



Fondation du Centre  
Pluridisciplinaire d'Oncologie

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CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

### ZOOM SAKK 56/07

<b>Indication</b>	Sarcome, <b>GIST</b> , 1ère ligne
<b>Title</b>	Dasatinib first-line treatment in gastrointestinal stromal tumors.
<b>Protocol ID</b>	<b>SAKK 56/07</b>
<b>Phase</b>	Phase II
<b>Sponsor</b>	SAKK (Swiss Group for Clinical Cancer Research)
<b>Local Principal Investigator</b>	Dr M. Montemurro
<b>Primary Objective</b>	Efficacy of dasatinib treatment as assessed by fusion PET/CT-scan.
<b>Inclusion/exclusion criteria</b>	<p><b>Inclusion Criteria include the following:</b></p> <ul style="list-style-type: none"><li>○ Patient has histologically proven diagnosis of GIST.</li><li>○ Positive PET/CT with [18F]-fluorodeoxyglucose uptake of the target lesion(s), performed within 2 weeks prior to registration.</li><li>○ Patient must have measurable disease according to RECIST.</li><li>○ WHO performance status 0-2.</li><li>○ Age <math>\geq</math> 18 years.</li><li>○ Adequate haematologic and hepatic function.</li><li>○ Women are not breastfeeding, are using contraception if sexually active and of childbearing potential, are not pregnant and agree not to become pregnant during participation in the trial or during the 12 months thereafter. Men agree not to father a child during participation in the trial or during the 12 months thereafter and use effective contraception method.</li><li>○ Patient's condition, compliance and geographic proximity. allow proper staging, complete treatment and follow-up.</li><li>○ Patient must give written informed consent before registration.</li></ul> <p>Exclusion Criteria include the following:</p> <ul style="list-style-type: none"><li>○ Previous malignancy within 5 years with the exception of adequately treated cervical carcinoma in situ or localized non-melanoma skin cancer.</li><li>○ Previous therapy against GIST (particularly tyrosine kinase inhibitors at any time).</li><li>○ Concurrent treatment with other experimental drugs or other anticancer therapy, treatment in a clinical trial within 30 days prior to trial entry.</li><li>○ Signs or history of CNS metastases.</li><li>○ Hypocalcemia.</li></ul>

	<ul style="list-style-type: none"><li>○ Clinically significant cardiovascular disease, including uncontrolled hypertension, congestive heart failure within 6 months prior to registration, QTc &gt; 450 msec or major conduction abnormality (unless a cardiac pacemaker is present).</li><li>○ Concurrent medical condition which could impair the ability of the patient (at the judgment of the investigator) to participate in the trial (e.g. active autoimmune disease, uncontrolled diabetes) or which may increase the risk of toxicity, including:<ul style="list-style-type: none"><li>a) pleural or pericardial effusion of any grade</li><li>b) clinically significant coagulation or platelet function disorder (e.g. known von Willebrand's disease)</li><li>c) infection requiring intravenous antibiotics</li><li>d) ongoing significant gastrointestinal bleeding</li><li>e) nausea, vomiting or malabsorption syndrome which could interfere with ingestion or absorption of oral drug</li></ul></li><li>○ Known hypersensitivity to trial drug.</li><li>○ Any concomitant drugs contraindicated for use with the trial drug according to the dasatinib investigator's brochure.</li></ul>
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