

AB009. OS02.03. Phase II trial of cetuximab and chemotherapy followed by surgical resection for locally advanced thymoma

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Background: The mainstay of treatment for thymoma is surgery with neoadjuvant chemotherapy recommended to patients with locally advanced disease. EGFR is overexpressed in thymoma. Clinical responses to single-agent cetuximab have been reported in patients with advanced cetuximab. We conducted this two-site prospective phase II trial of cetuximab combined with a standard induction chemotherapy regimen of cisplatin, doxorubicin and cyclophosphamide (PAC) in patients with locally advanced thymoma prior to surgical resection.

Methods: Patients with clinical Masaoka stage III–IVA thymoma were treated with cetuximab (250 mg/m² weekly ×4 weeks) followed by cetuximab (250 mg/m² weekly) combined with cisplatin (50 mg/m²), doxorubicin (50 mg/m²) and cyclophosphamide [(500 mg/m²) 3 weeks ×4 cycles]. Radiographic response was assessed by CT using RECIST 1.1 and FDG-PET using PERCIST. All patients

went on to surgery after completion of induction therapy. The primary endpoint was major pathologic response (MPR, >90% treatment effect). Planned enrollment was 18 patients in first stage of a two stage design. If 1 MPR was observed, then enrollment would expand to 28 patients.

Results: Eighteen patients were enrolled: 8 women, median age 53 (range, 32–73) years. WHO Histologic subtype A: 2, AB: 3, B1: 3, B2: 7, B3: 3. Final Masaoka stage I: 2, II: 2, III: 5, IVA: 9. There were no responses to cetuximab alone by RECIST criteria, although 1 patient had a 25% reduction in indicator lesions. Response rate (CR + PR), in evaluable patients after complete treatment course was 50% (8/16, 95% CI: 28–72%). Partial responses by PERCIST criteria were seen on PET in 11/18 (61%) evaluable patients. There were no MPRs. R0 resection was obtained in 7 patients; 5 had R1 and 6 had R2 resections.

Conclusions: The addition of cetuximab to PAC chemotherapy did not lead to pathologic complete responses in the neoadjuvant setting. Cetuximab alone appears to have little effect during 4 weeks of treatment. There was no apparent increase in radiographic response rate with the addition of cetuximab to PAC chemotherapy compared to historical series.

Keywords: Chemotherapy; cetuximab; thymoma

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