

Pazopanib shows promise in Phase II trial for relapsed/refractory urothelial cancer

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An ongoing Phase-II trial investigating a new, targeted therapy for metastatic urothelial cancer has generated promising early results, Italian researchers reported at the 35th Congress of the European Society for Medical Oncology (ESMO) in Milan, Italy.

Urothelial cancers affect the tissue lining the inner surfaces of the bladder and other parts of the urinary system. In cases of metastatic disease, median survival is approximately 12-15 months and there is a 10-15% chance of prolonging it by the use of standard chemotherapy regimens, particularly in otherwise healthy patients with good prognostic factors.

Those whose cancers relapse or do not respond to upfront therapy currently have few second-line treatment options and palliative care is the option in the majority of cases.

Dr Andrea Necchi from Fondazione IRCCS Istituto Nazionale dei Tumori of Milan and colleagues have begun a Phase-II trial using pazopanib in this setting. Pazopanib is a selective inhibitor of several signaling pathways that contribute to [tumor growth](#) and the development of new cancer-related blood vessels (angiogenesis).

So far, the researchers have enrolled 18 patients of a total of 41 planned. Each participant had metastatic urothelial cancer that had already failed to respond to at least one prior chemotherapy regimen. This means that investigators treated many patients who had already failed more than two

chemotherapy regimens. Patients were administered 800mg of the drug once daily until their disease progressed or they experienced unacceptable toxicity.

"Thus far, four patients have seen their tumors shrink but, much more interestingly, the great majority of the patients --twelve out of eighteen-- saw their metastases begin to die," Dr Necchi said.

The death of these metastatic tumors, described formally as 'necrotic evolution', was observed by the researchers on monthly computed tomography and positron [emission tomography](#) scans.

"Considering this drug partly acts to prevent tumors recruiting the blood supplies they need to live and grow, necrotic evolution of [metastases](#) is not completely surprising," Dr Necchi said. "But this is the first time we have seen this phenomenon in so many cases of urothelial cancer. The challenge is to translate this kind of activity into a survival advantage."

"Of course we are only at the first step of this Phase-II trial and caution is needed when interpreting results," Dr Necchi said. "A longer follow-up time and greater sample size are needed before we can declare the study a success. However, for the first time in this disease we are generating interest among investigators and, particularly, of pharmaceutical industry."

The current trial is independent of the pharmaceutical industry, Dr Necchi noted. The sponsor is Fondazione IRCCS Istituto Nazionale dei Tumori of Milan. "The study shows that it is possible in Europe to promote independent research that focuses attention on challenging problematic matters, such as salvage therapy in urothelial cancer."

"These preliminary results underline the value of angiogenesis as a target in bladder cancer," commented Dr Joaquim Bellmunt, Section Chief,

Solid Tumor Oncology at Hospital del Mar in Barcelona, Spain. "They add to results other groups have published recently using similar drugs to treat bladder cancer."

Provided by European Society for Medical Oncology

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