



## Lilly Oncology to Unveil More Than 50 Studies at ASCO 2010

INDIANAPOLIS, May 17, 2010 /PRNewswire via COMTEX News Network/ -- Eli Lilly and Company will unveil data from 57 studies at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Ill. from June 4 - 8, 2010, during which the company will present the latest research results on ALIMTA® (pemetrexed for injection) and GEMZAR® (gemcitabine HCl for injection), as well as ERBITUX® (cetuximab) with partners Bristol-Myers Squibb and Merck-Serono.

Of note are two Phase II ALIMTA studies (ASCO Abstracts #7082 and #7087), which both evaluate ALIMTA plus platinum-based chemotherapy in combination with concurrent radiation therapy in patients with advanced non-small cell lung cancer (NSCLC). Several studies evaluating GEMZAR in combination with other potential therapies are also slated for presentation at the meeting.

"Lilly Oncology research teams around the world are committed to finding new ways to improve and prolong the lives of people living with cancer," said John H. Johnson, president of Lilly Oncology. "We are constantly studying new uses for our established therapies and discovering new molecules - all in the hopes of changing the way we treat cancer."

In addition to studies on marketed Lilly Oncology products, new data will also be presented at ASCO on several Lilly Oncology molecules in clinical development, namely tasisulam (an anti-cancer agent), and ImClone's ramucirumab and cixutumumab (both are IgG1 monoclonal antibodies).

### Studies of note for ALIMTA include:

- Abstract #7082: General Poster Session: Sunday, June 6, 2010, 8:00 a.m. - 12:00 p.m.
- Ongoing phase II study of pemetrexed plus carboplatin or cisplatin with concurrent radiation therapy followed by pemetrexed consolidation in patients with favorable-prognosis inoperable stage IIIA/b non-small cell lung cancer: Interim update
- Author/Speaker: Hak Choy
- Location: S Hall A2; Poster Board 26F
  
- Abstract #7087: General Poster Session: Sunday, June 6, 2010, 8:00 a.m. - 12:00 p.m.
- A phase II study of concurrent pemetrexed/cisplatin/radiation (RT) for unresectable stage IIIA/b non-small cell lung cancer (NSCLC)
- Author/Speaker: Anthony M. Brade
- Location: S Hall A2; Poster Board 27C
  
- Abstract #TPS290: Trial in Progress Poster Session: Monday, June 7, 2010, 8:00 a.m. - 12:00 p.m.
- Randomized, open-label study of pemetrexed/carboplatin followed by maintenance pemetrexed versus paclitaxel/carboplatin/bevacizumab followed by maintenance bevacizumab in patients with advanced non-small cell lung cancer (NSCLC) of nonsquamous histology
- Author/Speaker: Ralph Zinner
- Location: S Hall A2
  
- Abstract #7591: General Poster Session: Sunday, June 6, 2010, 8:00 a.m. - 12:00 p.m.
- First-line treatment (txt) with pemetrexed-cisplatin (PC), followed sequentially by gefitinib (G) or pemetrexed, in Asian, never-smoker (n/smkr) patients (pts) with advanced NSCLC: An open-label, randomized phase II trial
- Author/Speaker: Jun Liang
- Location: S Hall A2; Poster Board: 41B

### Indications and Important Safety Information for ALIMTA (pemetrexed for injection)

ALIMTA is approved by the FDA in combination with cisplatin (another chemotherapy drug) for the initial treatment of advanced nonsquamous non-small cell lung cancer (NSCLC), a specific type of NSCLC. ALIMTA is not indicated for patients who have a different type of NSCLC called squamous cell.

ALIMTA is approved by the FDA for the treatment of patients with advanced nonsquamous nonsmall cell lung cancer (NSCLC), a specific type of NSCLC, to maintain the effect of initial treatment with chemotherapy and whose disease has not worsened.

ALIMTA is not indicated for patients who have a different type of NSCLC called squamous cell.

ALIMTA is approved by the FDA as a single agent (used alone) for the treatment of patients with advanced nonsquamous non-small cell lung cancer (NSCLC), a specific type of NSCLC, after prior chemotherapy. ALIMTA is not indicated for patients who have a different type of NSCLC called squamous cell.

ALIMTA is a treatment for malignant pleural mesothelioma (MPM), which is a cancer that affects the inside lining of the chest cavity. ALIMTA is given with cisplatin, another anticancer medicine (chemotherapy), when surgery is not an option.

ALIMTA may not be appropriate for some patients. If you are allergic to ALIMTA, tell your doctor because you should not receive it. If you think you are pregnant, are planning to become pregnant, or are nursing, please tell your healthcare team. ALIMTA may harm your unborn or nursing baby. Your physician may advise you to use effective contraception (birth control) to prevent pregnancy while you are being treated with ALIMTA.

If you have liver or kidney problems, be sure to tell your doctor. Your dose of ALIMTA may have to be changed, or ALIMTA may not be right for you. There is a risk of side effects associated with ALIMTA therapy. ALIMTA can suppress bone marrow function. It is very important to take folic acid and vitamin B12 prior to and during your treatment with ALIMTA to lower your chances of harmful side effects.

Your healthcare professional will prescribe a medicine called a corticosteroid, which lowers your chances of getting skin reactions with ALIMTA. Ask your healthcare professional before taking medicines called NSAIDs (nonsteroidal anti-inflammatory drugs used to treat pain or swelling). Tell your doctor if you are taking other medicines, including prescription and non-prescription medicines, vitamins, and herbal supplements.

The most common side effects of ALIMTA when given alone or in combination with cisplatin, another chemotherapy drug, are low blood cell counts (red blood cells, white blood cells, and platelets); tiredness; stomach upset, including nausea, vomiting, and diarrhea; mouth, throat, or lip sores; loss of appetite; rash; and constipation.

Call your healthcare professional right away if you have a fever, chills, diarrhea, or mouth sores. These symptoms could mean you have an infection. These are not all of the side effects of ALIMTA. If you have any side effect that bothers you or that does not go away, be sure to talk with your healthcare professional.

You will have regular blood tests before and during your treatment with ALIMTA. Your doctor may adjust your dose of ALIMTA or delay your treatment based on the results of your blood test and on your general condition.

For more information about ALIMTA, please see the full prescribing information (<http://pi.lilly.com/us/alimta-pi.pdf>) and patient prescribing information (<http://pi.lilly.com/us/alimta-ppi.pdf>). You may also learn more about ALIMTA at [www.alimta.com](http://www.alimta.com).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

### **Indications and Important Safety Information for GEMZAR (gemcitabine HCl for injection)**

GEMZAR is approved by the FDA in combination with cisplatin (another type of chemotherapy) for the first-line treatment of patients (for whom surgery is not possible) with locally advanced (stage IIIA or stage IIIB) or metastatic (stage IV or cancer that has spread) non-small cell lung cancer.

GEMZAR is approved by the FDA in combination with carboplatin (another type of chemotherapy) for the patient with advanced ovarian cancer that has returned at least 6 months after the patient had finished platinum-based therapy.

GEMZAR is approved by the FDA in combination with paclitaxel for the first-line treatment of patients with metastatic breast cancer after they have received another type of chemotherapy called an anthracycline, unless their medical condition did not allow them to receive an anthracycline.

GEMZAR is approved by the FDA as a single agent (given alone) as the first-line treatment for patients with locally advanced (stage II or stage III when surgery is not an option) or metastatic (stage IV) adenocarcinoma of the pancreas. GEMZAR is also indicated for patients previously treated with 5-FU (another type of chemotherapy).

GEMZAR can suppress bone marrow function, which may cause low blood cell counts.

GEMZAR may not be appropriate for some patients.

If you are allergic to GEMZAR, tell your doctor because you should not receive it.

GEMZAR given for longer than 60 minutes or more than once a week has caused increased side effects.

You should call your doctor right away if you have any symptoms of infection, such as a fever or chills. If you notice bleeding, unexplained bruising, or symptoms of anemia, contact your healthcare team, as these can be symptoms of low blood cell counts.

Serious lung problems, sometimes fatal, have been reported with GEMZAR. Tell your healthcare team if you develop breathing problems. There have been reports of serious kidney or liver damage including failure with GEMZAR treatment, sometimes fatal. If you have had kidney or liver problems or impairment, please tell your healthcare team. GEMZAR may not be right for you.

You will have regular blood tests before and during your treatment with GEMZAR. Your doctor may adjust your dose of GEMZAR or delay your treatment based on the results of your blood tests and on your general condition.

If you think you are pregnant, are planning to become pregnant, or are nursing, please tell your healthcare team.

Patients who receive radiation therapy before, during, or after receiving GEMZAR may sometimes experience more side effects, especially at the site of the radiation.

For more information about GEMZAR, please see the full prescribing information at <http://pi.lilly.com/us/gemzar.pdf>.

You may also learn more about GEMZAR at [www.Gemzar.com](http://www.Gemzar.com).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

## **Indications and Important Safety Information for ERBITUX® (cetuximab) Including BOXED WARNING**

### **Head and Neck Cancer**

ERBITUX® (cetuximab), in combination with radiation therapy, is indicated for the initial treatment of locally or regionally advanced squamous cell carcinoma of the head and neck.

ERBITUX, as a single agent, is indicated for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck for whom prior platinum-based therapy has failed.

### **Colorectal Cancer**

ERBITUX, as a single agent, is indicated for the treatment of EGFR-expressing metastatic colorectal cancer after failure of both irinotecan- and oxaliplatin-based regimens. ERBITUX, as a single agent, is also indicated for the treatment of EGFR-expressing metastatic colorectal cancer in patients who are intolerant to irinotecan-based regimens.

ERBITUX, in combination with irinotecan, is indicated for the treatment of EGFR-expressing metastatic colorectal carcinoma in patients who are refractory to irinotecan-based chemotherapy. The effectiveness of ERBITUX in combination with irinotecan is based on objective response rates. Currently, no data are available that demonstrate an improvement in disease-related symptoms or increased survival with ERBITUX in combination with irinotecan for the treatment of EGFR-expressing metastatic colorectal carcinoma.

Retrospective subset analyses of metastatic or advanced colorectal cancer trials have not shown a treatment benefit for ERBITUX in patients whose tumors had K-ras mutations in codon 12 or 13. Use of ERBITUX is not recommended for the treatment of colorectal cancer with these mutations.

## **Important Safety Information Including BOXED WARNING**

### **Infusion Reactions**

**Grade 3/4 infusion reactions occurred in approximately 3% of patients receiving ERBITUX® (cetuximab) in clinical trials, with fatal outcome reported in less than 1 in 1000. Serious infusion reactions, requiring medical intervention and immediate, permanent discontinuation of ERBITUX, included rapid onset of airway obstruction**

(bronchospasm, stridor, hoarseness), hypotension, shock, loss of consciousness, myocardial infarction, and/or cardiac arrest. Immediately interrupt and permanently discontinue ERBITUX infusions for serious infusion reactions.

Most (90%) of the severe infusion reactions were associated with the first infusion of ERBITUX despite premedication with antihistamines. Caution must be exercised with every ERBITUX infusion, as there were patients who experienced their first severe infusion reaction during later infusions. Monitor patients for 1 hour following ERBITUX infusions in a setting with resuscitation equipment and other agents necessary to treat anaphylaxis (eg, epinephrine, corticosteroids, intravenous antihistamines, bronchodilators, and oxygen). Longer observation periods may be required in patients who require treatment for infusion reactions.

### **Cardiopulmonary Arrest**

Cardiopulmonary arrest and/or sudden death occurred in 4 (2%) of 208 patients with squamous cell carcinoma of the head and neck treated with radiation therapy and ERBITUX, as compared to none of 212 patients treated with radiation therapy alone. Fatal events occurred within 1 to 43 days after the last ERBITUX treatment. Carefully consider the use of ERBITUX in combination with radiation therapy in head and neck cancer patients with a history of coronary artery disease, congestive heart failure or arrhythmias in light of these risks. Closely monitor serum electrolytes including serum magnesium, potassium, and calcium during and after ERBITUX therapy.

### **Pulmonary Toxicity**

Interstitial lung disease (ILD), which was fatal in one case, occurred in 4 of 1570 (<0.5%) patients receiving ERBITUX in clinical trials. Interrupt ERBITUX for acute onset or worsening of pulmonary symptoms. Permanently discontinue ERBITUX where ILD is confirmed.

### **Dermatologic Toxicities**

In clinical studies of ERBITUX, dermatologic toxicities, including acneform rash, skin drying and fissuring, paronychia inflammation, infectious sequelae (eg, *S. aureus* sepsis, abscess formation, cellulitis, blepharitis, conjunctivitis, keratitis, cheilitis), and hypertrichosis, occurred in patients receiving ERBITUX therapy. Acneform rash occurred in 76-88% of 1373 patients receiving ERBITUX in clinical trials. Severe acneform rash occurred in 1-17% of patients.

Acneform rash usually developed within the first two weeks of therapy and resolved in a majority of the patients after cessation of treatment, although in nearly half, the event continued beyond 28 days.

Monitor patients receiving ERBITUX for dermatologic toxicities and infectious sequelae. Sun exposure may exacerbate these effects.

### **ERBITUX Plus Radiation Therapy and Cisplatin**

The safety of ERBITUX in combination with radiation therapy and cisplatin has not been established. Death and serious cardiotoxicity were observed in a single-arm trial with ERBITUX, radiation therapy, and cisplatin (100 mg/m<sup>2</sup>) in patients with locally advanced squamous cell carcinoma of the head and neck. Two of 21 patients died, one as a result of pneumonia and one of an unknown cause. Four patients discontinued treatment due to adverse events. Two of these discontinuations were due to cardiac events.

### **Electrolyte Depletion**

Hypomagnesemia occurred in 55% (199/365) of patients receiving ERBITUX and was severe (NCI CTC grades 3 & 4) in 6-17%. The onset of hypomagnesemia and accompanying electrolyte abnormalities occurred days to months after initiation of ERBITUX therapy. Monitor patients periodically for hypomagnesemia, hypocalcemia and hypokalemia, during, and for at least 8 weeks following the completion of, ERBITUX therapy. Replete electrolytes as necessary.

### **Late Radiation Toxicities**

The overall incidence of late radiation toxicities (any grade) was higher with ERBITUX in combination with radiation therapy compared with radiation therapy alone. The following sites were affected: salivary glands (65%/56%), larynx (52%/36%), subcutaneous tissue (49%/45%), mucous membranes (48%/39%), esophagus (44%/35%), and skin (42%/33%) in the ERBITUX and radiation versus radiation alone arms, respectively. The incidence of grade 3 or 4 late radiation toxicities were similar between the radiation therapy alone and the ERBITUX plus radiation therapy arms.

### **Pregnancy and Nursing**

In women of childbearing potential, appropriate contraceptive measures must be used during treatment with ERBITUX and for 6 months following the last dose of ERBITUX. ERBITUX may be transmitted from the mother to the developing fetus, and has the potential to cause fetal harm when administered to pregnant women. ERBITUX should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.

It is not known whether ERBITUX is secreted in human milk. IgG antibodies, such as ERBITUX, can be excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from ERBITUX, a decision should be made whether to discontinue nursing or to discontinue ERBITUX, taking into account the importance of ERBITUX to the mother. If nursing is interrupted, based on the mean half-life of cetuximab, nursing should not be resumed earlier than 60 days following the last dose of ERBITUX.

## **Adverse Events**

The most serious adverse reactions associated with ERBITUX across all studies were infusion reactions, cardiopulmonary arrest, dermatologic toxicity and radiation dermatitis, sepsis, renal failure, interstitial lung disease, and pulmonary embolus.

The most common adverse reactions associated with ERBITUX (incidence greater than or equal to 25%) are cutaneous adverse reactions (including rash, pruritus, and nail changes), headache, diarrhea, and infection.

The most frequent adverse events seen in patients with carcinomas of the head and neck receiving ERBITUX in combination with radiation therapy (n=208) versus radiation alone (n=212) (incidence greater than or equal to 50%) were acneform rash (87%/10%), radiation dermatitis (86%/90%), weight loss (84%/72%), and asthenia (56%/49%). The most common grade 3/4 adverse events for ERBITUX in combination with radiation therapy (greater than or equal to 10%) included: radiation dermatitis (23%), acneform rash (17%), and weight loss (11%).

The most frequent adverse events seen in patients with metastatic colorectal cancer (n=288) in the ERBITUX + best supportive care arm (incidence greater than or equal to 50%) were fatigue (89%), rash/desquamation (89%), abdominal pain (59%), and pain-other (51%). The most common grade 3/4 adverse events (greater than or equal to 10%) included: fatigue (33%), pain-other (16%), dyspnea (16%), abdominal pain (14%), infection without neutropenia (13%), rash/desquamation (12%), and other-gastrointestinal (10%).

The most frequent adverse events seen in patients with metastatic colorectal cancer (n=354) treated with ERBITUX plus irinotecan in clinical trials (incidence greater than or equal to 50%) were acneform rash (88%), asthenia/malaise (73%), diarrhea (72%), and nausea (55%). The most common grade 3/4 adverse events (greater than or equal to 10%) included: diarrhea (22%), leukopenia (17%), asthenia/malaise (16%), and acneform rash (14%).

For more information about all of the side effects of ERBITUX, please talk with your healthcare team, see the full Prescribing Information at [http://packageinserts.bms.com/pi/pi\\_erbitux.pdf](http://packageinserts.bms.com/pi/pi_erbitux.pdf) or visit [www.ERBITUX.com](http://www.ERBITUX.com).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

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