



Lilly, Bristol-Myers Squibb Stop Enrollment in One of Two Phase III Lung Cancer Trials of Necitumumab

INSPIRE trial enrollment stopped; Enrollment in lung cancer trial SQUIRE continues

INDIANAPOLIS and PRINCETON, N.J., Feb. 2, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Bristol-Myers Squibb Company (NYSE: BMY) announced today that they have stopped enrollment in one of their two global Phase III studies evaluating necitumumab, an investigational anti-cancer agent, as a first-line treatment for advanced non-small cell lung cancer (NSCLC).

(Logo: <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>)

The randomized, multi-center, open-label Phase III trial, named INSPIRE, is evaluating the addition of necitumumab, a fully-human IgG1 monoclonal antibody, to a combination of ALIMTA[®] (pemetrexed for injection) and cisplatin compared to a regimen of ALIMTA and cisplatin, as a first-line treatment for patients with advanced nonsquamous NSCLC. No new safety issues were seen in the control arm with Alimta and cisplatin.

The decision to stop enrollment followed an independent Data Monitoring Committee (DMC) recommendation that no new or recently enrolled patients continue treatment in the trial because of safety concerns related to thromboembolism (blood clots) in the experimental arm of the study. The DMC also noted that patients who have already received two or more cycles of necitumumab appear to have a lower ongoing risk for these safety concerns. These patients may choose to remain on the trial, after being informed of the additional potential risks. Investigators will continue to assess patients after two cycles to determine if there is a potential benefit from treatment.

As noted earlier, necitumumab continues to be studied in a Phase III trial named SQUIRE. This study is evaluating necitumumab as a potential treatment for a different type of lung cancer called squamous non-small cell lung cancer in combination with GEMZAR[®] (gemcitabine HCl for injection) and cisplatin. The same independent DMC recommended that this trial continue because no safety concerns have been observed.

"Patient safety is paramount. While stopping enrollment in one of the two Phase III trials is disappointing, the SQUIRE Phase III study of necitumumab in lung cancer continues," said Richard Gaynor, M.D., vice president, oncology product development and medical affairs for Lilly. "Lilly remains committed to developing new medicines that can help treat this devastating disease."

Lilly has contacted all trial investigators to provide detailed information on how to manage individuals enrolled in the trial, and has notified all pertinent regulatory agencies of this decision.

Necitumumab is being developed in a partnership between Lilly and Bristol-Myers Squibb. The two companies share development costs and any potential commercialization within the U.S., Canada and Japan, while Lilly has exclusive commercialization rights in all other countries.

Notes to Editor

Data Monitoring Committee

A Data Monitoring Committee (DMC) is an independent body consisting of physicians and statisticians. Their responsibility is to review interim analysis data from clinical trials and make a decision on whether the trial is still set up correctly or needs modifications.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit www.bms.com, or follow us on Twitter at <http://twitter.com/bmsnews>.

About Lilly Oncology

For more than four decades, Lilly Oncology, a division of Eli Lilly and Company, has been dedicated to delivering innovative solutions that improve the care of people living with cancer. Because no two cancer patients are alike, Lilly Oncology is committed to developing novel treatment approaches. To learn more about Lilly's commitment to cancer, please visit www.LillyOncology.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs.

ALIMTA® (pemetrexed for injection), Lilly

GEMZAR® (gemcitabine HCl), Lilly

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 non-small 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.

What is the most important information that I should know about ALIMTA?

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

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 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.

Your doctor will prescribe a medicine called a "corticosteroid" to take for 3 days during each treatment with ALIMTA. Corticosteroids lower your chances for getting skin reactions with ALIMTA.

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.

- You must take folic acid every day for at least 5 days out of the 7 days before your first dose of ALIMTA. You must keep taking folic acid every day during the time you are getting treatment with ALIMTA, and for 21 days after your last treatment.
- Your doctor will give you vitamin B₁₂ injections while you are getting treatment with ALIMTA. You will get your first vitamin B₁₂ injection during the week before your first dose of ALIMTA, and then about every 9 weeks during treatment.

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.

What should I tell my doctor before receiving ALIMTA?

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.

Tell your doctor if you are taking other medicines, including prescription and nonprescription medicines, vitamins, and herbal supplements. ALIMTA and other medicines may affect each other, causing serious side effects. Especially, tell your doctor if you are taking medicines called "nonsteroidal anti-inflammatory drugs" (NSAIDs) for pain or swelling.

What are the possible side effects of ALIMTA?

Most patients taking ALIMTA will have side effects. Sometimes it is not always possible to tell whether ALIMTA, another medicine, or the cancer itself is causing these side effects.

Call your doctor right away if you have a fever, chills, diarrhea, or mouth sores. These symptoms could mean you have an infection, which may be severe and could lead to death.

The most common side effects of ALIMTA when given alone or in combination with cisplatin are:

- **Stomach upset, including nausea, vomiting, diarrhea, or constipation.** You can obtain medicines to help control some of these symptoms. Call your doctor if you get any of these symptoms.
- **Low blood cell counts:**
- **Low red blood cells.** Low red blood cells may make you feel tired, get tired easily, appear pale, and become short of breath.
- **Low white blood cells.** Low white blood cells may give you a greater chance for infection. If you have a fever (temperature above 100.4°F) or other signs of infection, call your doctor right away.
- **Low platelets.** Low platelets give you a greater chance for bleeding. Your doctor will do blood tests to check your blood counts before and during treatment with ALIMTA.
- **Tiredness.** You may feel tired or weak for a few days after your ALIMTA treatments. If you have severe weakness or tiredness, call your doctor.
- **Mouth, throat, or lip sores** (stomatitis, pharyngitis). You may get redness or sores in your mouth, throat, or on your lips. These symptoms may happen a few days after ALIMTA treatment. Talk with your doctor about proper mouth and throat care.
- **Loss of appetite.** You may lose your appetite and lose weight during your treatment. Talk to your doctor if this is a problem for you.
- **Rash.** You may get a rash or itching during treatment. These usually appear between treatments with ALIMTA and usually go away before the next treatment. Rarely, these reactions may be severe (can lead to Stevens-Johnson syndrome or toxic epidermal necrolysis) and could lead to death. Call your doctor if you get a severe rash, itching, or blistering.

Talk with your doctor, nurse, or pharmacist about any side effect that bothers you or that doesn't go away.

These are not all the side effects of ALIMTA. For more information, ask your doctor, nurse, or pharmacist.

How is ALIMTA given?

ALIMTA is slowly infused (injected) into a vein. The injection or infusion will last about 10 minutes. You will usually receive ALIMTA once every 21 days (3 weeks).

For more information about all of the side effects of ALIMTA, please talk with your healthcare team, see the Patient Prescribing Information and full Prescribing Information, visit www.ALIMTA.com, or call 1-800-545-5979.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit 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.

Tell your doctor if you are taking other medicines, including prescription and nonprescription medicines, vitamins, or herbal supplements.

There is a risk of side effects associated with GEMZAR therapy. The most common side effects are low blood cell counts (red blood cells, white blood cells, and platelets); fever; infection; hair loss; tiredness; nausea; vomiting; constipation; diarrhea; rash; shortness of breath; muscle aches; blood in urine; hearing changes and numbness or tingling in your toes or fingers. These are not all of the side effects of GEMZAR. Lab work may identify additional side effects. If you have any side effect that bothers you or that does not go away, be sure to talk with your doctor. Call your healthcare team right away if you have fever or chills. These symptoms could mean you have an infection.

If you are pregnant, GEMZAR may cause fetal harm to your unborn baby. It is not known if GEMZAR passes into breast milk; because of the potential for serious side effects in nursing infants, discuss breast feeding and GEMZAR with your doctor. The safety and effectiveness of GEMZAR in children has not been established.

For more information about all of the side effects of GEMZAR, please talk with your healthcare team, see the full Prescribing Information, visit www.GEMZAR.com, or call 1-800-545-5979.

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

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This press release contains forward-looking statements about the potential of necitumumab for the treatment of non-small cell

lung cancer and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that the product will receive regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995, regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Forward-looking statements in the press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2009, its Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise

SOURCE Eli Lilly and Company

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