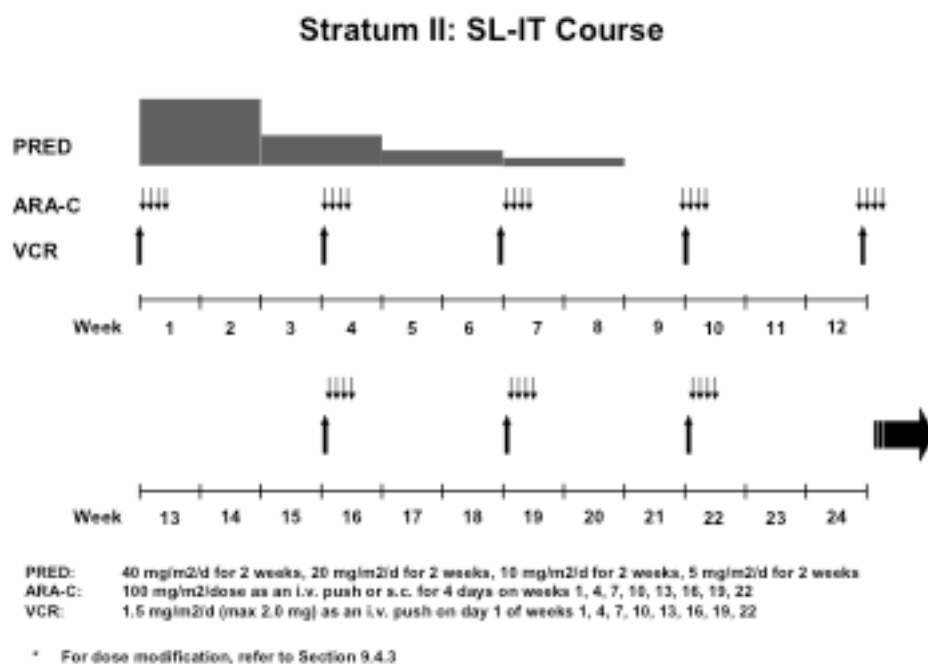


## Second-line Initial Therapy (SL-IT)



- Prednisone (PRED) 40mg/m<sup>2</sup>/d orally in three doses, daily for 2 weeks, tapering over a period of 6 weeks.
- Cytosine-arabinoside (Ara-C) 100mg/m<sup>2</sup>/dose as an i.v. push for 4 days on weeks 1, 4, 7, 10, 13, 16, 19, 22. ***Ara-C can be given subcutaneously without need for dose adjustment.***
- Vincristine (VCR) 1.5mg/m<sup>2</sup>/dose (max. 2.0mg) as an i.v. push on day 1 of weeks 1, 4, 7, 10, 13, 16, 19, 22.

**Response evaluation at week 13:** Treatment discontinuation and switch to another treatment only in case of unequivocal progression (new lesions or unequivocal enlargement of the size of existing lesions). All other patients have to continue the protocol treatment according to Stratum II.

**Response evaluation at week 24:** Patients with NAD and AD Better will be randomized for the continuation treatment. In the case of AD Intermediate (no changes in bone lesions since six months) verification of disease activity has to be performed by functional imaging (PET) and/or biopsy.

In the case of active disease alternative options should be discussed with the National Coordinator.

In case of AD Worse (disease progression or reactivation) at any time after week 13 the patient will be off study and alternative options should be discussed with the National

Coordinator.