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Informing Patients About Options, Advancing Lung Cancer Research

December 2006

New Directions

Stay Current 2006 Research Highlights

Lung Cancer Treatments are Evolving Constantly.

Medical science is continually studying advances that may help in the fight against lung cancer. It is important to learn about treatments being developed to determine what might be most appropriate for your medical situation. Most new drugs and therapies are investigated through clinical trials – research studies that help to evaluate new cancer treatments for both early stage and advanced lung cancer patients.

How Can I Learn About New Advances in Lung Cancer Research?

Each year, over 30,000 oncology physicians, scientists, and researchers, as well as advocates, gather together to share cutting-edge information about cancer at the American Society of Clinical Oncology's (ASCO's) Annual Meeting. ASCO is the world's leading professional organization representing physicians of all oncology subspecialties who care for people with cancer. Lung Cancer Alliance attends each ASCO meeting and listens carefully so that we can bring relevant information to you. We also partner with EmergingMed, the nation's leading

cancer clinical trial matching service, so you can easily find research studies that fit your medical profile.

Why is it Important to Stay Current?

Patients sometimes rush into treatment before investigating clinical trial options, only to find later that they are not eligible for clinical trials because of earlier decisions. Be sure to ask about the availability of a clinical trial. If you are considering participation in a clinical trial, discuss it thoroughly with your physician and make certain you understand the informed consent form before you sign it. For thousands of patients, clinical trials provide an opportunity for the best available treatment. Not only do patients frequently express feeling satisfied that they have obtained quality treatment, but they often report feeling a sense of contributing to the greater good for people with cancer in general.

We've tried to save you time by sharing the most promising lung cancer research findings directly with you. The following list does not include all new therapies or diagnostics being studied. Rather, it provides a brief overview of some of the major areas of discovery. ■

News

New Biomarker Test for Lung Cancer New Blood Test May Detect Non-Small Cell Lung Cancer Early

A multi-biomarker blood test may be able to detect non-small cell lung cancer (NSCLC) significantly earlier and with better accuracy than current methods. Today, less than 25 percent of NSCLC is diagnosed at an early, curable stage; however, when the disease is detected early and can be removed surgically, the five-year survival rate can reach 85 percent. Researchers have identified antibodies generated by the body's immune system in response to very early stage NSCLC, which may be present in the blood 3-5 years before tumors reach the size detectable by current

imaging technology. The study found that the presence and amounts of these antibodies in the blood predicted NSCLC with about 85 percent accuracy. Additional research will continue in order to validate these results.

News for Those With Early Stage Lung Cancer

Annual CT Scanning Can Detect Early-Stage Lung Cancers and Increase Survival

A new study reported that low-dose CT (computed tomography) scanning of adults at high risk of developing lung cancer can find small tumors that are curable, significantly improving the chance

continued on page 2

Purpose and Design of Clinical Trials

Clinical trials are scientific studies of how a new medicine or treatment works in people. Through clinical studies, doctors find new and better ways to prevent, detect, diagnose, control, and treat illnesses. The majority of medical treatments assessed through clinical trials are in the form of drugs. Clinical trials are conducted in a progressive series of steps, called phases, each with distinct research goals. Progression to the next phase requires success of the research goal with the benefits being greater than the risks presented to patients.

Primary Research Goals in Clinical Trials

Phase I

Is the treatment safe?

Phase II

Does the treatment work?

Phase III

How does the new treatment compare to standard care?

To see if you or a loved one is eligible to participate in a clinical study, contact the LCA's free and confidential matching service powered by EmergingMed. Call 1-800- 698-0931.

continued from page 1

of long-term survival. The study involved over 31,000 people at high risk of developing lung cancer because of exposure to cigarettes or to environmental triggers. Lung cancer (both small cell and non-small cell types) was found in 484 study participants, with the majority of these – 85 percent – diagnosed as stage I lung cancer (the earliest stage of the disease). None of the participants in this study had any symptoms of lung cancer such as persistent cough, shortness of breath, or chest pain. The research suggests that diagnosing lung cancer early through annual CT scans and treating it immediately could save millions of lives. Ongoing and additional studies are evaluating the benefits of CT scans versus X-rays for lung cancer detection, as well as the relationship between early detection, survival, and mortality.

Gene Test Could Help Predict Lung Cancer Outcomes

Researchers are studying a new genetic test they say predicts which patients with early stage lung cancer are at risk of recurrence with up to 90 percent accuracy. In early studies, the “Lung Metagene Model” was consistent across all early stages of NSCLC. This test could potentially help doctors and patients determine which patients are likely to need surgery alone and which patients need surgery and chemotherapy. Researchers expect to begin a larger study involving 1,200 patients at multiple medical centers in early 2007 to confirm the preliminary results.

Elderly Patients Benefit from Chemotherapy After Surgery

Elderly patients with early stage NSCLC who receive chemotherapy following surgery live longer than those who have surgery alone, without increased treatment-related toxicity or hospitalization, a new study reports. Patients over age 65 are likely to have additional health problems that can cause doctors to question whether the risks from aggressive cancer treatment outweigh the benefits. A study found that adjuvant chemotherapy can be given safely to elderly patients who, despite receiving fewer and less intense doses, derive a substantial survival benefit from this treatment.

News for Patients With Advanced Lung Cancer (“First Line” treatments)

New Vaccine Boosts Immune System to Attack Tumors

A new vaccine called Lucanix may help to delay the progression of disease in patients with NSCLC.

In contrast to conventional cancer therapies, where systemic chemotherapy drugs nonspecifically kill both the tumor and normal cells, the vaccine specifically induces the patient's own immune system to attack the tumor. Side effects were also reported to be minimal compared with many traditional cancer therapies. A Phase III clinical trial of Lucanix is planned for late 2006.

New Drug Increases Survival for NSCLC Patients Not Previously Treated with Chemotherapy

Bortezomib (Velcade) is a new type of cancer drug called a proteasome inhibitor. Proteasomes are enzymes found in cells, and play a role in regulating cell function and growth. Bortezomib blocks the activity of proteasomes, and that blockage can lead to cancer cell death. A Phase II clinical trial evaluating bortezomib in combination with gemcitabine (Gemzar) and carboplatin (Paraplatin) in patients with advanced NSCLC not previously treated with chemotherapy resulted in increased overall survival. Forty-seven percent of study participants survived one year, including five-months without measurable disease growth. A phase III study is needed to confirm these promising results.

Drug Significantly Increases Survival Time for Women With Advanced Lung Cancer

PIONEER is the first study of a lung cancer drug exclusively with women. Although PIONEER has temporarily suspended enrollment, when it resumes it will test whether single agent paclitaxel poliglumax (CT-2103, Xyotax) provides improved overall survival compared to paclitaxel (Taxol) in women with NSCLC who are having trouble performing daily activities. While the active ingredient in both drugs is the same, PIONEER involves a new compound that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. This new compound is expected to spare normal tissue's exposure to high levels of active chemotherapy and reduce toxicities. Data from earlier clinical trials found that paclitaxel poliglumax had a significant survival advantage in women versus men as compared to standard chemotherapy treatments.

Lung Cancer Patients With Brain Metastases Benefit from New Treatment

Further analysis of two Phase III trial results concludes that motexafin gadolinium (Xcytrin), when combined with whole brain radiation therapy for NSCLC patients with brain metastases, can

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delay the effect of brain metastases. The benefit is greatest for patients who begin therapy soon after a diagnosis of brain metastases – delayed therapy was found to be less effective. Based on the results of this trial, the manufacturer plans to submit an application to the FDA by the end of 2006 asking for their approval.

Docetaxel Analysis Demonstrates Benefits for Patients With NSCLC

A meta-analysis of seven clinical trials evaluating docetaxel (Taxotere) in patients with NSCLC showed significant benefits of the agent as a first-line treatment for NSCLC. As compared with vindesine or vinorelbine, docetaxel was found to have superior efficacy (positive results) and safety.

New Drug Targets Tumor Blood Vessels

Researchers in the UK have announced promising results from an early phase study of the drug known as AS1404 (DMXAA). This drug is one of a new class of compounds called vascular disrupting agents, which work by destroying blood vessels that solid tumors depend on to survive and grow. In the study of 70 patients with NSCLC, half received AS1404 plus chemotherapy and half received chemotherapy alone. Those taking AS1404 lived for 14 months on average compared with 8.8 months for those given chemotherapy alone. A larger phase III trial is planned.

News for Patients With Advanced Lung Cancer (“Second or Third Line” Treatments)

FDA Approves New Drug for Patients With Advanced Non-Squamous NSCLC

Bevacizumab (Avastin), an anti-angiogenesis drug already approved by the FDA for use against colorectal cancers, was approved for patients with advanced non-small cell lung cancer in October. Bevacizumab inhibits a protein that causes cancer to grow, thereby increasing survival in patients with advanced lung cancer. In addition to the completed trial (ECOG 4559) on which this approval was based, bevacizumab is currently being tested in Phase II and III trials against multiple types of lung tumors, including in combination with erlotinib (Tarceva). The most common side effects of bevacizumab for lung cancer were low white blood cells, fatigue, high blood pressure, infection and hemorrhage. Prior to this approval, the drug sponsor issued a warning on the Avastin label about the neurological disorder RPLS, which was seen in studies (not including ECOG 4559) in less than 1 of 1000 of participants.

New Oral Drugs Show Significant Promise Against Advanced Lung Cancer

Background: Researchers have announced results from Phase II trials of three “anti-angiogenesis” drugs: ZD6474 (Zactima), sunitinib (Sutent/SU11248), and sorafenib (Nexavar/BAY 43-9006). Anti-angiogenesis means inhibiting growth of blood vessels by tumors. All three drugs target multiple key signaling pathways involved in cancer growth and spread. All are administered orally. Each of the three drugs has slightly different target specificities and toxicities. Clinical trials to date show that these drugs show activity alone – that is, not in combination with chemotherapy. However most of the clinical trials currently underway are designed with a belief that these therapies will be more effective if used in combination with chemotherapy and/or other treatments, if approved. Some specific results:

ZD6474 (Zactima) is in Phase III trials in NSCLC and in Phase II trials in small cell lung cancer (also thyroid cancer). Studies to date have found an increased progression free survival for patients with different stages of lung cancer, including advanced NSCLC that has not responded to first line treatments. The drug has also shown potential for patients with adenocarcinoma and other lung cancer histologies, including squamous

continued on last page

Definitions

Adjuvant therapy

Therapy given after a primary treatment (such as surgery to remove cancer), to reduce the chances of a recurrence. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, or biological therapy.

First-line treatment

A drug or other therapy offered initially following diagnosis.

Second- or Third-line treatment

Treatment that is given after the cancer has not responded to a first course of therapy or a patient ceases first-line of therapy.

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continued from page 3

cell carcinoma. It has generally been well-tolerated by patients. Further trials are ongoing.

Sunitinib (Sutent), already approved for use in gastrointestinal tumors and renal cell carcinoma, is now being investigated against lung cancer. Researchers recently presented the initial results from a Phase II trial evaluating sunitinib, which showed that the majority of previously treated participants with recurrent and advanced NSCLC experienced results that were very similar that of other currently approved agents. The drug was well tolerated, and most side effects were mild to moderate. Further trials are ongoing.

Sorafenib (Nexavar) is similarly showing activity in treating advanced lung cancer in multiple clinical trials. In a recently completed study with sorafenib as a single agent therapy, 59 percent of patients showed improvements in important

brain functions. The study included patients with brain metastases and squamous cell carcinoma. A Phase III trial is currently recruiting patients.

Adding Erbitux to Standard Chemotherapy Improves Anti-Cancer Response

Cetuximab (Erbitux/IMC-C225) has demonstrated anti-cancer activity in colorectal cancer and is being evaluated in clinical trials involving other cancers, including NSCLC. Erbitux is a “monoclonal” antibody, made in a laboratory to target a specific molecule, and must be given intravenously. Preliminary results indicate that adding Erbitux to a standard chemotherapy combination improves anti-cancer responses as initial therapy for advanced NSCLC, while maintaining an acceptable side effect profile. Erbitux has also shown promise for patients with early-stage lung cancer. Clinical trials of Erbitux in combination with chemotherapy drugs are ongoing. ■

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