



Fondation du Centre
Pluridisciplinaire d'Oncologie

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CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

ZOOM SAKK 22/99

Indication	Sein Métastatique, 1 ^{ère} -2 ^{ème} ligne
Title	Randomized phase III trial of Herceptin® followed by chemotherapy plus Herceptin® versus the combination of Herceptin® and chemotherapy as palliative treatment in patients with HER2-overexpressing advanced/metastatic breast cancer
Protocol ID	SAKK 22/99
Phase	Phase III
Sponsor	SAKK (Swiss Group for Clinical Cancer Research)
Local Principal Investigator	Dr. K. Zaman
Primary Objective	To compare efficacy, toxicity and quality of life of the sequential administration of Her alone followed, at PD, by the combination with Chemotherapy (Arm A) vs. the upfront combination of Her and Chemotherapy (Arm B) in patients with advanced/metastatic breast cancer.
Inclusion/exclusion criteria	<p>Inclusion criteria include the following :</p> <ul style="list-style-type: none"> ○ Histologically proven diagnosis of HER2-overexpressing breast carcinoma (2+ or 3+ by HercepTest™; see section 13). ○ Advanced/metastatic breast carcinoma. ○ Clinically or radiologically measurable or evaluable disease defined as: presence of bidimensionally or unidimensionally measurable lesions by physical or radiological examination. ○ Patients may have received chemotherapy as neo/adjuvant treatment or at most 2 regimens for metastatic disease. Patients may have received hormonal therapy as adjuvant treatment or for metastatic disease. ○ Age 18-70 years, inclusive. ○ Adequate liver, hematological and renal functions ○ Adequate cardiac function: left ventricular ejection fraction (LVEF) at rest measured by echocardiography must be no lower than the local normal limit. ○ Adequate contraceptive measures in women with child bearing potential. ○ Life expectancy > 12 weeks. ○ ECOG/SAKK performance status 0-1. <p>Exclusion criteria include the following:</p> <ul style="list-style-type: none"> ○ Patients who have received -cumulative doses of anthracyclines as neo/adjuvant treatment or for metastatic disease exceeding 360 mg/m² of Doxorubicin or 720 mg/m² of Epidoxorubicin;

	<p>-3 or more regimens of chemotherapy for metastatic disease; -the last dose of Taxanes or Herceptin treatment less than 12 months prior to randomization.</p> <ul style="list-style-type: none"> ○ Non evaluable lesions (osteoblastic bone metastases, ascitic, pleural and pericardial effusions, carcinomatous lymphangitis of the lung) as the only indicator lesions. ○ Presence of known clinical brain or meningeal involvement. ○ History of atrial ventricular arrhythmia, congestive heart failure or angina pectoris, even if medically controlled; uncontrolled hypertension; history of 2nd or 3rd degree heart blocks. Patients with a history of 1st degree heart block will be eligible providing that continuous electrocardiographic monitoring will be performed during the taxane infusion. ○ Any history of a second neoplasm except for curatively treated non melanoma skin cancer or carcinoma in situ of the cervix. ○ Concomitant treatment with other anticancer drugs. ○ Concomitant treatment with corticosteroids unless started > 6 months prior to study entry and at low doses (≤ 20 mg methylprednisolone or equivalent). ○ Definite contraindications for the use of corticosteroids. ○ Concomitant treatment with any other experimental drug. ○ Male patients. ○ Concomitant treatment with biphosphonates initiated less than 3 months prior to study entry (chronic use is allowed provided bone metastases are not the only indicator lesions). ○ Pre-existing motor or sensory neuropathy NCIC-CTG expanded common toxicity grade ≥ 2.
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