STUDY N.: LF-PB/14/05
EUDRACT N.: 2014-005289-31

A multicentre, double blind, randomized placebo controlled trial, to assess the effect of LF-PB on seroma formation in women with breast cancer undergoing Axillary Lymph Node Dissection

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Print:
- Selected patients

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Screening

CRF1

DATE OF VISIT

Date of Visit 10/Aug/2015

INFORMED CONSENT

Date of Informed Consent Form 12/08/2015

DEMOGRAPHY

Date of birth 12/08/1985

Race

- ○ Caucasian
- ● Black
- ○ Asian
- ○ Other

CRF2

INCLUSION CRITERIAS

1. Signed informed consent form
   - ● Yes
   - ○ No

2. Female aged ≥ 18 years
   - ● Yes
   - ○ No

3. Undergoing breast cancer surgery with axillary lymph node dissection during the current clinical trial
   - ● Yes
   - ○ No

4. Negative serum pregnancy test for women of childbearing potential
   - ○ Yes
   - ○ No
   - ● Not applicable

5. Aspartate aminotransferase and alanine aminotransferase < 2 x the upper limit of normal
   - ● Yes
   - ○ No

6. Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1
   - ○ Yes
   - ● No

7. Compliant with the protocol requirements
● Yes
○ No

CRF3

EXCLUSION CRITERIAS

	Yes	No
1. Previous axillary surgery on the same armpit (sentinel lymph node surgery is not exclusionary)		
2. Previous radiotherapy within five years from study drug administration on the same armpit undergoing surgery in this study		
3. Concomitant participation to other clinical trial		
4. Uncontrolled diabetes		
5. Cholelithiasis		
6. Human immunodeficiency virus or hepatitis B or C by screening serology		
7. Uncontrolled hypothyroidism: if patient is being administered Eutirox/ Levothyroxine (or analogues) and levels of T3, T4 and TSH are confirmed to be within the normal ranges at screening, the patient can be enrolled in this study.		
8. Pregnant or lactating		
9. Ascertained or presumptive hypersensitivity to the active principle and/or the ingredients of the study drug formulation		
10. Corrected QT (using the Bazett formula, QTc) interval at screening or baseline > 450 msec (as the mean of 3 consecutive readings 5 minutes apart). Presence of any disease or use of concomitant medication known to increase the QT interval		
11. Clinically significant or relevant abnormal medical history, vital sign, physical examination or laboratory evaluation finding		

12. Corticosteroid treatment on a long-term basis (i.e. treatment for more than 3 consecutive days). Acute use of corticosteroids to prevent hypersensitivity reactions before surgery is not considered an exclusion criterion
13. Current or recurrent disease that could affect the results of the clinical or laboratory assessment required for the study