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Investigational immunotherapy safe, tolerable, shows activity against melanoma

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The investigational immunotherapeutic IMC-20D7S was safe, well tolerated, and showed signs of modest clinical activity for patients with advanced melanoma, according to results from a first-in-human phase I clinical trial published in *Clinical Cancer Research*, a journal of the American Association for Cancer Research.

"Even though immunotherapy has significantly improved outcomes for some patients with advanced melanoma, many patients have tumors that do not respond to currently available treatments or have tumors that initially respond but then become resistant to them," said Jedd D. Wolchok, MD, PhD, the Lloyd J. Old/Virginia and Daniel K. Ludwig Chair in Clinical Investigation and chief of the Melanoma and Immunotherapeutics Service at Memorial Sloan Kettering Cancer Center (MSK) in New York. "In this study, we evaluated the safety and early clinical activity of a new antimelanoma immunotherapy.

"We were pleased to see that IMC-20D7S was safe and none of the patients had high-grade serious adverse events related to treatment," continued Wolchok, who is also director of the Parker Institute for Cancer Immunotherapy and associate director of the Ludwig Center for Cancer Immunotherapy at MSK. "Given that IMC-20D7S monotherapy resulted in only modest clinical activity for patients, I would anticipate that future studies will focus on evaluating agents such as this in combination with other treatments."

Wolchok explained that IMC-20D7S is a therapeutic antibody that

attaches to a molecule in melanoma cells called TYRP1. After attaching to the melanoma cells it recruits cells of the immune system to the area, and these cells then attack the melanoma cells.

Wolchok, Danny N. Khalil, MD, PhD, a medical oncology fellow working in Wolchok's laboratory, and colleagues enrolled 27 patients ages 44–84 with advanced melanoma in the clinical trial. All the patients had unresectable stage 3 or stage 4 disease that had progressed after or during prior treatment.

The study was designed to test escalating doses of IMC-20D7S in two different dosing schedules, an every-two-week schedule and an every-three-week schedule.

No patients had treatment-related adverse events classed as grade 3 or greater and there were no dose-limiting toxicities. Fourteen patients had low-grade treatment-related adverse events, most commonly fatigue and constipation. As a result, the maximum tolerated dose was not determined.

The disease-control rate, defined as stable disease or better, was 41 percent. One patient had a complete response, as assessed by RECIST1.1 criteria, which lasted almost six months. Ten patients had stable disease as the best response.

"The patients enrolled in this trial were all heavily pretreated; as a result, their immune systems may not have been sufficiently robust to be reinvigorated by IMC-20D7S," said Wolchok. "We hope that we can increase the clinical activity of IMC-20D7S by using it in combination with other treatments or by using it as a tool to deliver chemotherapeutics or radioactive particles to the melanoma cells."