Aromatase inhibitor letrozole guards against breast cancer relapse for up to 8 years

September 25 2011

Stockholm, Sweden: Results from the longest-running trial comparing tamoxifen with the aromatase inhibitor letrozole show unequivocally that letrozole has withstood the test of time and continues to prevent breast cancer recurrences and reduce the risk of death in post-menopausal women with hormone receptor-positive early breast cancer.

Professor Richard Gelber told delegates at the 2011 European Multidisciplinary Cancer Congress, in Stockholm today that a 12-year update of results from the Breast International Group (BIG) 1-98 trial showed that if women with early breast cancer (cancer that has not spread from the breast) were given letrozole after surgery for at least five years, they continued to do better and have fewer recurrences of the disease than those who were given tamoxifen.

"Over a median of eight years of follow-up, women who were assigned to receive five years of letrozole after surgery had an 18% reduced risk of relapse and a 21% reduced risk of death compared with those assigned to receive tamoxifen," said Prof Gelber, Director of the International Breast Cancer Study Group (IBCSG) Statistical and Data Management Center at the Dana-Farber Cancer Institute, Boston, MA, USA.

"The current 12-year update is the longest follow-up to date and includes much more information than we had after ten years. For instance, there have been 32% more relapses and 39% more deaths since the ten-year update, which increases substantially the reliability of the results and

provides reassurance regarding the long-term value of letrozole. This additional follow-up and accumulation of information on relapses and deaths show that the overall survival advantage for adjuvant letrozole compared to tamoxifen continues to be statistically significant."

Adjuvant therapy (treatment that is given after surgery), using drugs that target hormones such as oestrogen, is given to patients with early breast cancer who have hormone receptor-positive tumours. These tumours occur in approximately 75% of breast cancer cases. Tamoxifen has been the "gold standard" hormone treatment for women with early, oestrogen-receptor-positive breast cancer and works by blocking the growth-promoting action of oestrogen on the cancer cells. Aromatase inhibitors, such as letrozole, are newer and alter the function of aromatase, an enzyme involved in oestrogen production. They can be used in sequence with, or as an alternative to tamoxifen for post-menopausal women.

In the BIG 1-98 trial, researchers enrolled 8,010 patients to receive letrozole and tamoxifen either alone or in sequence, with a total of 4,922 patients included in the monotherapy arms of the study.

Efficacy analyses comparing the treatment groups were conducted every two years following the initial report of results, because the patients had a long-term risk of recurrence. This 12-year update shows that, among all 8,010 patients, there were 2,074 relapses and 1,284 deaths, compared with 1,569 relapses and 923 deaths at the ten-year update.

"The data also show that the sequential use of letrozole and tamoxifen (two years of one agent followed by three years of the other) provided similar outcomes compared with five years of letrozole alone for patients who are not at high risk for recurrence," said Prof Gelber.

"The optimal regimen remains an open question in many areas of the world, and this large trial presents definitive results for the treatment of

the largest group diagnosed with breast cancer: post-menopausal women with hormone-responsive early breast cancer."

He added: "Letrozole and tamoxifen have different side effects, and clinicians should consider the individual patient's medical history when prescribing treatment. Both agents are considered to be safe, especially in view of the substantial reduction in the risk of recurrence and the improved survival provided by these two endocrine therapies. While long-term safety data are available for tamoxifen, follow-up of patients who have received letrozole or other aromatase inhibitors is still relatively short. Thus, assessment of the long-term safety of letrozole is a critical objective for the BIG 1-98 follow-up study."

The IBCSG recently launched a long-term observational study that will extend patient follow-up for an additional five years in order to provide further information on efficacy and side effects of five years of adjuvant hormone therapy. "The follow-up study includes collection of yearly updates of survival, disease status and long-term adverse events. We plan to continue to update results every two years. This study is critically important as more than 74% of the patients enrolled in BIG 1-98 were still alive without a relapse at their most recent study visit. Assessment especially of long-term side effects for these patients is critically important," he said.

"BIG 1-98 and other large randomised clinical trials have firmly established the benefits of adjuvant treatment programmes including aromatase inhibitors, such as letrozole. Improved disease control and extended survival will reduce burdens on healthcare systems by reducing the number of patients requiring treatment for metastatic breast cancer. Furthermore, the cost of aromatase inhibitor treatment will decrease in the near future as generic products become available," Prof Gelber added.

Professor Michael Baumann, president of ECCO said: "This 12-year update of the study sheds more light on the advantages of aromatase inhibitors over tamoxifen in the adjuvant treatment of early breast cancer. It also clearly demonstrates how important it is to perform long-term follow-up and analysis of clinical studies especially for breast cancer. Long-term analysis is essential for reliably ensuring the efficacy of treatments but also to detect potential long-term side-effects which may affect quality of life. Although it is very difficult and costly to perform such long-term trials, the return for optimising treatments for cancer patients cannot be overemphasised."

Commenting on the study, which he was not involved with, ESMO member Professor Christoph Zielinski from the Medical University of Vienna, Vienna, Austria, said: "The BIG 1-98 trial demonstrates the clinical benefits of the aromatase inhibitor, letrozole and also provides further insight into the biology of the disease and how to improve outcomes with the upfront use of letrozole, compared to tamoxifen. This is important for daily clinical practice."

Provided by ECCO-the European CanCer Organisation

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