



Fondation du Centre  
Pluridisciplinaire d'Oncologie

## Fondation du Centre Pluridisciplinaire d'Oncologie

CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

### ZOOM SAKK 17/04

<b>Indication</b>	<b>Mésothéliome, 1<sup>er</sup> diagnostic</b>
<b>Title</b>	Neoadjuvant chemotherapy and extrapleural pneumonectomy of malignant pleural mesothelioma (MPM) with or without hemithoracic radiotherapy
<b>Protocol ID</b>	<b>SAKK 17/04</b>
<b>Phase</b>	Phase II
<b>Sponsor</b>	<b>SAKK</b> (Swiss Group for Clinical Cancer Research)
<b>Local Principal Investigator</b>	Dr. R. Stupp
<b>Primary Objective</b>	The primary objectives of this trial are to evaluate the short-term outcomes and feasibility of neoadjuvant chemotherapy and extrapleural pneumonectomy in Part 1, and long-term outcomes and feasibility of hemithoracic radiotherapy in patients with R0 and R1 resection in Part 2.
<b>Inclusion/exclusion criteria</b>	<p>Inclusion Criteria include the following :</p> <ul style="list-style-type: none"><li>○ Histological/cytological proof of malignant pleural mesothelioma</li><li>○ T ≤ 3, N ≤ 2, M0 according to the IMIG staging system</li><li>○ Patients must have a WHO performance score of 0-1 and be considered fit for chemotherapy, surgery and postoperative radiotherapy</li><li>○ Age &lt; 70 years and ≥ 18 years</li><li>○ Calculated creatinine clearance &gt; 60 ml/min</li><li>○ Normal hematologic function (hemoglobin ≥ 100 g/l, WBC ≥ 3.5 x 10<sup>9</sup>/l, neutrophils ≥ 1.5 x 10<sup>9</sup>/l, thrombocytes ≥ 100 x 10<sup>9</sup>/l)</li><li>○ Bilirubin and liver function tests (ASAT/ALAT/AP) ≤ 1.5 LUN</li><li>○ Written informed consent has been obtained</li><li>○ Acceptance of patient for surgery by a multidisciplinary tumor board including a thoracic surgeon</li><li>○ 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 is mandatory for all women &lt;50 years, unless considered</li></ul>

unnecessary by the investigator. Men agree not to father a child during participation in the trial or during the 12 months thereafter.

Exclusion criteria include the following:

- Obvious invasion of mediastinal structures on CT scan (heart, aorta, spine, esophagus, etc.)
- Obvious widespread chest wall invasion (resectable chest wall lesions are accepted)
- Predicted post-operative FEV1 < 40 % based on spirometry and lung perfusion scan if necessary
- Prior chemotherapy
- Concurrent treatment with other experimental drugs or other anti-cancer therapy, treatment within a clinical trial within 30 days prior to trial entry
- Prior pleurectomy and lung resection
- Prior radiotherapy of the lower neck, thorax and upper abdomen
- 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)
- Any concomitant drugs contraindicated for use with the trial drugs according to the product information