TAXOGEM

Final results of a FNCLCC French Sarcoma Group multicenter randomized phase II study of Gemcitabine (G) versus Gemcitabine and Docetaxel (G+D) in patients with metastatic or relapsed leiomyosarcoma

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ABSTRACT #10516

Background

Docetaxel (D) and Gemcitabine (G) have demonstrated activity in metastatic soft tissue sarcomas (STS). We have previously reported a 5% response (RR) in 41 patients treated with G+D. This multicenter phase II study compared the combination in STMs with metastasis or relapse after primary therapy (metastatic or recurrent STMs) in patients with one or more prior anthracycline-based regimens.

Methods

Eligible patients had histologically proven metastatic or unresectable LMS, at least one prior anthracycline-based regimen, and measurable disease. Patients were randomly assigned to receive either G or D in combination with G+D. Treatment was administered every 2 cycles. Stratification was by primary tumor location (uterus vs. extra-uterus).

Results

44 patients were enrolled in the "non-uterus" study, 40 patients in the "uterus" study. The median number of cycles was 5 (range 0-8) and dose received/dose planned was 96% (range 78-110%); 8 cycles were planned. In the "non-uterus" study, 25 patients were evaluable and 19 (76%) had an objective response (OR) with a response rate (RR) of 13% (95% CI 4%-25%) and a progression-free survival (PFS) of 5.6 months. In the "uterus" study, 25 patients were evaluable and 12 (48%) had an objective response (OR) with a response rate (RR) of 20% (95% CI 9%-37%) and a progression-free survival (PFS) of 6.7 months.

Conclusion

G+D failed to demonstrate any advantage (OR, PFS) compared to G, but the combination may be active and warrants further investigation. A phase III randomized study is currently ongoing.

INTRODUCTION - RATIONAL

STS are a group of heterogeneous malignancies. Although chemotherapy has improved survival, its impact is still limited. Due to the high toxicity of first-line regimens, second-line chemotherapy (or taxanes) may be warranted.

METHODS

Patients with measurable disease following first-line chemotherapy were randomized to receive G or G+D. Treatment was administered every 2 cycles. Stratification was by primary tumor location (uterus vs. extra-uterus).

RESULTS

44 patients were enrolled in the "non-uterus" study, 40 patients in the "uterus" study. The median number of cycles was 5 (range 0-8) and dose received/dose planned was 96% (range 78-110%); 8 cycles were planned. In the "non-uterus" study, 25 patients were evaluable and 19 (76%) had an objective response (OR) with a response rate (RR) of 13% (95% CI 4%-25%) and a progression-free survival (PFS) of 5.6 months. In the "uterus" study, 25 patients were evaluable and 12 (48%) had an objective response (OR) with a response rate (RR) of 20% (95% CI 9%-37%) and a progression-free survival (PFS) of 6.7 months.

CONCLUSION

G+D failed to demonstrate any advantage (OR, PFS) compared to G, but the combination may be active and warrants further investigation. A phase III randomized study is currently ongoing.

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REFERENCES

3. ASCO 2009.