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IELSG PHASE II STUDY OF RITUXIMAB IN MALT LYMPHOMAS: FINAL RESULTS

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This phase II study aimed to evaluate safety and activity of the monoclonal anti-CD20 antibody rituximab in either untreated or relapsed, biopsy-proven MALT lymphomas.

Treatment consisted of rituximab 375 mg/m² i.v. weekly for 4 weeks; restaging procedures were planned at 2, 6 and 12 months after treatment start. Between January 2000 and May 2001 35 patients (pts), 24 females and 11 males, were registered; 11 previously received chemotherapy. Median age was 57 years (range 27-85). Fifteen pts had a primary gastric MALT lymphoma, 2 of them had no evidence of prior H. pylori (HP) infection, the remaining progressed after a median time of 25 months (range 5-89) from eradication of HP. Twenty pts had a primary non-gastric localisation (7 skin/subcutaneous, 4 lung, 4 salivary gland, 3 orbit, 1 breast and 1 liver) in 7 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; bone marrow involvement was documented 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 the third and fourth planned doses and was lost to follow-up. At a median follow-up of 12 months, the overall response rate was 71% (95%CI: 54%-85%) with 15 CRs and 10 PRs. The median time to best response was 2.2 months (range 1.6-6.3) from treatment start.

Three pts had disease progression immediately after treatment, 3 pts relapsed after CR, 2 after a PR. The favorable toxicity profile of rituximab was confirmed with no grade 4 toxicities. Based upon our results, rituximab as significant antineoplastic activity in MALT lymphoma. A randomised clinical trial is planned to test rituximab in combination with chemotherapy.