



Fondation du Centre  
Pluridisciplinaire d'Oncologie

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CHUV BH 06 - Rue du Bugnon 46 - 1011 Lausanne

### ZOOM SAKK 38/08

<b>Indication</b>	<b>Lymphome agressif à cellules B</b> récidivant ou réfractaire
<b>Title</b>	Rituximab, bendamustine and lenalidomide in patients with relapsed or refractory aggressive B-cell lymphoma not eligible for high dose chemotherapy.
<b>Protocol ID</b>	<b>SAKK 38/08</b>
<b>Phase</b>	A phase I/II trial.
<b>Sponsor</b>	SAKK (Swiss Group for Clinical Cancer Research)
<b>Local Principal Investigator</b>	Dr Nicolas Ketterer
<b>Primary Objective</b>	<p>The objective of phase I is to determine the maximum tolerated dose (MTD) (based upon first cycle DLTs) and to identify the recommended dose (RD) of the combination of rituximab, bendamustine and lenalidomide in patients with relapsed or refractory aggressive B-cell lymphoma not eligible for high dose therapy (HDT) with autologous stem cell transplantation (ASCT) for Phase II.</p> <p>The objective of phase II is to determine the efficacy and safety of the combination of rituximab, bendamustine and lenalidomide in patients with refractory or relapsed aggressive B-cell lymphoma not eligible for HDT with ASCT.</p>
<b>Inclusion/exclusion criteria</b>	<p><b>Inclusion Criteria include the following :</b></p> <ul style="list-style-type: none"> <li>○ Patient must give written informed consent before registration.</li> <li>○ Histologically confirmed diagnosis of DLBCL not otherwise specified (according to [27] including: centroblastic, immunoblastic, anaplastic variants), transformed follicular lymphoma, or follicular lymphoma grade 3b.</li> <li>○ First relapse or refractory aggressive B-cell lymphoma according to above mentioned histology.</li> <li>○ Patient is not eligible for high dose therapy with autologous stem cell transplantation.</li> <li>○ Patient has had at least two cycles of first-line chemo- or chemo-immunotherapy for aggressive B-cell lymphoma with a CHOP-like regimen with or without rituximab.</li> <li>○ <b>Phase II only:</b> pre-treatment cancer-specific geriatric assessment/Quality of Life questionnaire has been completed.</li> <li>○ <b>Phase I:</b> WHO performance status 0-2. <b>Phase II:</b> WHO performance status 0-2, in case of lymphoma related impaired general condition, WHO performance status 0-3 allowed.</li> <li>○ Age <math>\geq 18</math> years.</li> </ul>

- Adequate hematological, hepatic, renal and cardiac function.
- **Phase II only:** measurable disease defined as at least 1 lesion  $\geq 2$  cm in greatest transverse diameter on cross-sectional imaging.
- Negative HIV test.
- Patient compliance and geographic proximity allow proper staging and follow-up.
- Patients agree to follow the special prescribing requirements of Revlimid® (lenalidomide [28]). Women are not breastfeeding, are using effective contraception (double-barrier method) if sexually active, are not pregnant and agree not to become pregnant during participation in the trial and during the 12 months thereafter. A negative pregnancy test before inclusion into the trial is required for all women <50 years (unless considered unnecessary by the investigator). Men agree not to father a child during participation in the trial and during the 12 months thereafter.

**Exclusion Criteria include the following:**

- Previous malignancy within 5 years with the exception of adequately treated cervical carcinoma in situ or localized non-melanoma skin cancer.
- Immunohistological evidence of bone marrow involvement  $\geq 25$  %.
- Known CNS-involvement (diagnostic procedures required only in case of specific symptoms).
- Unstable cardiovascular disease.
- Psychiatric disorder precluding understanding of information on trial related topics, giving informed consent, or interfering with compliance for oral drug intake.
- Treatment with other experimental drugs within 30 days prior to trial entry.
- 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. acute or ongoing infection, uncontrolled diabetes mellitus, active autoimmune disease).
- Known hypersensitivity to any component of the trial drugs.
- Any concomitant drugs contraindicated for use with the trial drugs according to the Swissmedic-approved product information.