U.S. District Court Rules Against Lilly Regarding Gemzar Patent

Lilly Plans Appeal to Defend Gemzar's Intellectual Property

INDIANAPOLIS, Aug 17, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) today announced that the U.S. District Court for the Eastern District of Michigan has granted a motion by Sun Pharmaceuticals for partial summary judgment. The Court's ruling invalidates Lilly's '826 patent, or method-of-use patent, for Gemzar((R)) (gemcitabine HCl for injection) which had been set to expire in 2013. The ruling has no bearing on Gemzar's compound patent, which remains valid until November 2010.

"We strongly disagree with the Court's ruling granting summary judgment in favor of the generic challenger," said Robert A. Armitage, senior vice president and general counsel for Lilly. "We continue to believe that our Gemzar method-of-use patent is valid and will be upheld by the courts. We intend to pursue an appeal of this decision with the Court of Appeals for the Federal Circuit. It is also important to note that today's court decision does not allow for the immediate entry of generic gemcitabine in the U.S. market. Gemzar's compound patent remains in force until November 2010."

Important Safety Information for GEMZAR (gemcitabine HCl for injection)

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 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 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 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 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 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, 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 doesn't 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, see the full Prescribing Information, 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.

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. Additional information about Lilly is available at www.lilly.com. C-LLY

This release contains forward-looking statements regarding the U.S. Gemzar patent litigation. These statements are based on management's current expectations but actual results may differ materially. There can be no assurance that the company will prevail at trial or any appeal. Also, the company cannot predict whether generic gemcitabine will be marketed prior to the resolution of this litigation. Other risk factors that may affect the company results can be found in company's Form 10-K dated February 2009 and Form 10-Q dated July 2009.

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

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