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Gemzar Combination Therapy Receives European Regulatory Approvals for Treatment of Ovarian Cancer

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Eli Lilly and Company's Gemzar[®] (gemcitabine), approved to treat patients with pancreas, non-small-cell lung, metastatic breast and bladder cancers, receives approvals for a fifth indication.

Lilly announced today that regulatory officials in several European markets including but not limited to Germany, Sweden, Denmark, Finland, Belgium, Hungary, Portugal, and Romania, have approved Gemzar in combination with carboplatin, a standard chemotherapy agent, for the treatment of recurrent epithelial ovarian cancer.

Ovarian cancer causes more deaths in Europe than any other cancer of the female reproductive tract, with approximately 20,000 new cases of ovarian cancer diagnosed annually¹. Ovarian cancer is particularly lethal because of the disease's vague symptoms and high recurrence rate. Ninety percent of women with advanced ovarian cancer will experience a recurrence of the disease after initial treatment.²

"This new Gemzar combination provides women prolonged time without cancer progression, and relief of cancer symptoms. When ovarian cancer progresses it is frequently associated with significant symptoms that impede daily activities," said Jacobus Pfisterer, M.D., Ph.D., University of Kiel, Department of Gynecology and principal investigator of the registration trial.

"Physicians must aggressively address recurrent disease with effective treatment that allows the patient to maintain everyday activities. To return to a state of normalcy is quite meaningful for a woman battling ovarian cancer."

European approvals are based on an international study in more than 100 trial sites by the AGO (Arbeitsgemeinschaft Gynaekologische Onkologie) Ovarian Cancer Study Group, which is based in Germany. AGO worked in cooperation with the National Cancer Institute of Canada - Clinical Trials Group (NCIC-CTG) and the European Organization for Research and Treatment of Cancer - Gynecological Cancer Group (EORTC-GCG).

The data from this study were presented recently at the 40th annual meeting of the American Society of Clinical Oncology. The findings demonstrate a statistically significant improvement in time to disease progression, the study's primary endpoint, for Gemzar in combination with carboplatin as compared to carboplatin alone, a current standard of care for women with recurrent ovarian cancer.

"We are pleased that Gemzar can now be used to treat women with recurrent ovarian cancer. The consistent clinical efficacy and generally manageable side effects Gemzar provides across tumor types can now be expanded to a patient population that has seen few advances in therapy in the last decade," said Paolo Paoletti, M.D., vice president of oncology clinical research at Lilly. "With the aggressive nature of this disease, it is increasingly important to offer new innovative therapeutic options."

About the Study

The randomized Phase III study compared Gemzar plus carboplatin with carboplatin alone in locally advanced or metastatic disease in patients previously treated with platinum-based therapy such as carboplatin or cisplatin. The primary endpoint of this 356-patient trial was time to disease progression, the measure of time after cancer is treated until the disease begins to worsen. Many ovarian cancer patients will receive additional treatments each time their disease recurs. Time to disease progression endpoint is a meaningful measurement because it is unaffected by subsequent treatments. Quality of life, response rate and survival were secondary endpoints.

Results showed median time to progressive disease was increased by 48 percent - a finding that was statistically significant - in the Gemzar and carboplatin arm compared to the carboplatin arm (8.6 months versus 5.8 months). The overall response rate for the Gemzar combination was significantly higher than carboplatin alone, with 47 percent and 31 percent of patients responding respectively. Additionally, the combination of Gemzar and carboplatin maintained the overall quality of life seen with carboplatin single-agent.

The most commonly observed side effects of the Gemzar combination therapy in this study was a decrease in white blood cell counts (technically known as neutropenia), but the rate of serious infection was limited (less than 3%). As anticipated when

cytotoxic combination therapy is compared with cytotoxic single-agent, toxicity was observed more frequently in the combination arm. Grade 3 and 4 toxicities were primarily hematologic laboratory toxicities, such as anemia and thrombocytopenia (a decrease in platelets that may result in easy bruising or excessive bleeding). However, these laboratory toxicities infrequently resulted in symptomatic side effects such as febrile neutropenia and Grade 3 hemorrhage.

About Gemzar®

Gemzar is approved in more than 90 countries. It is the standard of care worldwide for pancreatic cancer. Gemzar is also a standard of care in many parts of the world for non-small-cell lung and bladder cancers and is currently being approved in many European countries as a combination therapy with Taxol® (paclitaxel) for metastatic breast cancer. Gemzar is a nucleoside analogue that interferes with the processes of DNA production; by doing so, Gemzar prevents cancer cells from replicating and thus slows or stops tumour growth.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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.

This press release contains forward-looking statements about the potential of Gemzar for the treatment of recurrent epithelial ovarian cancer and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of commercialization. There is no guarantee that the product will continue to be commercially successful, or that Gemzar will be commercially successful with regard to this new indication. 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.

Gemzar® (gemcitabine, Lilly)
Taxol® (paclitaxel, Bristol-Myers Squibb Oncology/Immunology)

References

1. Europa Donna - The European Breast Cancer Coalition
2. Handbook of Gynecologic Oncology, 2nd edition. Written by M. Steven Piver (1996), page 26.



Gemzar