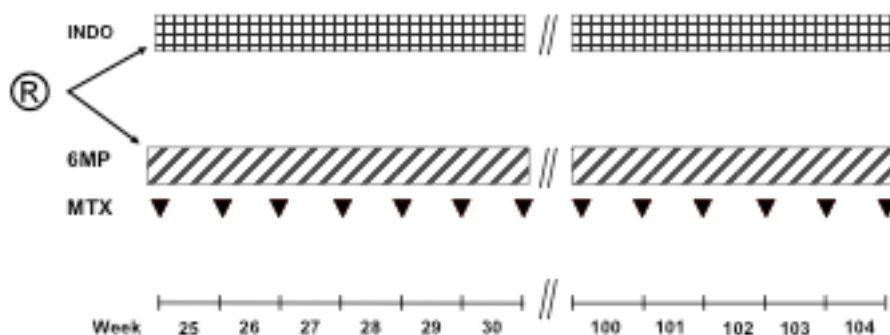


## Second-line Continuation Therapy (SL-CT)

### Stratum II: SL-CT Course



R= Randomization time point, refer to Section 7.7.2

INDO (Indomethacin): 2mg/kg/d daily orally with gastric protection

6-MP (Mercaptopurine): 50mg/m<sup>2</sup>/d daily orally

MTX (Methotrexate): 20mg/m<sup>2</sup>/d weekly orally

\* For dose modification, refer to Section 9.4.3

Patients who after SL-IT (week 24) have a response (NAD or AD better) are eligible for randomization between the continuation arms “INDOMETHACIN” and “6-MP/MTX”.

#### Treatment Arm “INDOMETHACIN”

Indomethacin 2mg/kg/day given daily orally in two divided doses with gastric protection for total treatment duration of 24 months.

#### Treatment Arm “6-MP/MTX”

- 6-mercaptopurine 50mg/m<sup>2</sup>/dose daily orally for total treatment duration of 24 months.
- Methotrexate 20mg/m<sup>2</sup>/dose weekly orally for total treatment duration of 24 months.