care focused on patient education about lung cancer treatment, symptom



management, stress, decision making, and coping skills. Twelve weeks into the study, patients who received early supportive care also were found to be less depressed than those who did not receive supportive care early on. Most patients who received standard care did not see a supportive care team within 12 weeks of joining the

study. However, nearly 90 percent of those who received supportive care had at least three such visits during this time.

WHAT PATIENTS NEED TO KNOW

Supportive care is given to improve the quality of life of a person who has a serious or life-threatening illness. Researchers in this clinical trial were surprised to learn that supportive care not only improved the quality of life for people with metastatic lung cancer, it also extended their lives as well. This clinical trial is the first study of supportive care in people with newly diagnosed lung cancer. More

studies are needed to confirm the survival advantages of supportive care in these patients.

Metastatic and Resistant NSCLC: New Treatments on the Horizon

Two new medications—PF299804 and ARQ197—hold promise in the treatment of people with lung cancer, according to two very early-stage clinical trials.

The first trial tested the drug PF299804 in patients whose NSCLC no longer responded to earlier chemotherapy treatment. The tumor disappeared or shrank in more patients who received this new drug (17 percent) than in those who received erlotinib (Tarceva; four percent). It also took longer for the cancer to continue growing with PF299804 compared with erlotinib (12.4 weeks versus 8.3 weeks).



In the second trial, the combination of erlotinib and ARQ197 appeared to be a more effective treatment than erlotinib and a placebo (a look-alike pill containing no active ingredient). Patients who received erlotinib and ARQ197 went longer before their cancer continued growing compared to patients who received erlotinib and a placebo (16.1 weeks versus 9.7 weeks). Those who received erlotinib and ARQ197 also lived longer than those who did not (36.2 weeks versus 29.4 weeks).

WHAT PATIENTS NEED TO KNOW

Although researchers are pleased with these results, it's important to remember that the information is from early-stage clinical trials. Additional studies of both PF299804 and ARQ197 are either ongoing or being planned to confirm

how best to use these new drugs and which people with lung cancer would benefit most from them.

Crizotinib for Advanced NSCLC Patients With a Specific Cancer Gene

In an early-stage clinical trial, a new drug called crizotinib showed promise in treating people who have a specific cancer gene that promotes the growth of lung tumors and plays a role in their spread to other organs. The gene is found in about one-fourth of all nonsmokers with lung cancer and in up to five percent of all patients with NSCLC.

In this study, tumors shrank in nearly all patients who received crizotinib. In 60 percent of those patients, the tumor disappeared or shrank by at least 50 percent. Six months after treatment with crizotinib, the tumor had not continued to grow in more than 70 percent of patients.

WHAT PATIENTS NEED TO KNOW

At present, crizotinib is the only drug in clinical trials that targets this cancer gene. Researchers are impressed with the high number of patients who responded to crizotinib and believe that crizotinib may soon prove to be a new standard of care for the thousands of people worldwide who have this type of NSCLC. To confirm these encouraging results, later-stage clinical trials of crizotinib in this group of people with advanced NSCLC are ongoing. Researchers suggest that lung cancer patients, especially those who are nonsmokers, consider having their tumors screened to find out whether they are eligible for these clinical trials.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Melanoma

This was an exciting year for melanoma research. Targeted treatments, which focus on and block specific cancer cell mechanisms, have led to a whole new shift in our approach to melanoma. We now have truly personalized cancer therapies for people with this disease. The new targeted treatment ipilimumab will almost certainly be approved by the U.S. Food and Drug Administration for melanoma patients whose cancer has spread. And another new medication, called GSK2118436, is in the earlier phases of research and showing great promise. It is designed to benefit a specific group of patients who have a changed, or mutated, gene. We must continue to look for other “targets” in melanoma that medications can zero in on.

Jeffrey A. Sosman, MD
Vanderbilt University School of Medicine

Ipilimumab for Metastatic Melanoma

For the first time ever, a new drug, called ipilimumab, has improved the survival of people whose melanoma no longer responds to other treatments and has spread beyond the skin to other parts of the body (metastatic melanoma). In a clinical trial comparing ipilimumab with and without vaccine to a vaccine alone, 46 percent of those who received ipilimumab were still alive one year after treatment, compared with 25 percent of those who received just the vaccine. Two years after treatment, the benefits of ipilimumab continued: 24 percent of those treated with ipilimumab were still alive, compared with 14 percent of those who received the vaccine alone.



WHAT PATIENTS NEED TO KNOW

This is the first time in 30 years and 70 clinical trials that a treatment has extended the lives of people with metastatic melanoma. Ipilimumab is a targeted treatment designed to zero in on a substance that limits the body's ability to attack cancerous cells. It may well become a new standard of care, changing the way people with metastatic melanoma are treated in the future. A few questions about ipilimumab remain to be answered in further clinical trials, such as what is the best dose.

Melphalan for Melanoma Metastases to the Liver

In people with metastatic melanoma, melphalan (Alkeran) given through a catheter (thin tube) from the skin directly into a blood vessel that goes to the liver was able to better control melanoma within the liver than other standard chemotherapy that was given by IV (through a vein) or by mouth. It took much longer for the cancer to grow in the liver of people who received this treatment—called percutaneous hepatic perfusion—than in those who received standard chemotherapy (245 days versus 49 days). However, percutaneous hepatic perfusion did not extend the lives of these patients.

WHAT PATIENTS NEED TO KNOW

In most cases, when melanoma spreads to other parts of the body, it travels to the liver. Standard chemotherapy may not stop the cancer from growing in the liver, and so researchers continue to search for a better way to treat metastatic melanoma. Percutaneous hepatic perfusion makes it possible for doctors to increase the dose of a drug by giving it directly to the liver, limiting its side effects throughout the body. But it is a very complicated and expensive procedure that may only be appropriate for

people whose melanoma has nearly all spread to the liver. The small benefit from this treatment may not be enough to make it a new standard of care.

Interferon for Melanoma

Based on the results of a recent clinical trial, two different forms of the drug interferon seem to be equally effective at stopping melanoma from recurring (returning). The two forms of interferon studied were low-dose interferon alfa-2b (Intron A) and pegylated interferon alfa-2b (PegIntron). Despite being equally effective at stopping cancer, these two treatments were not the same in terms of side effects. During the first 18 months of treatment, fewer serious side effects (27%) occurred among people who received low-dose interferon alfa-2b than among those who received the pegylated form of this drug (45 percent).



WHAT PATIENTS NEED TO KNOW

Interferon alfa-2b is an anti-viral drug that may interfere with the growth of tumor cells. But researchers are not convinced that it offers much benefit in terms of improved survival, so other treatments for stopping melanoma from returning are still being studied. However, the information they learned about the side effects of these two different forms of this medication is useful for patients to know.

GSK2118436 for Metastatic Melanoma

GSK2118436 is another new targeted treatment being studied in early clinical trials. It appears to be very effective in shrinking tumors in a certain group of people with

metastatic melanoma. The patients most likely to benefit are those whose tumors have a mutated (changed) gene known as *BRAF*. The mutated *BRAF* gene produces a substance that promotes the growth of cancer. This new medication blocks that substance. Among patients receiving the drug at one of the higher but safe doses, 60 percent had their tumor decrease in size by more than 30 percent. Researchers consider this a major benefit.

WHAT PATIENTS NEED TO KNOW

Although these results are from an early stage of clinical research, GSK2118436 is a promising drug that is being studied further in larger, ongoing trials. With results reported this past year on a medication called PLX4032, targeted treatments are now shifting the approach to melanoma treatment. Researchers consider GSK2118436 to be a truly personalized treatment for people with melanoma.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Ovarian Cancer

Over the past several years, advances in treatment have improved survival rates and overall quality of life for women with ovarian cancer. Researchers believe that in the near future, the findings of clinical studies reported at this year's ASCO Annual Meeting—several of which are highlighted here—will lead to additional benefits for these patients.

Maurie Markman, MD
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MD Anderson Cancer Center

Bevacizumab Plus Chemotherapy for Advanced Ovarian Cancers

The combination of bevacizumab (Avastin) and standard chemotherapy (carboplatin and paclitaxel [Taxol and others]) followed by treatment with bevacizumab alone may extend the time it takes for cancer to continue growing in women with advanced ovarian and related gynecologic cancers. In a clinical trial, women who received bevacizumab plus standard chemotherapy and then bevacizumab alone went an average of 14.1 months without their cancer growing, compared with an average of 10.3 months for those who received just the standard chemotherapy.



WHAT PATIENTS NEED TO KNOW

Bevacizumab is the first targeted treatment to show such a benefit in women with advanced ovarian cancer. (Targeted treatments are drugs that block certain cell activities thought

to be important for the growth of cancer cells. They work differently from traditional chemotherapy.) Some researchers believe that the new combination of bevacizumab plus chemotherapy should be considered a standard option for women with this type of cancer. However, others are more cautious and suggest that further study is needed to learn whether this new combination treatment can also help these women live longer.

AMG 386 and Paclitaxel for Advanced Ovarian Cancers

A new drug called AMG 386 combined with the standard drug paclitaxel may be a promising way to shrink tumors and stop them from growing in women with advanced



ovarian and related gynecologic cancers. In a clinical trial, it took longer for the tumor to grow in women who received either of two different doses of AMG 386 along with paclitaxel (an average of 7.2 months for the higher dose versus an average of 5.7 months for the lower dose) than in those who received a placebo (an average of 4.6 months). (A placebo is a

look-alike medication that contains no active ingredient.) The tumor shrank in more than 35 percent of patients who received the higher dose of this new drug, in 19 percent of those who received the lower dose, and in 27 percent of those who received the placebo.

WHAT PATIENTS NEED TO KNOW

AMG 386 is the first in a new class of anti-cancer drugs, called peptibodies, designed to block the growth of blood vessels that encourage the growth of cancer cells. These

encouraging results are from an early-stage of clinical research, and doctors plan to study it further in larger clinical trials.

Farletuzumab for Relapsed Ovarian Cancer

Early results from a clinical trial still in progress show that a new medication called farletuzumab combined with the standard anti-cancer drug paclitaxel (Taxol and others) seems to do a better job of shrinking tumors than does paclitaxel alone. Farletuzumab appears to increase the length of time that resistant ovarian cancer remains in remission. (Remission is a decrease in or disappearance of the signs and symptoms of cancer.)

WHAT PATIENTS NEED TO KNOW

Researchers hope that in future clinical trials, farletuzumab will be able to stop tumors from growing in women with relapsed ovarian cancer. (A relapse is when cancer returns after a period of improvement in signs and symptoms.) However,

the results with farletuzumab are from very early-stage clinical trials, and further studies are ongoing. Researchers also hope to learn which women with relapsed ovarian cancer will benefit most from farletuzumab. This medication belongs to a class of drugs called monoclonal antibodies. These drugs zero in on cancer cells that have a target molecule, in this case folate receptor alpha. This molecule is found in certain types of ovarian cancers but not in healthy tissue.



Abagovomab After Chemotherapy for Ovarian Cancer

Repeated monthly injections of a new medication called abagovomab may be a safe way to boost or restore the immune system's ability to fight cancer in women with epithelial ovarian cancer (cancer that begins in the cells on the surface of the ovaries). In an ongoing clinical trial, these injections are being given to women whose advanced cancer has completely disappeared after initial treatment with chemotherapy. Early results of this trial showed that improved immune responses lengthened the time it took for the cancer to continue growing in select patients. But it is unclear whether the improved immunity was due directly to abagovomab or would have happened anyway.

WHAT PATIENTS NEED TO KNOW

Abagovomab mimics a substance on ovarian cancer cells known as CA125. Injections of this drug stimulate the body's immune system to fight against CA125 by seeking out cancer cells and destroying them. Researchers are hopeful that the results of a later stage of research, which are expected early in 2011, will establish whether women with advanced ovarian cancer who receive abagovomab remain free of cancer for a longer time than those who have not been treated with it.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Pancreatic Cancer

The complex genetic makeup of pancreatic cancer has made it difficult to improve treatment. But as the studies highlighted here illustrate, we saw a number of important advances in treating pancreatic cancer this year, including drugs that target specific cell mechanisms. The positive results of these newly reported studies are very welcome, as they represent important steps forward.

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Princess Margaret Hospital

FOLFIRINOX Versus Gemcitabine for Metastatic Pancreatic Cancer

A chemotherapy combination known as FOLFIRINOX (fluorouracil, leucovorin, irinotecan, and oxaliplatin) appears to be more effective than the standard drug gemcitabine (Gemzar) as a first-line (first-time) treatment for people with metastatic pancreatic cancer. In a recent clinical trial, patients who received FOLFIRINOX lived longer than those who received gemcitabine (11.1 months versus 6.8 months). Also, it took longer for the cancer to continue growing in those who received FOLFIRINOX than in those who received gemcitabine (6.4 months versus 3.3 months).



WHAT PATIENTS NEED TO KNOW

This is the first time in a later-stage clinical trial that people with metastatic pancreatic cancer have survived this long after treatment. Researchers are calling these early results

remarkable, but they warn that FOLFIRINOX causes more side effects than gemcitabine. For instance, more people who received FOLFIRINOX experienced a severe side effect known as febrile neutropenia than did those who received gemcitabine. Febrile neutropenia is a condition that is marked by a fever and lower-than-normal levels of white blood cells, which fight infection. Further studies of this new treatment are needed to discover how best to use it and which people with metastatic pancreatic cancer would benefit most from it.

Chemotherapy Combinations for Advanced Pancreatic Cancer

Two chemotherapy combinations—one using the standard of care and the other using a newer alternative—seem to be



equally effective in extending the lives of people with advanced pancreatic cancer. The standard treatment for these patients is the combination of gemcitabine and erlotinib (Tarceva), followed by capecitabine (Xeloda) if gemcitabine and erlotinib are no longer effective. In this clinical trial, researchers compared the standard to a newer treatment, which switches the order of these drugs: capecitabine plus erlotinib are given first, followed by gemcitabine. People

treated with the standard of care lived 6.6 months, and those treated with the newer alternative lived 6.9 months.

WHAT PATIENTS NEED TO KNOW

These results seem to suggest that it does not matter what order the drugs gemcitabine, erlotinib, and capecitabine are given to people with advanced pancreatic cancer. Although researchers do not believe doctors should change the way patients with advanced pancreatic cancer are treated, this

study confirms that capecitabine is an acceptable second-line treatment for these patients. Capecitabine will be studied further, to determine how best to use it.

Conatumumab and AMG 479 for Metastatic Pancreatic Cancer

When combined with the standard drug gemcitabine, two new monoclonal antibodies—conatumumab and AMG 479—have shown encouraging results in helping people live longer with metastatic pancreatic cancer. (Monoclonal antibodies are medications that zero in on a target molecule on cancer cells to block tumors from growing.) After treatment, patients who received gemcitabine plus either of the monoclonal antibodies lived longer than those who received just gemcitabine. Those who received gemcitabine plus conatumumab survived 7.5 months; those who received gemcitabine plus AMG 479 survived 8.7 months. Those who took gemcitabine alone survived 5.9 months. Also, it took longer for the tumor to grow in those treated with gemcitabine plus conatumumab (3.9 months) and gemcitabine plus AMG 479 (5.1 months) than in those treated with just gemcitabine (2.1 months).

WHAT PATIENTS NEED TO KNOW

These results, even though they are very early, are important steps toward finding effective new treatments for people with metastatic pancreatic cancer. The patients who took part in these studies will continue to be evaluated as these drugs are tested further in later-stage clinical trials.

Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Prostate Cancer

This year, we saw some real “game changers” in prostate cancer research. We now know that, for men with locally advanced prostate cancer, adding radiation treatments to hormone medications clearly improves survival. Also, the new chemotherapy cabazitaxel (Jevtana), which offers another proven treatment for advanced prostate cancer, is the first drug to improve survival for men whose cancer came back after using docetaxel (Taxotere). And we now recognize that it is critical to pay attention to bone health in men with advanced prostate cancer who are receiving hormone therapies. All in all, it was an exciting year for prostate cancer research.

Judd W. Moul, MD
Duke University Medical Center

Hormone Therapy Plus Radiation for Locally Advanced Prostate Cancer

Adding radiation treatment to hormone therapy appears to extend the lives of men with locally advanced prostate cancer (cancer that has spread to nearby tissues). In a clinical

trial, seven years after treatment, 74 percent of men who received the combined treatment were alive, compared with 66 percent of those who received only hormone therapy.



WHAT PATIENTS NEED TO KNOW

Hormone therapy is a standard treatment for men with advanced prostate cancer. It lowers the levels of the male hormone testosterone, which encourages the growth of prostate cancer. Researchers consider the benefits of hormone

therapy plus radiation to be substantial. They are very encouraged by the results of this trial. In the future, hormone therapy plus radiation may even become the standard of care for treating men with this type of prostate cancer.

Cabazitaxel in Combination With Prednisone for Metastatic Prostate Cancer

In a clinical trial, men with metastatic prostate cancer (cancer that has spread to distant parts of the body) who received a new drug called cabazitaxel (Jevtana) in combination with prednisone (a type of steroid) lived longer than patients who received mitoxantrone (Novantrone and others) plus prednisone (15.1 months versus 12.7 months). (Mitoxantrone is used to treat advanced prostate cancer that does not respond to hormonal treatments.) All of the men in this late-stage clinical trial, called TROPIC, had already been treated with the anti-cancer drug docetaxel (Taxotere).



WHAT PATIENTS NEED TO KNOW

Earlier this year, the combination of cabazitaxel and prednisone was approved by the U.S. Food and Drug Administration (FDA) for men with metastatic prostate cancer. It is the only approved treatment reported to extend the lives of patients previously treated with docetaxel. As with any newly approved treatment, the men in the TROPIC study will be closely watched to monitor their progress and to manage side effects.

Bevacizumab in Combination for Metastatic Prostate Cancer

In a late-stage clinical trial of more than 1,000 men, researchers tested another combination treatment for metastatic prostate cancer: bevacizumab (Avastin), a targeted treatment, plus the standard treatment of docetaxel and prednisone. The men who received the bevacizumab combination treatment went longer before their cancer grew than the men who received just docetaxel and prednisone (9.9 months versus 7.5 months). However, the bevacizumab combination treatment did not lengthen the lives of the men who received it, and it was associated with an increase in serious side effects such as infection-related deaths and low white blood cell counts.

WHAT PATIENTS NEED TO KNOW

Sometimes, clinical trials yield these types of mixed results. Although bevacizumab may be an effective way to shrink tumors and stop them from growing, it does not appear to help men with metastatic prostate cancer live longer. Researchers believe that the benefits of adding bevacizumab to standard treatment must be balanced against the increase in serious side effects. Thus, this combination treatment will be studied further to learn whether the benefits will ultimately outweigh the risk of increased side effects.

Bone Health and Metastatic Prostate Cancer

A new bone-strengthening drug called denosumab (Xgeva) may be an effective way to prevent or delay bone problems in men with prostate cancer that has spread to the bone. According to a late-stage clinical trial, patients who received denosumab went longer without experiencing bone complications or problems than did those who received

zoledronic acid (Zometa): 20.7 months versus 17.1 months. However, both denosumab and zoledronic acid seem equally effective in lengthening the survival of these men and the time it takes for the cancer to continue growing.



WHAT PATIENTS NEED TO KNOW

Like zoledronic acid, denosumab has been approved by the FDA for the treatment of postmenopausal osteoporosis (a condition that causes bones to become fragile in women). It is now also approved to prevent bone problems in patients with cancer that has spread into the bone. Researchers plan to continue

to study the use of these two drugs to learn how best to use them to treat bone side effects in men with metastatic prostate cancer.

Please note: Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.

Managing Side Effects

Over the past 20 years, clinical trials on managing the side effects of cancer and cancer treatment have been an important part of research. This work has been most successful when it comes to preventing the nausea and vomiting that result from many types of chemotherapy. Researchers have also been successful, to a certain degree, in treating pain, constipation, and mouth sores. In the future, there will be more strides in these areas and in fighting nerve damage caused by chemotherapy. As the following studies show, we are also making strides in treating fatigue, bone complications, and hand-foot syndrome.

Charles L. Loprinzi, MD
Mayo Clinic

Yoga for Sleep Problems and Fatigue

In the largest clinical trial of its kind, researchers found that a yoga program designed specifically for cancer survivors may improve sleeping problems and fatigue. The study showed that patients who took part in two yoga classes a week for four weeks reported a higher rate of improved quality of sleep than those who did not take part in the classes (22 percent better sleep versus 12 percent). Those who practiced yoga also used less sleep medication. In addition, more people who attended yoga classes reported a greater decrease in fatigue than those who did not (42 percent versus 12 percent).

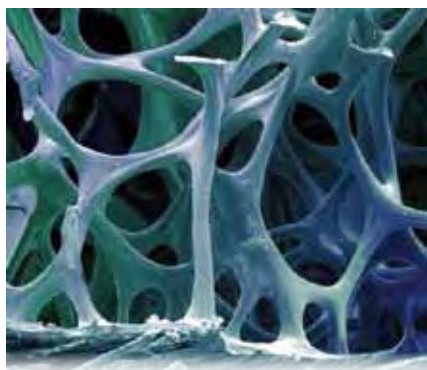


WHAT PATIENTS NEED TO KNOW

Often used to relieve stress, yoga is an ancient system of practices to balance the mind and body through breathing exercises, movement, and meditation. Side effects of cancer treatment such as sleep problems and fatigue can disrupt a person's quality of life. Thus, researchers believe that yoga classes may be a useful way for cancer survivors to manage these symptoms.

Bone Health and Cancer Treatment

A newer drug called denosumab (Xgeva) appears to do a better job, by 17 percent, than the standard drug zoledronic acid (Zometa) in delaying or preventing bone complications in people whose cancer has spread into the bone. Both of these medications have been used to strengthen bone and reduce bone pain. Some of the patients in these studies had breast cancer, and some had other types of advanced cancer.



Bone, very highly magnified

WHAT PATIENTS NEED TO KNOW

A person whose cancer has spread into the bone may experience bone pain and an increased risk of bone breaks (fractures). Based on these results and those of other studies, the U.S. Food and Drug Administration has just approved denosumab to help prevent bone problems in people whose cancer has spread into the bone.

What Works (and What Doesn't Work) for Hand-Foot Syndrome

A cream containing urea and lactic acid does not appear to be an effective way to prevent the symptoms of hand-foot syndrome (HFS) in people whose cancer is being treated with capecitabine (Xeloda). In a clinical trial, the results suggested that the cream made HFS worse. HFS is a skin reaction that appears on the palms of the hands and/or the soles of the feet as a result of certain chemotherapy drugs, such as capecitabine. Symptoms often include swelling, redness, tenderness, and skin peeling; it can occur in about one-half to three-quarters of patients taking capecitabine.

WHAT PATIENTS NEED TO KNOW

Because of earlier clinical trials indicating that this cream was beneficial, it was recommended by treatment guidelines and used by many doctors. But the results of this study should change these guidelines and practices.

Although researchers always hope to find a treatment that benefits patients, sometimes discovering what does not work may point them in a new direction.

As the search for an effective way to manage HFS continues, there are some common tips for coping with the symptoms of HFS: avoid tightly fitting footwear; refrain from activities that put pressure on the palms or soles; and regularly apply a moisturizer to the affected skin.

Chemotherapy-Induced Nausea and Vomiting

Olanzapine (Zyprexa) may prove to be an effective way to prevent nausea and vomiting caused by chemotherapy. In a clinical trial, people who received olanzapine were about twice as likely to avoid having delayed nausea (which may

occur one to five days after receiving chemotherapy) as those who received the standard treatment of aprepitant (Emend) combined with other drugs used to prevent vomiting (68 percent versus 37 percent).

WHAT PATIENTS NEED TO KNOW

According to the results of this late stage of clinical research, both olanzapine and aprepitant worked equally well for preventing acute nausea (occurring within 24 hours) and delayed vomiting. Doctors do not yet understand why olanzapine appeared to be more effective than treatment with aprepitant in controlling delayed nausea. However, these early results in treating delayed nausea are encouraging because, currently, there are more effective treatments available for vomiting than for nausea. More studies are needed to confirm the results of this clinical trial.



Please note: *Although the treatments discussed in this chapter are showing promise, most are still in clinical trials—some in earlier phases of research—and may not be available yet to the general public. Your doctor can help guide you as to which new medications could be right for you and whether you are eligible to take part in the clinical trials of these new treatments.*

Resources

Additional diagnosis-specific resources are available in the online version of this booklet, which can be viewed at www.cancer.org/asco2010.

CancerCare

1-800-813-HOPE (4673)
www.cancer.org

American Cancer Society

1-800-227-2345
www.cancer.org

CancerCare Co-Payment Assistance Foundation

1-866-55-COPAY
www.cancer.org/copy

Cancer.Net

Patient information from the American Society of Clinical Oncology
www.cancer.net

National Cancer Institute

1-800-422-6237
www.cancer.gov

National Comprehensive Cancer Network

The patient website of this nonprofit alliance provides free treatment summaries and guidelines for various diagnoses.
www.nccn.com

National Library of Medicine (MedlinePlus)

www.medlineplus.gov

To find out about clinical trials:

Coalition of Cancer Cooperative Groups
www.CancerTrialsHelp.org

National Cancer Institute
1-800-422-6237
www.cancer.gov/clinicaltrials



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