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HEMATOLOGICAL CANCER

## A NEW OPTION FOR PATIENTS WITH PTCL

For patients diagnosed with peripheral T-cell lymphoma (PTCL) the outlook has looked grim. There are no agents currently approved to treat patients in the first-line setting, and until recently that was also the case for patients who relapsed. Now, there are two options for these relapsed patients, the histone deacetylase (HDAC) inhibitor romidepsin and the antifolate pralatrexate. Following the approval of romidepsin in 2011, the full details of the clinical trial data have been published this year by a team led by Bertrand Coiffier.

Based on previous work undertaken at the National Cancer Institute, Coiffier pointed out that "romidepsin seemed promising compared to what existed for relapsing patients with PTCL 5 years ago." Therefore, the researchers initiated an open-label, single-arm, phase II clinical trial in 131 patients with relapsed PTCL who had received any number of previous therapies. This trial design was decided on because there was no standard therapy to use as a comparator.

Coiffier describes the importance of this study: "this was one of the largest studies with an HDAC inhibitor and the results prove that this class of drugs has activity in cancer patients and that it merits further development." The results of the trial were impressive; 25% of patients achieved an objective response, with 15% defined as complete responses. Importantly, "responses were observed quickly, during the first 2 months, and patients with complete response have a long duration of response, most of them being still in complete response at the time of publication," says Coiffier.

The trial population included patients with the most frequently occurring PTCL subtypes, and responses were observed in patients from each group. This finding did not extend to the most-rare forms of the disease, but this could be because the patient population was not large enough to demonstrate efficacy in these cases.

The approval of romidepsin and pralatrexate now opens the doors to investigation of combinations of agents in these patients, with the aim of improving the efficacy of the therapy. Indeed, studies of this type are underway and have already reported some promising results.

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**Original article** Coiffier, B. *et al*. Results from a pivotal, open-label, phase II study of romidepsin in relapsed or refractory peripheral T-cell lymphoma after prior systemic therapy. *J. Clin. Oncol.* doi:10.1200/JCO.2011.37.4223