

## **SOFT TISSUE SARCOMAS: combined therapy with doxorubicin-trabectedin shown to have a role as first-line treatment of leiomyosarcomas**

**A phase-II study conducted by Gustave Roussy and the French Sarcoma Group examined the efficacy of combination chemotherapy with doxorubicin and trabectedin as first-line treatment of locally advanced or metastatic leiomyosarcomas (uterine and soft tissue). Overall survival figures after seven years of follow-up, to be presented at the 2020 ASCO Conference, show this dual therapy to be promising for treatment of patients with these tumors.**

Soft tissue sarcomas arise from muscle and connective tissue cells. These cancers are rare in adults and constitute a very heterogeneous group composed of a number of histological subtypes. One of them is the broad subgroup of leiomyosarcomas (LMS), which arise from soft muscle tissue. One third of these tumors are uterine. Leiomyosarcomas have a poor prognosis when metastatic regardless of the site.

As no specific molecular target has yet been identified, they are not amenable to targeted therapy. At present therapeutic options are limited: *“For the great majority of all types of soft tissue sarcomas, standard treatment is doxorubicin alone. When this fails, trabectedin, is one of the most active agent in this histologic subtype, explaining why we propose to combine with doxorubicin in first line treatment”* explained Dr. Patricia Pautier, Gustave Roussy’s oncologist and principal investigator for the phase-II study conducted by the French Sarcoma Group. In this trial, a new approach was tested: to evaluate dual chemotherapy administered from the outset in the leiomyosarcoma histological subgroup with patients stratified between LMS of the uterus (U-LMS) and LMS arising from other soft tissues (ST-LMS). *“Up to that point, all the combinations that had been tested, regrouping anthracyclines with ifosfamide or targeted therapies, had yielded negative results. It increases the response rates, but not patient overall survival,”* emphasized Dr. Patricia Pautier.

Oral presentation  
by Dr. Patricia Pautier

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N° 11506

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**Combining two  
chemotherapies from  
the outset results in a  
median progression-  
free survival value of  
10.1 months and median  
overall survival of  
34.4 month.**

The phase-II clinical trial, the findings of which are to be presented at a virtual oral session of the ASCO 2020 meeting, was not a comparative one. The doxorubicin-trabectedin combination was administered as first-line treatment to patients with metastatic leiomyosarcoma. The overall median survival was 34.4 months (27.5 months in the U-LMS group and 38.7 months in the ST-LMS group), a better result than that usually reported with doxorubicin alone or in other combinations. These seven-year follow-up results confirm the promising findings from this study published in *The Lancet Oncology* in 2015. The trial, started in 2013 and conducted in 20 sites, assessed the benefits of this new approach in 107 patients (45 U-LMS and 62 ST-LMS), all of these leiomyosarcoma patients having local inoperable relapse or metastatic disease. To be enrolled in the trial, they had to be chemotherapy-free. All of them then received intravenous combined therapy at the doses recommended on completion of the phase-I study (60 mg/m<sup>2</sup> of doxorubicin followed by 1.1 mg/m<sup>2</sup> of trabectedin over 3 hours), for a minimum of six cycles. Surgery was allowed after the 6 cycles if complete resection of the tumour or of metastases was possible.

***“The initial results of this phase-II study had established that this new combined therapy produced a level of disease control (level of response to treatment + stabilization of disease) of around 90% in both situations (87.2% for U-LMS, and 91.8% for ST-LMS),”*** pointed out Dr. Pautier. In addition, the treatment enabled a quarter of the patients of both groups to undergo surgery, thus increasing the chances of a longer survival.

The research teams from Gustave Roussy and the French Sarcoma Group (GSF) are continuing work to compare progression-free survival in patients receiving conventional first-line chemotherapy (doxorubicin alone) versus dual therapy. The results of this phase-III study are expected this year.



**A quarter of the patients  
were able to undergo  
surgery after dual  
chemotherapy.**

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**PRESS CONTACT**

**GUSTAVE ROUSSY**

**Media relations**

**CLAIRE PARISEL**

Tel. 33 (0)1 42 11 50 59 – 33 (0)6 17 66 00 26

[claire.parisel@gustaveroussy.fr](mailto:claire.parisel@gustaveroussy.fr)



[www.gustaveroussy.fr/en](http://www.gustaveroussy.fr/en)

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