

# 1. FLWSHEET

## 1.1. Induction Therapy with A-FMC

### Registration with the GCLLSG Central Study Office and Submission of Samples for Central Testing

After completion of the screening procedures a report will be sent to the DCLLSG study office for approval of enrollment

- Cytogenetics: 20-40 ml heparin blood (to Ulm)
- Immunophenotype/ TCL1 signaling: 30 ml EDTA blood (to Cologne)

#### **A-FMC cycle 1-2**

Alemtuzumab 10 mg s.c., days 1-3  
 Fludarabine 20 mg/m<sup>2</sup> i.v., days 1-3  
 Mitoxantrone 6 mg/m<sup>2</sup> i.v., day 1  
 Cyclophosphamide 200 mg/m<sup>2</sup> i.v., days 1-3

#### **Interim staging after 2 cycles A-FMC**

Patients in CR, PR or SD → Cycle 3-4 A-FMC  
 Patients in PD → Off Treatment

#### **ONLY PATIENTS IN CR: A-FMC cycle 3-4**

Alemtuzumab **10 mg s.c.**, days 1-3  
 Fludarabine 20 mg/m<sup>2</sup> i.v., days 1-3  
 Mitoxantrone 6 mg/m<sup>2</sup> i.v., day 1  
 Cyclophosphamide 200 mg/m<sup>2</sup> i.v., days 1-3

#### **ONLY PATIENTS IN PR or SD A-FMC cycle 3-4**

Alemtuzumab **30 mg s.c.**, days 1-3  
 Fludarabine 20 mg/m<sup>2</sup> i.v., days 1-3  
 Mitoxantrone 6 mg/m<sup>2</sup> i.v., day 1  
 Cyclophosphamide 200 mg/m<sup>2</sup> i.v., days 1-3

**Initial Response Assessment 1 month (±7 days) after the beginning of the last cycle**

**Final Staging 2 months after the Initial Response Assessment**

## 1.2. Maintenance Therapy with Alemtuzumab

