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Informing Patients About Options, Advancing Lung Cancer Research

December 2007

New Directions

Stay Current

Lung Cancer Alliance (LCA) partners with EmergingMed, the nation's leading cancer clinical trial matching service, so that you can easily find research studies that fit your medical profile. Each year, over 30,000 oncology physicians, scientists, and advocates gather together to share new information about cancer at the American Society of Clinical Oncology's (ASCO) Annual Meeting. ASCO is the world's leading professional organization representing physicians of all oncology subspecialties who care for people with cancer. Representatives from LCA attended this year's ASCO annual meeting in Chicago, where progress regarding targeted therapies was especially important.

What is Targeted Therapy?

A new approach to fighting cancer was born when scientists began to identify specific traits that were unique to cancer cells. These findings have led to the development of numerous ways of "targeting" cancer cells while leaving healthy cells untouched. Targeted therapy is different from standard chemotherapy, which affects all rapidly dividing cells. Today, many targeted therapies are being studied in clinical trials alone and in combination with standard chemotherapy. These approaches are proving to be effective strategies in fighting cancer.

Summaries of recent clinical trials based on targeted therapy as well as variations of current standard therapies and diagnostic tests are listed below. The following information does not include all new findings, but gives a brief overview of some of the major areas of discovery. ■

2007 Research Highlights

News for Patients with Operable Non-Small Cell Lung Cancer

GlaxoSmithKline Announces Largest Ever Phase III Trial in Lung Cancer Treatment

This Phase III study is testing a new cancer immunotherapy called MAGE-A3 ASCI (Antigen-Specific Cancer Immunotherapeutic) in patients with completely resected (Stage Ib, II, IIIa) non-small cell lung cancer (NSCLC). This cancer therapy works by trying to teach the patient's immune system to identify and specifically target cancer cells. MAGE-A3 is a tumor-specific antigen—or molecule that stimulates an immune response—that is expressed in a large variety of cancers, including NSCLC, but not in normal cells. A Phase II study of MAGE-A3 ASCI in NSCLC showed promising results in the reduction of cancer relapse, and led to the current Phase III study.

News for Patients with Advanced Lung Cancer (First Line Treatments)

Common Chemotherapy Regimens Compared in New Study

Researchers with the Norwegian Lung Cancer Group are evaluating both quality of life and patient survival in a study comparing two common chemotherapy regimens. In the study, pemetrexed (Alimta®)/carboplatin (Paraplatin®) is being compared to the commonly used gemcitabine (Gemzar®)/carboplatin (Paraplatin®). Pemetrexed works by preventing the formation of DNA and RNA that contribute to cancerous cell growth. Gemcitabine works by preventing DNA replication and stopping tumor growth via cellular death. Initial results suggest that late stage NSCLC patients receiving pemetrexed have a comparable

continued on page 2

Definitions

Primary Research Goals in Clinical Trials:

Phase I

These first studies in people evaluate the safety and dosage of a new drug or treatment.

Phase II

These studies continue to test the safety of the drug, and begin to evaluate how well the new drug works.

Phase III

These studies confirm the effectiveness of the study drug or treatment and compare it to the current standard of care.

Randomized Trial

Trial design in which participants are assigned by chance to a treatment group. The researchers do not know which treatment is better.

Double-Blind Study

A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug.

Controlled Trials for Cancer

One group of participants is given standard of care (i.e., the control group), while another group is given a standard treatment plus an experimental drug or therapy.

continued from page 1

quality of life to patients receiving gemcitabine, but with fewer side effects. There are no differences in patient survival rates when both drugs are compared.

Lung Cancer Vaccine Developed for NSCLC

Initial results from a Phase II study of the therapeutic vaccine EP2101 demonstrated an increase in survival rates in NSCLC patients treated with the vaccine. EP2101 introduces new substances called tumor antigens into the immune system to stimulate an immune response against cancer cells. According to IDM Pharma Inc., further clinical studies will be conducted to confirm the potential benefit of the vaccine as both a single-agent and in combination with other therapies that trigger an immune system response.

Bevacizumab Studied for the Treatment of NSCLC in Previously Untreated Patients

Results from a Roche-sponsored Phase III study of more than 1,000 previously untreated NSCLC patients indicate that treatments adding the drug bevacizumab (Avastin®) to chemotherapy produce higher survival rates than chemotherapy alone. The AVAiL (Avastin®) study compared bevacizumab (Avastin®) combined with cisplatin (Platinol®)/gemcitabine (Gemzar®) to a common chemotherapy regimen. Results of the study showed increased survival rates in the patients with bevacizumab added to their treatment regimen. Bevacizumab inhibits angiogenesis—the growth of a network of blood vessels that supply nutrients and oxygen to the tumor. By inhibiting angiogenesis, bevacizumab cuts off the blood supply that is essential for the growth of the tumor. Patients in the study that received half the dose of bevacizumab had similar disease-free survival outcomes to those on the approved dose of the drug. Future studies will determine if the lower dose is equally effective with fewer side effects.

Cetuximab May Increase Survival and Response Rates in NSCLC Patients

Cetuximab (Erbix®) in combination with platinum-based chemotherapy improved survival compared to chemotherapy alone as a first line therapy in NSCLC patients, according to ImClone Systems Inc. The study, completed by ImClone's European marketing partner, Merck KGaA, met its primary endpoint (goal) and the data will be released at an upcoming medical conference. Cetuximab is approved to treat advanced colorectal cancers, and works by locating and binding to the surface of some types of cancer cells, and it could enhance the anti-tumor

effectiveness of other treatments. Phase III trials are ongoing. It should be noted that the company also released results of a large Phase III trial in July that found cetuximab in combination with either paclitaxel (Taxol®) or docetaxel (Taxotere®) and carboplatin failed to slow the growth of tumors in patients with NSCLC.

News for Patients with Advanced Lung Cancer (Second and Third Line Treatments)

Drug May Help Delay Brain Damage in Patients with Metastasized NSCLC

A new therapeutic developed by Pharmacyclics that may make tumor cells more sensitive to radiation therapy has been proven safe for patients. Previous studies have shown that motexafin gadolinium (Xcytrin®) can slow neurological progression in NSCLC patients whose cancers have spread (metastasized) to the brain. Motexafin gadolinium may also help by making cancer cells more susceptible to radiation treatments. Several Phase II studies are now testing motexafin gadolinium in combination with standard therapies for second line treatment in NSCLC with brain metastases.

Immune Boosting Protein Successful Against Lung Cancer

In a recent Phase II clinical trial sponsored by Agennix, a new therapeutic was shown to increase survival rates for patients with NSCLC that had not responded to previous treatments (i.e. refractory cancer). In the trial, the refractory patients were given oral talactoferrin, a protein that initiates a response in the immune system to kill cancer cells. According to the researchers, the patients given oral talactoferrin had better survival rates than those given standard supportive care alone. A Phase III trial using talactoferrin as both a stand-alone treatment and as part of a combination therapy with other treatments will soon begin testing to confirm these results.

Targeted Oral Therapeutic May Prevent Progression of Late-Stage Lung Cancer

Enzastaurin, a new therapeutic under development by Eli Lilly, blocks multiple cell signaling pathways which are commonly associated with poor prognosis and treatment resistance in NSCLC. In a recent Phase II study, oral enzastaurin prevented disease progression. It will continue to be evaluated.

News for Patients with Small Cell Lung Cancer

Amrubicin May Be Beneficial in Treating Small Cell Lung Cancer

A recent study has shown that Pharmion's amrubicin, a synthetic drug that prevents cell division by disrupting the structure of the DNA, may be more beneficial than traditional standards of care for treating small cell lung cancer (SCLC). These initial results were reported from a Phase II study that compared amrubicin and topotecan (Hycamtin®)—the standard treatment for platinum-sensitive SCLC patients. Platinum-based chemotherapies include carboplatin and cisplatin. In the study, patients who had difficulty tolerating platinum therapy reacted favorably to amrubicin. A Phase III study using amrubicin will begin recruiting soon. Amrubicin is also being assessed in Phase II studies as a stand-alone treatment for SCLC patients that have not responded to first line treatment, and in combination with other chemotherapies for previously untreated extensive-stage patients.

Radiation Helps Limit the Spread of Cancer In SCLC Patients

A first study to evaluate preventive cranial irradiation in extensive SCLC patients found that the procedure can reduce the risk of cancer spreading to the brain and it can also help patients live longer. Only patients whose tumors had previously shrunk with chemotherapy were chosen for the study. Half were given radiation to the head for one or two weeks, and half were not. One year later, those who received the radiation treatment showed improved survival rates and had a lower incidence of cancer spreading to the brain.

Other News of Interest

Pre-Treatment Blood Test May Help Patients Choose Treatment Course

Blood samples taken from NSCLC patients before treatment may help predict how they will respond to targeted therapies, according to researchers. By analyzing pre-treatment blood samples, Vanderbilt-Ingram Cancer Center investigators were able to identify specific proteins in the blood that were linked to an increased response to targeted therapies, which prolonged survival. The investigators, in collaboration with the Eastern Cooperative Oncology Group, are currently working to develop a national Phase III study for lung cancer patients who are just beginning treatment. Their goal is to develop an inexpensive test that would identify the most effective treatment for each person.

Targeted Therapies for Lung Cancer Improved by Gene Analysis

The DNA of a patient's tumor may be analyzed to reveal which targeted therapies may work best, according to researchers at Duke University. The tests that the researchers developed identified common patterns within the DNA of tumor cells. The scientists then classified the DNA patterns that corresponded to abnormal genes. Using this information, doctors can better identify the best treatment plan for each person. The Duke team plans to begin clinical trials of the genetic tests within the year.

Diversity Study Launched to Help Improve Treatment Options

Eli Lilly is actively analyzing the safety and effectiveness of two common cancer drugs—pemetrexed (Alimta®) and gemcitabine (Gemzar®)—in treating diverse populations. Lung cancer is the leading cause of cancer related deaths in both African-American and Hispanic men. Analysis of prior trials suggests genetic differences may call for different treatment regimens. Over 1,000 NSCLC patients, including 200 African-Americans, 200 Hispanics, 200 Asians, and 400 Caucasians, are now being enrolled in the Phase III study. Since genetic differences may cause similar tumors to respond differently to the same medications, the study will aim to discover how each group responds to particular treatments, including which treatment options may be best for particular groups.

Second Phase Treatment Produces Negative Results

A new study presented by the Hoosier Oncology Group showed that a high dosage of the drug docetaxel (Taxotere®) demonstrated no significant benefits for patients with inoperable Stage III NSCLC. In the study, docetaxel was administered as consolidation therapy (a high-dosage second cycle of chemotherapy) after induction therapy (the first cycle) with cisplatin (Platinol®) and etoposide (VP-16®).

Updates on Research from December 2006 LCA Newsletter

Studies Focus on Women with NSCLC

The PIONEER study has closed because patients in the control group (those receiving standard of care chemotherapy) were outliving those taking the new drug. Cell Therapeutics has announced that these unexplained results are not due to toxic effects from the drug. Two new trials will open soon, known as PGT306 and PGT307, to focus exclusively on NSCLC in women with normal estrogen levels. ■

Placebo

A placebo is an inactive pill, liquid, or powder that has no treatment value. In cancer clinical trials it is very rare for a patient to receive only a placebo. Experimental treatments can be compared with placebos to assess the treatment's effectiveness.

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When to search:

When are clinical trials looking for volunteers?

1. Just before a biopsy (if the trial involves studying tissue from a tumor).
2. Just prior to the first surgery or radiation treatment ("neo-adjuvant" studies).
3. Immediately after surgery or radiation treatment ("adjuvant" studies).
4. After cancer has recurred, spread (metastasized), or is still growing despite another treatment
 - First-line studies: These studies offer the first treatment given once lung cancer has advanced.
 - Second-line studies: These studies offer the second treatment given once lung cancer has advanced and a first-line therapy has failed.

A clinical trial may not turn out to be a patient's best option at any particular time, but the only way to decide is to learn about available studies and be prepared for each window of opportunity to explore. ■

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