Further treatment possible

according to other protocol

FLOW CHART AND STUDY SCHEDULE

1.1 Flow chart

Diagnosis of chronic lymphocytic leukemia requiring therapy according to NCI criteria ("active disease") with at least one of the following: (1) fludarabine-refractory a (no PR or CR after a fludarabine-based regimen, or progression within six months after a fludarabine-based regimen) or

(2) associated with 17p deletion (treated or untreated) Enrolment (signing of informed consent, approval of inclusion and submission of samples for central diagnostics) Alemtuzumab 30 mg s.c. $3 \times$ weekly for 28 days (Days 1, 3, 5; 8, 10, 12; etc.) + dexamethasone 40 mg p.o. on days 1-4 and 15-18 and prophylactic pegfilgrastim 6 mg on days 1 and 15 PD Staging in Week 4 Within the framework of PR, SD this trial, the term Option "fludarabine-refractory" A or B* is synonymous to a Alemtuzumab + dexamethasone + pegfilgrastim refractory status to any 4-week course as above established purine analogue (i.e. pentostatin, cladribine), and also encompasses bendamustine. PD Staging in Week 8 CR, complete remission PR, SD (including imaging Option techniques and bone A or B* marrow histology) PR, partial remission SD, stable disease Alemtuzumab + dexamethasone + pegfilgrastim PD, progressive disease 4-week course as above (For definitions, see Appendix) PD Option Staging in Week 1 *If and only if A or B* patient is eligible for allogeneic SCT according to protocol (i.e. CLLX2), HLAcompatible donor and informed consent are Alemtuzumab maintenance Option A available. **Mandatory** PD 30 mg s.c. every 14 days Decision: A or B Staging every three months Continued for a maximum of 2 years if no PD Option B* End of study participation.

Consolidation with allogeneic SCT after reduced-intensity conditioning (end

of CLL2O study participation) according to current protocol (e.g. CLLX2)