

### 3. Synopsis

Title	Efficacy of maintenance therapy with rituximab after induction chemotherapy (R-CHOP vs. R-FC) for elderly patients with mantle cell lymphoma not suitable for stem cell transplantation
Study design	Prospective, multicenter, randomised phase III trial of the <i>European MCL Network</i>
Primary study objectives: - first randomisation - second randomisation:	Reduction of lymphoma mass measured by the CR rate Progression-free survival after end of initial chemotherapy
Secondary study objectives	Overall survival after start/end of initial therapy
Inclusion criteria	<ul style="list-style-type: none"><li>- Patients with histologically confirmed mantle cell lymphoma</li><li>- advanced stages II-IV</li><li>- previously untreated</li><li>- 65 years and older or 60-65 if not eligible for high dose chemotherapy</li></ul>
Treatment	Initial cytoreductive therapy: randomisation between 8 x CHOP-21 + rituximab versus 6 x FC-28 + rituximab  For CR/PR patients second randomisation between 2-monthly rituximab 375 mg/m <sup>2</sup> versus Interferon- $\alpha$ 3x 3M IU or Peg-Intron 1 $\mu$ g/kg weekly until progression
Number of study centres	unlimited; centres can join the ongoing study after authorisation
Number of patients	Max. 570 patients
Duration of recruitment	4-6 years
Planned start	01-1-2004