



## ABSTRACT # 3354

### ACTIVITY OF RITUXIMAB IN EXTRANODAL MARGINAL ZONE LYMPHOMAS (MZL)

Annarita Conconi<sup>1,2</sup>, Catherine Thiéblemont<sup>3</sup>, Giovanni Martinelli<sup>4</sup>, Andrés J. M. Ferreri<sup>5</sup>, Liliana Devizzi<sup>6</sup>, Fedro Peccatori<sup>4</sup>, Maurilio Ponzoni<sup>5</sup>, Virginio Filipazzi<sup>7</sup>, Pierre-Yves Dietrich<sup>8</sup>, Massimo A. Gianni<sup>6</sup>, Bertrand Coiffier<sup>3</sup>, Franco Cavalli<sup>1</sup>, Emanuele Zucca<sup>1</sup> on behalf of the International Extranodal Lymphoma Study Group (IELSG)

<sup>1</sup>Istituto Oncologico della Svizzera Italiana, Bellinzona, Switzerland;

<sup>2</sup>Università "Amedeo Avogadro", Novara, Italy, <sup>3</sup>Centre Hospitalier Lyon Sud, Lyon, France, <sup>4</sup>Istituto Europeo di Oncologia, Milano, Italy; <sup>5</sup>Istituto Scientifico Ospedale San Raffaele, Milano, Italy, <sup>6</sup>Istituto Nazionale per la Cura e lo Studio dei Tumori, Milano, Italy; <sup>7</sup>Ospedale "L. Sacco", Milano, Italy; <sup>8</sup>Hopital Cantonal, Genève, Switzerland.

This phase II study aimed to evaluate tolerability and activity of the monoclonal anti-CD20 antibody rituximab (*Mabthera*®, Roche) in either untreated or relapsed, biopsy-proven extranodal MZL of MALT type with measurable or evaluable disease. Treatment consisted of rituximab 375 mg/m<sup>2</sup> i.v. weekly for 4 weeks; response assessments were planned at 2, 6 and 12 months after treatment start. Between January 2000 and May 2001, when the enrollment was closed, 35 patients (pts), 24 females and 11 males, were registered; 4 of them had been previously treated with anthracycline-containing chemotherapy and 7 with alkylating agents. Median age was 57 years (range 27-85). Fifteen pts had a primary gastric MZL, 2 of them had no evidence of prior *H. pylori* (*HP*) infection, the remaining previously received an anti-*HP* therapy and were *HP* negative with evidence of lymphoma progression at study entry, after a median time of 25 months (range 5-89) from eradication. Twenty pts had a primary non-gastric localisation (7 skin/subcutaneous, 4 lung, 4 salivary gland, 3 orbit, 1 breast and 1 liver) in 6 of these cases multiple mucosal sites were involved. At study entry 12 pts had Ann Arbor stage I, 3 stage II and 20 stage IV disease; lymph node involvement was documented in 13 pts, bone marrow involvement in 9 pts, 2 pts had B-symptoms; LDH was elevated in 3 cases. All pts had ECOG PS =0-1. Thirty four pts completed the treatment program, one pt refused to receive the third and fourth planned doses and was lost to follow-up. At a median follow-up of 11.6 months, the overall response rate was 73% (95%CI: 56%-87%) with 15 CRs and 10 PRs. The median time to best response was 2.2 months (range 1.6-6.3) from the beginning of treatment. Three pts had disease progression immediately after treatment and 3 pts relapsed after CR and 3 after a PR. Toxicity was mild with only two cases of rapidly regressing grade 3 toxicity (bronchospasm and glottis oedema) during the first infusion and 1 case of grade 3 infection (pneumonia); grade 1-2 allergic skin rashes were reported in 3 pts, grade 1 asthenia and myalgias in 2 pts; 2 cases of infusion-related grade 1-2 hypotension and 2 cases of grade 2 fever were documented. These results show promising efficacy of rituximab as single agent in pts with extranodal MZL.