guards against breast cancer relapse

for up to 8 years...

EMCC 2011: Aromatase inhibitor letrozole guards

BEACON Pharma introduces

Lexel

Letrozole USP 2.5 mg Tablet

Guards against breast cancer relapse for up to 8 years

According to the result of European Multidisciplinary Cancer Congress 2011, Stockholm, Sweden:

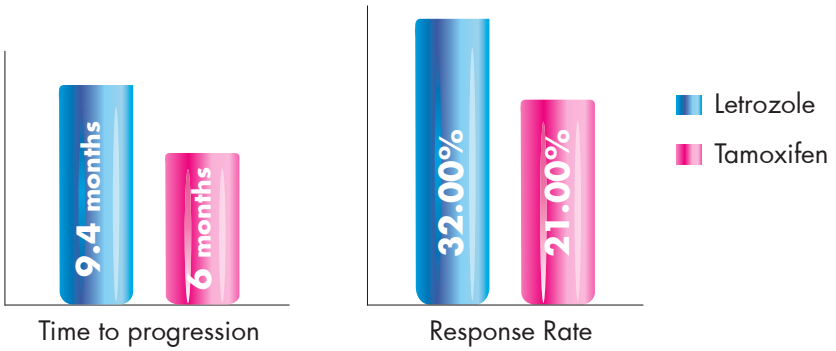
Trial name	:	BIG 1-98 trial
Total enrolled patient	:	8,010 patients
Drug used	:	Letrozole (2.5 mg tablet) and tamoxifen (20 mg tablet) either alone or in sequence, with a total of 4,922 patients included in the monotherapy arms of the study.
Follow up time	:	Over a median of eight years
Treatment time	:	5 years
Result	:	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.

against breast cancer relapse for up to eight years

Moreover, Letrozol Showed **72% Reduction in Risk of Distant metastases** in Postmenopausal Women with Early Breast Cancer who switched to Letrozol after Placebo in Study

Prevents breast cancer recurrence effectively

First-line superiority over Tamoxifen for hormone sensitive advanced breast cancer



Median time to progression was significantly prolonged than tamoxifen

More effective drug compared to other Aromatase inhibitors concerning

- Total aromatase inhibition
- Superssion of both Tissue and Plasma Estrogen Levels
- Superior overall response rate
- Superior Tolerability and patient preference
- No Rheumatologic symptoms (Arthralgia or Myalgia) unlike Anastrozole

Offers Superior Quality of Life for HR+ early breast cancer

Lexel

Letrozole USP 2.5 mg Tablet

Guards against breast cancer relapse for up to 8 years

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- **FDA Approved First line treatment for Post Menopausal women with hormone-receptor -positive or hormone-receptor unknown locally advanced or metastatic breast cancer**
- **Greater clinical benefit to postmenopausal women with HR+ early breast cancer at increased risk of early recurrence**
- **Effective Neoadjuvant Therapy for ErbB-1- and/or ErbB-2-Positive and Estrogen receptor- positive Primary Breast Cancer[3]**

Prescribing Information

COMPOSITION: ***Lexel Tablet:*** Each film coated tablet contains Letrozole USP 2.5 mg. **DESCRIPTION:** Letrozole is a nonsteroidal aromatase inhibitor (inhibitor of estrogen synthesis). It is a white to yellowish crystalline powder, practically odorless, freely soluble in dichloromethane, slightly soluble in ethanol, and practically insoluble in water. It has a molecular weight of 285.31, empirical formula $C_{17}H_{11}N_5$, and a melting range of 184°C-185°C. **INDICATIONS:** ***Adjuvant Treatment of Early Breast Cancer:*** Lexel is indicated for the adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer. **Extended Adjuvant Treatment of Early Breast Cancer:** Letrozole is indicated for the extended adjuvant treatment of early breast cancer in postmenopausal women, who have received 5 years of adjuvant Tamoxifen therapy. The effectiveness of Letrozole in extended adjuvant treatment of early breast cancer is based on an analysis of disease-free survival in patients treated with Letrozole for a median of 60 months. **First and Second-Line Treatment of Advanced Breast Cancer:** Lexel is indicated for first-line treatment of postmenopausal women with hormone receptor positive or unknown, locally advanced or metastatic breast cancer. Letrozole is also indicated for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy. **DOSAGE AND ADMINISTRATION: Recommended Dose:** The recommended dose of Lexel is one 2.5 mg tablet administered once a day, without regard to meals. **Use in Adjuvant Treatment of Early Breast Cancer:** In the adjuvant setting, the optimal duration of treatment with Letrozole is unknown. The planned duration of treatment in the study was 5 years with 73% of the patients having completed adjuvant therapy. Treatment should be discontinued at relapse. **Use in Extended Adjuvant Treatment of Early Breast Cancer:** In the extended adjuvant setting, the optimal treatment duration with Letrozole is not known. The planned duration of treatment in the study was 5 years. In the final updated analysis, conducted at a median follow up of 62 months, the median treatment duration was 60 months. Seventy-one percent of patients were treated for at least 3 years and 58% of patients completed least 4.5 years of extended adjuvant treatment. The treatment should be discontinued at tumor relapse. **Use in First and Second-Line Treatment of Advanced Breast Cancer:** In patients with advanced disease, treatment with Lexel should continue until tumor progression is evident. **PRECAUTIONS:** ***Bone Effects:*** Use of Letrozole may cause decreases in bone mineral density (BMD). Consideration should be given to monitoring BMD. Results of a substudy to evaluate safety in the adjuvant setting comparing the effect on lumbar spine (L2-L4) bone mineral density (BMD) of adjuvant treatment with Letrozole to that with Tamoxifen showed at 24 months a median decrease in lumbar spine BMD of 4.1% in the Letrozole arm compared to a median increase of 0.3% in the Tamoxifen arm (difference = 4.4%) (P<0.0001). Updated results from the BMD sub-study in the extended adjuvant setting demonstrated that at 2 years patients receiving Letrozole had a median decrease from baseline of 3.8% in hip BMD compared to a median decrease of 2.0% in the placebo group. The changes from baseline in lumbar spine BMD in Letrozole and placebo treated groups were not significantly different. In the adjuvant trial the incidence of bone fractures at any time after randomization was 13.8% for Letrozole and 10.5% for Tamoxifen. The incidence of osteoporosis was 5.1% for Letrozole and 2.7% for Tamoxifen. In the extended adjuvant trial the incidence of bone fractures at any time after randomization was 13.3% for Letrozole and 7.8% for placebo. The incidence of new osteoporosis was 14.5% for Letrozole and 7.8% for placebo. **DRUG INTERACTIONS:** ***Tamoxifen:*** Coadministration of Letrozole and Tamoxifen 20 mg daily resulted in a reduction of Letrozole plasma levels of 38% on average. Clinical experience in the second-line breast cancer trials indicates that the therapeutic effect of Letrozole therapy is not impaired if Letrozole is administered immediately after Tamoxifen. ***Cimetidine:*** A pharmacokinetic interaction study with cimetidine showed no clinically significant effect on Letrozole pharmacokinetics. ***Warfarin:*** An interaction study with Warfarin showed no clinically significant effect of Letrozole on Warfarin pharmacokinetics. ***Other anticancer agents:*** There is no clinical experience to date on the use of Letrozole in combination with other anticancer agents. **PHARMACEUTICAL INFORMATION:** ***Storage condition:*** Store in a cool and dry place, away from light. Keep out of the reach of children. **Packaging: Lexel Tablet:** Each commercial box contains 30 tablets in Alu-Alu blister pack.

(Full prescribing information will be available on request)

BEACON® Pharmaceuticals Limited
Light for life

1. esmo.org/events/milan-2010-congress/news
2. Breast Cancer Res Treat (2007) 105:67-74
3. Journal of Clinical Oncology, Vol 19, No 18 (September 15), 2001

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