Medicines Control Council approves Tarceva® in South Africa for treatment of non-small cell lung cancer

Thousands of South African lung cancer patients could now live longer and with improved quality of life if they receive Tarceva® (erlonitib), a novel alternative to traditional chemotherapy, recently approved by the Medicines Control Council (MCC).

Tarceva®, an oral, once daily treatment is now available for the treatment of second line non small cell lung cancer (NSCLC) and has been shown, not only to improve survival by an impressive 42.5%, but also to improve disease symptoms and quality of life for patients suffering from NSCLC, the most common form of lung cancer.

Treating patients immediately following first-line chemotherapy, versus waiting for the cancer to grow or spread before giving additional treatment represents a new approach to treatment of advanced NSCLC.

Currently most lung cancer patients are treated with chemotherapy which can be very debilitating due to its toxic nature. Tarceva® works differently to chemotherapy by specifically targeting tumour cells, so avoiding the unpleasant side-effects of chemotherapy.

The approval by the MCC was based on a pivotal Phase III study published in the *New England Journal of Medicine* (NEJM)[1]. The study was conducted by the National Cancer Institute of Canada Clinical Trials Group based at Queen's University, in collaboration with OSI Pharmaceuticals, with the participation of 86 sites from 17 countries around the world. This Phase III study (NCIC-CTG BR.21) involved 731 patients with advanced NSCLC whose cancers had progressed after first- or second-line chemotherapy. The study compared patients receiving Tarceva® monotherapy with placebo.

The key study results were:

- Treatment with Tarceva® in patients with advanced NSCLC resulted in significantly longer survival compared to placebo, a 42.5% improvement (6.7 months vs. 4.7 months).
- 31% of patients receiving Tarceva® were alive at one year compared to 22% in the placebo arm.
- Patients receiving Tarceva® had stability or control of their lung cancer-related symptoms such as cough, shortness of breath and pain, for significantly longer.
- Patients also had a superior quality of life and improved physical function compared to those on placebo.
- The benefits of Tarceva® were shown in a broad spectrum of patients.

Professor Federico Cappuzzo, M.D., Istituto Clinico Humanitas IRCCS, Milan and principal investigator of the SATURN study is currently in South Africa to present the benefits of Tarceva® to Oncologists around the country.

According to Professor Cappuzzo, this study (NCIC-CTG BR.21) has not only confirmed that immediate treatment with Tarceva® after initial chemotherapy delayed the progression of disease, but also importantly helped patients in the study to live longer. "This is good news for doctors and their patients since advanced lung cancer is one of the most challenging cancers to treat and is often associated with a very short life expectancy."

Professor Cappuzzo has presented benefits of Tarceva® to Oncologists in Durban on September 30th, Cape Town on October 1st and Johannesburg/Pretoria on October 3rd.

About Tarceva®

Tarceva® is an investigational small molecule that targets the human epidermal growth factor receptor (HER1) pathway. HER1, also known as EGFR, is a key component of this signalling pathway, which plays a role in the formation and growth of numerous cancers. Tarceva® blocks tumour cell growth by inhibiting the tyrosine kinase activity of the HER1 signalling pathway inside the cell.

New data presented during the 13th World Conference on Lung Cancer in San Francisco (July 31 – August 4, 2009) showed that SATURN[2], a pivotal phase III study, met a key secondary endpoint of extending overall survival in patients with advanced non-small cell lung cancer (NSCLC) who received Tarceva® (erlotinib) immediately after their initial chemotherapy. A statistically significant improvement in overall survival was seen in the pre-planned final analysis of the total patient population in the study.

References

1. Shepherd F, Rodrigeus Pererira J, et al. Erlotinib in previously treated non-small cell lung cancer. *N Engl J Med* 2005;353 (2):123-32.
2. Cappuzzo F, Coudert B, Wierzbicki R et al. Efficacy and safety of erlotinib as first-line maintenance in NSCLC following non-progression with chemotherapy: results from the phase III SATURN study. Presented at 13th World congress on lung cancer; 2009 July 31 – August 4; San Francisco, USA.
3. World Health Organisation – *World Cancer Report*, 2003
4. Wyndeham et al., 1986; Mzileni, et al., 1999; Pacella-Norman, et al., 2002