

Pemetrexed approved for use in first-line treatment of most common lung cancer



Johannesburg, 7 October 2009: Lilly today announced that their pemetrexed for injection has been approved for a histologically- based use in the first-line treatment of advanced non-small-cell lung cancer (NSCLC)¹, the most common form of lung cancer².

Pemetrexed in combination with another chemotherapy drug, cisplatin, has been approved as a first-line treatment for patients with advanced non squamous non-small cell lung cancer (NSCLC), a specific type of NSCLC¹.

Lung cancer is the leading cause of cancer-related mortality in both men and women throughout the world². In South Africa, lung cancer is the leading cause of cancer deaths among South African men, the second most common cancer in men, and the sixth leading cancer in women, in terms of diagnosis³. Non-small cell lung cancer (NSCLC) accounts for approximately 85% of all lung cancers².

NSCLC is further defined as a group of histologies, that is, tumor types differentiated by cellular structure. Non squamous histology includes adenocarcinoma and large cell carcinoma - which account for about 70% of all NSCLC diagnoses - as well as histologies classified as "other". About 30% of all NSCLC cases are squamous². Pemetrexed is not indicated for patients with squamous NSCLC¹.

"This is an important result for patients and physicians and will improve our ability to select the optimal treatment for patients with NSCLC. Furthermore, this data demonstrates that histology can be a powerful tool in choosing the right drug for the right patient," said Dr Zi Chapanduka, Medical, Regulatory and Corporate Affairs Director, Lilly South Africa.

"We hope that this novel application of histology information opens the door for a more tailored approach for treating the world's leading cause of cancer deaths, and we are conducting further studies to understand the mechanism of pemetrexed's efficacy in NSCLC patients with other than predominantly squamous histology," said Dr Chapanduka.

The approval in first-line NSCLC is based on a Phase III randomized study that evaluated pemetrexed plus cisplatin versus gemcitabine plus cisplatin. The 1 725-patient study, the largest Phase III clinical trial undertaken in

the first-line setting of NSCLC, met its primary endpoint of non-inferiority relative to overall survival. However, when it came to survival by histology, the study found, in a pre-planned histological analysis, that patients with either adenocarcinoma or large-cell carcinoma had a clinically relevant improvement in overall survival when treated with the pemetrexed regimen in the first-line setting. In comparison, patients with squamous cell histology were found to have a more favorable overall survival when treated with the gemcitabine regimen⁴.

The lead investigator of the study, Giorgio Scagliotti, M.D., Department of Clinical and Biological Sciences Thoracic Oncology Unit, University of Torino, Orbassano, Italy, said the approval of pemetrexed plus cisplatin in a first-line setting marked an important step forward in treating the world's leading cause of cancer deaths." This study provides further evidence of the need to use a tailored approach to treating lung cancer patients, rather than simply using a particular medicine because of the treatment stage," said Dr. Scagliotti.

This approval follows approvals in Europe and the USA for pemetrexed in combination with cisplatin, as a first-line treatment for NSCLC patients with other than predominantly squamous cell histology.

This new approval will accompany the current indications for pemetrexed use in second- line NSCLC (indication revised to patients with other than predominantly squamous cell histology) and Malignant Pleural Mesothelioma in combination with Cisplatin¹.



Group: Jodi Aigner (Lilly Oncology), Dr Adam Nosworthy (local oncologist), Dr Mark Vincent (international guest speaker) and Dr Christos Nathaniel (Lilly Oncology)

References:

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2. Huq, S et al. Lung Cancer, Non Small Cell. <http://emedicine.medscape.com/article/279960-overview>
3. More information about lung cancer. Cancer Association of South Africa. (http://www.cansa.org.za/cgi-bin/giga.cgi?cmd=cause_dir_news_item&cause_id=1056&news_id=33621&cat_id=820).
4. Scagliotti G et al. Phase III study comparing cisplatin plus gemcitabine with cisplatin plus pemetrexed in chemotherapy-naïve patients with advanced-stage non small cell lung cancer. *J Clin Oncol* 2008; 26: 3543-51.