

THORACIC MALIGNANCIES, OTHER

disease progression. The primary endpoint was overall survival (OS). This single arm study assumed historical control with a median survival of 12.1 months (Vogelzang et al. 2003). The sample size provided 80% power with a two-sided alpha of 0.05 to detect an increase in median OS of 5.5 months.

Results: All patients had a minimum follow up of 12 months. Median age was 67 (range 27–78), 84% were male and 56% smokers. 16% (13 patients) had metastatic disease and 44% (35 patients) had an ECOG PS of 1. 66% (53 patients) had epithelioid histology. Compliance with TTFields was 68% (16.3 hours/day) during the first 3 months of therapy. Median OS was 18.2 months (95% CI 12.1–25.8) compared to 12.1 months in historical controls. Median PFS was 7.6 months (95% CI 6.7–8.6) compared to 5.7 months in historical controls. Partial responses were seen in 40.3% of patients and clinical benefit (PR+SD) was seen in 97.2% of patients. No device-related serious adverse events (AEs) were reported. Expected TTFields-related dermatitis was reported in 46% (37 patients). Only 4 patients (5%) had grade 3 dermatitis.

Conclusions: The study met its primary endpoint of significant extension of survival for previously untreated mesothelioma patients. Secondary efficacy endpoints were also improved compared to historical control. The study demonstrated no safety concerns for the combination of TTFields to the thorax with chemotherapy. These results support the addition of TTFields to chemotherapy in the first-line treatment of malignant pleural mesothelioma.

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1807P **STELLAR: Final results of a phase II trial of TTFields with chemotherapy for first-line treatment of pleural mesothelioma**

F. Grosso¹, J.G. Aerts², J. Madrzak³, R. Dziadziuszko³, R. Ramlau⁴, S. Cedres⁵, B. Hiddinga⁶, J.P. van Meerbeeck⁶, M. Mencoboni⁷, D. Planchard⁸, A. Chella⁹, L. Crino¹⁰, M.J. Krzakowski¹¹, G.L. Ceresoli¹²

¹Oncology, SS Antonio e Biagio Hospital, Department of Oncology, Alessandria, Italy, ²Oncology, Erasmus University Medical Center, Rotterdam, Netherlands, ³Oncology, Medical University of Gdansk Clinical Hospital, Gdansk, Poland, ⁴Oncology, Medical University of Poznan, Poznan, Poland, ⁵Oncology, Vall d'Hebron University Hospital, Barcelona, Spain, ⁶Oncology, Antwerp University Hospital, Antwerp, Belgium, ⁷Oncology, Ospedale Villa Scassi, Genoa, Italy, ⁸Oncology, Institut Gustave Roussy, Villejuif, France, ⁹Oncology, Cisanello University Hospital Pisa, Pisa, Italy, ¹⁰Oncology, Ospedale S. Maria della Misericordia, Perugia, Italy, ¹¹Department of Lung & Thoracic Tumours, The Maria Skłodowska-Curie Memorial Institute and Oncology Centre, Warsaw, Poland, ¹²Oncology, Humanitas Gavazzeni, Bergamo, Italy

Background: Tumor Treating Fields (TTFields) are an anti-mitotic, regional treatment modality, using low intensity alternating electric fields delivered non-invasively to the tumor using a portable, medical device. In vitro, human mesothelioma cells were highly susceptible to TTFields. TTFields have been shown to extend survival of patients with glioblastoma when added to chemotherapy.

Methods: The trial accrued 80 patients with unresectable, untreated mesothelioma. Patients were treated with continuous 150 kHz TTFields in combination with pemetrexed and platinum. Inclusion criteria included ECOG 0–1 and at least one measurable lesion according to modified RECIST. Patients were followed q3w (CT scan q6w) until