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Plateformes du DO
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Indication	**NSCLC, avancé (stade IIIB) mais opérable**
Title	Preoperative chemotherapy and radiotherapy concomitant to Cetuximab in non-small cell lung cancer (NSCLC) patients with IIIB disease. A multicenter phase II trial.
Protocol ID	**SAKK 16/08**
Phase	Phase II
Sponsor	SAKK (Swiss Group for Clinical Cancer Research)
Local Principal Investigator	Dr S. Peters
Primary Objective	The main objective of this trial is to evaluate efficacy and safety of sequential neoadjuvant chemoradiotherapy with concomitant targeted therapy of cetuximab in patient with operable stage IIIB NSCLC.
Inclusion/exclusion criteria	**Inclusion Criteria include the following :** o Patient must give written informed consent before registration. o Histologically or cytologically confirmed NSCLC (squamous, adeno-, large cell and poorly differentiated NSCLC), proven on either the primary tumor or lymph node(s). o Tumor stage IIIB. T4N0-3M0 or T1-4N3M0, excluding stages IIIB with malignant pleural or pericardial effusion, invasion of the aorta, esophagus, myocardium and supraclavicular or scalene nodes N3; or stages IIIB defined only by satellite lesions in the same lobe. o PET/CT scan, brain CT scan or MRI and bronchoscopy of the primary tumor within 28 days before registration. o Mediastinoscopy within 28 days before registration for assessment of N+ disease, if a lymph node in the mediastinum is positive in PET (SUV above mediastinum background SUV) or CT (size of > 10 mm in the smallest diameter). Only in case the lymph node is not accessible with mediastinoscopy (ATS nodes #5/6), fine needle aspiration biopsy can be performed, e.g. by EBUS, TBNA or VATS. Mediastinoscopy and fine needle aspiration biopsy can be omitted only if PET and CT are negative in the mediastinum (all N2 and N3 are negative) and if there is no suspicion of T4 tumor invading the trachea. o Patient is considered operable according to local standards. Careful evaluation of inclusion should be performed by a local multidisciplinary tumor board in patients presenting a tumor requiring a right pneumectomy at diagnosis, considered as a high risk procedure after induction. o WHO performance status 0-1 o Age ≥ 18 years and ≤75 o Adequate hematological values: neutrophils ≥ 1.5 x 10^9/l, platelets ≥ 100 x 10^9/l o Adequate hepatic function: bilirubin within normal limits, AST ≤

	1.5 x ULN, AP ≤ 2.5 xULN o Adequate renal function: calculated creatinine clearance ≥ 60 ml/min (according to the formula of Cockcroft-Gault) o Women are not breastfeeding, are using effective contraception if sexually active, are not pregnant and agree not to become pregnant during participation in the trial or during the 12 months thereafter. A negative pregnancy test before inclusion into the trial is required for all women with child-bearing potential. Men agree not to father a child during participation in the trial or during the 12 months thereafter. o Patient compliance and geographic proximity allowing proper staging and follow-up. **Exclusion Criteria include the following :** o Pretreatment with any cytostatic therapy o Previous radiotherapy to the chest o Previous malignancy within 5 years with the exception of adequately treated cervical carcinoma in situ or localized non-melanoma skin cancer. o Psychiatric disorder precluding understanding of information on trial related topics and giving informed consent. o Preexisting peripheral neuropathy (> grade 1) o Unstable cardiac disease requiring treatment, congestive heart failure or angina pectoris even if medically controlled, significant arrhythmia, or prior history of myocardial infarction in the last 3 months. o Any serious underlying medical condition (at the judgment of the investigator) which could impair the ability of the patient to participate in the trial (e.g. active autoimmune disease, uncontrolled diabetes, uncontrolled infection). o Known hypersensitivity to trial drug(s) or hypersensitivity to any other component of the trial drugs. o Absolute contraindications for the use of corticosteroids as premedication. o Concurrent treatment with corticosteroids, except for the prophylactic medication regimen before treatment, treatment of acute hypersensitivity reactions or chronic treatment (initiated > 6 months prior to trial entry) at low dose (< 20 mg methylprednisolone or equivalent). o Concurrent treatment with other experimental drugs or other anti-cancer therapy, treatment in a clinical trial within 30 days prior to trial entry. o Any concomitant drugs contraindicated for use with the trial drugs according to the Swissmedic-approved product information.