



Fondation du Centre  
Pluridisciplinaire d'Oncologie

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CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

### ZOOM LAPATAX (EORTC10054)

<b>Indication</b>	<b>Sein néoadjuvant</b> , localement avancé, inflammatoire, grosse tumeur opérable
<b>Title</b>	A phase I-II study of Lapatinib and Docetaxel as neoadjuvant treatment for HER-2 positive locally advanced/inflammatory or large operable breast cancer
<b>Protocol ID</b>	Lapatax (EORTC 10054)
<b>Phase</b>	Phase I-II
<b>Sponsor</b>	EORTC (European Organisation for Research and Treatment of Cancer)
<b>Local Principal Investigator</b>	Dr. K. Zaman
<b>Primary Objective</b>	<ul style="list-style-type: none"> <li>○ <b>Phase I</b> : The primary objective of this part of the trial is to recommend a dose of Lapatinib and Docetaxel to be given pre-operatively over 3 cycles to HER-2 positive breast cancer patients, following 3 cycles of FEC. In order to achieve this, the study will first determine the maximum tolerated dose (MTD) based on the documentation of the acute dose limiting toxicity (DLT), and then confirm the safety of this dose after 3 cycles of FEC in a bridging phase.</li> <li>○ <b>Phase II</b> : The primary objective of the phase II is to assess the activity of the combination FEC followed by Docetaxel + Lapatinib. The pathological response rate will be used as a surrogate for activity. The reference arm will be FEC 100 (3 cycles) followed by Docetaxel + Trastuzumab (3 cycles). In the investigational arm, Lapatinib will replace Trastuzumab</li> </ul>
<b>Inclusion/exclusion criteria</b>	<p><b>Part I</b> : Inclusion criteria include the following :</p> <ul style="list-style-type: none"> <li>○ Female patients with locally advanced or inflammatory breast cancer for whom neo-adjuvant chemotherapy is appropriate defined as: <ul style="list-style-type: none"> <li>- Clinical T4 a,b,c,d, any N (inflammatory breast carcinoma: tumor mass, breast enlargement, oedema and warmth of the skin are often present but not mandatory for the diagnosis)</li> <li>– Or any clinical T, N2 or N3 (ipsilateral supraclavicular nodes)</li> </ul> </li> <li>○ Presence of bilateral breast cancer is allowed</li> <li>○ Patients with minimal lung, skin, or nodal metastatic disease shall be discussed case-by-case with the study co-ordinators.</li> </ul>

Patients with bone, liver or other extensive metastases are non eligible

- No prior therapy for any cancer, including chemotherapy, radiotherapy, hormonotherapy for breast cancer, EGFR or HER-2 or antibody therapy.

**Bridge step :**

In addition, female patients with large operable T2 or T3 breast cancers, are eligible.

**Part II :**

- Female patients with large operable T2 or T3 breast cancers, M0
- Or female patients with locally advanced or inflammatory breast cancer defined as:
  - Clinical T4 a,b,c,d, any N (inflammatory breast carcinoma: tumor mass, breast enlargement, oedema and warmth of the skin are often present but not mandatory for the diagnosis)
  - Or any clinical T, N2 or N3 (ipsilateral supraclavicular nodes)
  - And M0
- No presence of bilateral breast cancer
- No prior history of malignancies except:
  - basal cell or squamous cell carcinoma of the skin
  - carcinoma in situ of the cervix
  - the patient has been free of any other malignancies for > 3 years.