

Sylvester Part of International Study on Promising New Renal Cell Carcinoma Treatment

Sylvester Comprehensive Cancer at the University of Miami Miller School of Medicine played a significant role in a study released simultaneously on February 13 in [The New England Journal of Medicine](#) and the 2021 Genitourinary Cancers Symposium.

Jaime Merchán, M.D., is one of the co-authors and the principal investigator at Sylvester for the CLEAR Trial, a multicenter, open-label, phase 3 study comparing lenvatinib and pembrolizumab, lenvatinib and everolimus, or sunitinib in patients with advanced renal cell carcinoma (RCC).



Dr. Jaime Merchán

“We were the third major accruer in the U.S. for this important trial, whose positive results bring new hope for thousands of patients suffering from advanced RCC, an aggressive malignancy associated with a poor prognosis when untreated,” said Dr. Merchán.

The study enrolled more than 1,000 patients with previously untreated, advanced RCC from 200 sites and 20 countries around the world. They were randomly assigned to one of the three arms. Findings demonstrated that pembrolizumab and lenvatinib were superior to sunitinib. This combination was associated with a significantly higher overall response rate (71%), a promising complete response rate (approximately 16% of patients), and importantly, a significant improvement in progression-free survival and overall survival. Side effects were manageable and consistent with the known safety profile

of each agent.

“The findings from this important study are significant, because this novel combination proved to be well tolerated and effective at improving outcomes in patients with this devastating disease,” said Dr. Merchán, director of Sylvester’s Phase 1 Clinical Trials Program who specializes in genitourinary cancers. “While we cannot compare results from different, independent studies, looking at the response rates and outcomes from this study, this combination seems to be associated with higher efficacy rates than existing treatment combinations. The results from this study suggest that the combination of pembrolizumab and lenvatinib is a feasible, effective option for metastatic RCC.”

Dr. Merchán points out that in the last six years, new treatments have been approved for metastatic RCC that improve the outlook for this disease, but cures are uncommon.

“While the results of this study represent a step forward in the treatment of this type of cancer, further research is urgently needed to develop newer, better and safer therapies for advanced renal cell carcinoma,” he said.

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