



Study Showed Lilly's GEMZAR(R) (gemcitabine HCl for injection) Improved Progression-Free Survival in Cervical Cancer Patients

ORLANDO, Fla., May 31, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company announced today that Phase III trial data showed the addition of Lilly's GEMZAR(R) (gemcitabine HCl for injection) to the current standard of care provided a statistically significant increase in progression-free survival at three years for women with locally advanced cervical cancer.

Cervical cancer is the world's second most commonly diagnosed women's cancer, and the second most common cause of cancer death in women.(1)

The current standard of care for women with locally advanced cervical cancer consists of the chemotherapy cisplatin and radiation (chemoradiation). This has been the recommended course of treatment since 1999.

Results from this global, multicenter, open-label, randomized Phase III trial were presented at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO) during an ASCO-sponsored press conference on May 31 at 8:30 a.m. EDT, and as an oral presentation at the meeting at 10:30 a.m. EDT (ASCO Abstract #CRA5507).(2)

With 515 patients evaluated, the data showed a statistically significant ($p=0.029$) increase in progression-free survival at three years for patients treated with the gemcitabine chemoradiation combination versus those treated only with chemoradiation (74% vs. 65%, respectively). Patients on the gemcitabine arm experienced significantly more grade 3/4 toxicities. Additionally, two patients on the gemcitabine arm died due to causes possibly attributed to treatment-related toxicities. Most side effects were hematologic, including anemia (low red blood cell count), neutropenia (low white blood cell count) and thrombocytopenia (low blood platelet count).

"While there have been tremendous advances in cervical cancer prevention in the form of early screening and vaccination, oncologists have essentially been using the same treatment standard for the last decade," said study lead author Alfonso Duenas-Gonzalez, M.D., Ph.D., Investigador de la Unidad de Investigacion Biomedica en Cancer, Instituto Nacional de Cancerologia e Instituto de Investigaciones Biomedicas in Mexico.

"Lilly continues to look for ways to improve the survival of people living with cancer and fill unmet needs in difficult to treat cancers," said Richard Gaynor, M.D., vice president, cancer research and global oncology platform leader for Lilly.

Researchers also found that overall survival ($p=.0224$) and time-to-progressive disease ($p=.0008$) improved significantly. However, results for these two secondary endpoints are considered interim.

The 515 patients had a median age of 46 years and had either stage IIB, III, or IVA carcinoma of the cervix. Patients in the trial were randomly assigned to two arms with well-balanced baseline characteristics between both. Patients on arm A were treated with cisplatin (40 mg/m²) and gemcitabine (125 mg/m²) weekly for six doses along with concurrent external radiation (50.4 Gy: 1.8 Gy/day, 5 days per week), followed by brachytherapy (30-35 Gy) and then two adjuvant 21-day cycles of gemcitabine (1000 mg/m²) on days 1 and 8 plus cisplatin (50 mg/m²) on day 1. Patients on arm B were treated with cisplatin (40 mg/m²) weekly for six doses along with concurrent external radiation (50.4 Gy: 1.8 Gy/day, 5 days per week), followed by brachytherapy (30-35 Gy).

Important Safety Information for GEMZAR (gemcitabine HCl for injection)

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

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

GEMZAR is indicated 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 in combination with paclitaxel is approved by the FDA 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 may not be appropriate for some patients.

If you are allergic to GEMZAR, tell your doctor you should not receive it. GEMZAR can suppress bone marrow function. There have been rare reports of serious kidney or liver toxicity with GEMZAR treatment, sometimes fatal. Serious lung toxicity has also been reported, sometimes fatal. If you think you are pregnant, are planning to become pregnant, or are nursing, please tell your healthcare team. GEMZAR may harm your unborn or nursing baby.

If you have had prior kidney or liver problems or impairment, please tell your healthcare professional. GEMZAR may not be right for you. GEMZAR has not been shown to work in children. Tell your doctor if you are taking other medicines, including prescription and non-prescription 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, and diarrhea; rash; shortness of breath; muscle aches; and numbness or tingling in your toes or fingers. These are not all of the side effects of GEMZAR. If you have any side effect that bothers you or that does not go away, be sure to talk with your healthcare professional. Call your healthcare professional right away if you have fever or chills. These symptoms could mean you have an infection.

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 test and on your general condition.

For more information about all of the side effects of GEMZAR, please talk with your healthcare team or to 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.

Notes to Editor

About Cervical Cancer

With approximately 470,000 cases diagnosed globally each year, cervical cancer is the second most common cancer diagnosed among women worldwide. Additionally, approximately 232,000 women will die from the disease each year, giving it the second highest rate of cancer mortality among women worldwide. Eighty percent of diagnoses and nearly 83 percent of deaths from cervical cancer occur in developing nations.(3)

About Lilly Oncology, a Division of Eli Lilly and Company

For more than four decades, Lilly Oncology 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. Our quest is to develop a broad portfolio of tailored therapies that accelerate the pace and progress of cancer care. 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 first-in-class and best-in-class 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.

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GEMZAR(R) (gemcitabine HCl for injection), Lilly

This press release contains forward-looking statements about the potential of GEMZAR for the treatment of cervical cancer and reflects Lilly's current beliefs. However, as with any pharmaceutical product under development, there are substantial risks and uncertainties in the process of development, commercialization, and regulatory review. There is no guarantee that the products

will receive additional regulatory approvals. There is also no guarantee that the products will continue to 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.

(1) World Health Organization. Vaccine research and development - Vaccines against Human Papillomavirus. Available at: <http://www.who.int/vaccines/en/hpvrd.shtml>. Accessed May 1, 2009.

(2) Duenas A, Zarba JJ, Alcedo JC, et al: Phase III Randomized Comparison Of Concurrent Gemcitabine, Cisplatin, And Radiation Followed By Adjuvant Gemcitabine And Cisplatin Versus Concurrent Cisplatin And Radiation In Cancer Of The Cervix Stages IIb To Iva. Abstract #CRA5507, 45th American Society of Clinical Oncology (ASCO) annual meeting 2009.

(3) World Health Organization. Vaccine research and development - Vaccines against Human Papillomavirus. Available at: <http://www.who.int/vaccines/en/hpvrd.shtml>. Accessed May 1, 2009.

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