# Researcher leads first in-human multiple myeloma study with over 90% response rate

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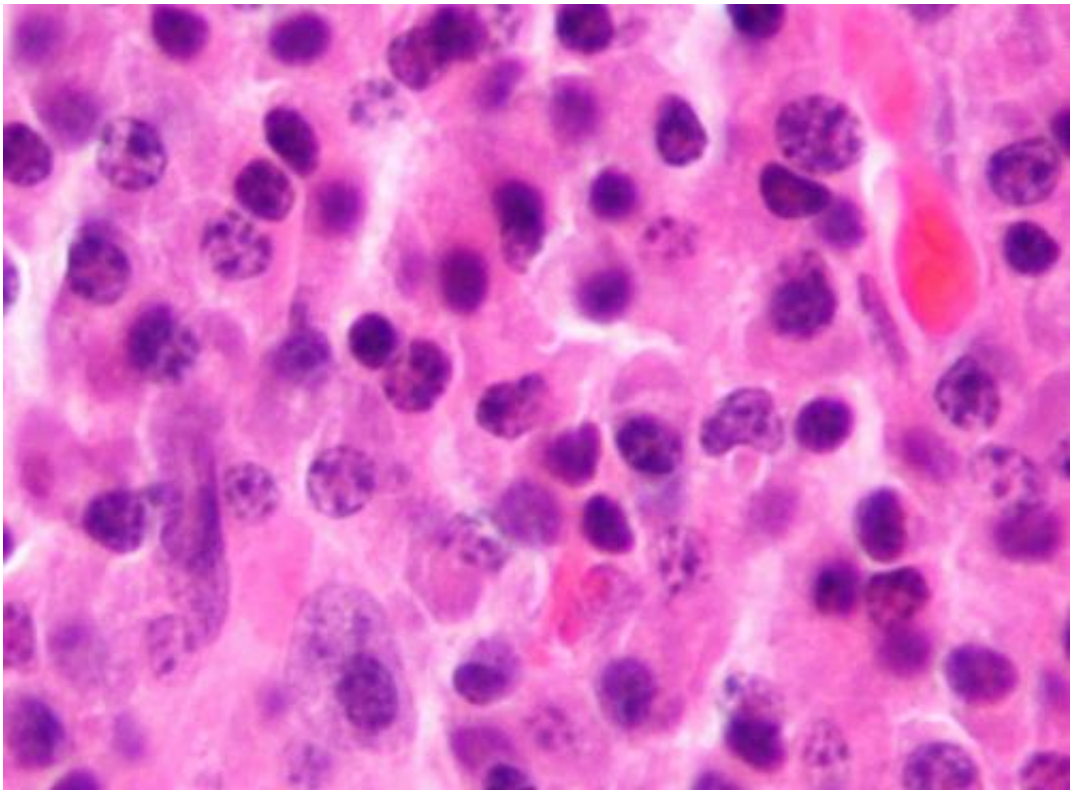

Micrograph of a plasmacytoma, the histologic correlate of multiple myeloma. H&E stain. Credit: Wikipedia/CC BY-SA 3.0

Indiana University Melvin and Bren Simon Comprehensive Cancer Center served as the lead site for a promising first-in-human clinical trial for patients with relapsed multiple myeloma. Patients treated with higher doses of the immunotherapy called REGN5459 resulted in a 90.5%

overall response rate.

IU Simon Comprehensive Cancer Center physician-scientist Attaya Suvannasankha, MD, will present the findings on April 17 at the American Association for Cancer Research (AACR) 2023 Annual Meeting in Orlando. The study was selected for the AACR press program, chosen from the nearly 6,300 research abstracts that are part of the meeting, which brings together the best minds in cancer research from around the world.

In the Phase I and Phase II clinical trial, Suvannasankha and colleagues enrolled 43 patients with multiple myeloma who had stopped responding to treatment or relapsed after three or more lines of therapy. During the Phase I portion of the study, patients received doses of REGN5459 ranging from 3 mg to 900 mg. A 480 mg dose was chosen for the Phase II portion of the study. While the overall response rate in the study was 65.1%, those who received the higher doses (480 mg and 900 mg) achieved a 90.5% response rate.

The study is ongoing, and at the time of the analysis, patients in the trial had been followed for an average of nine months, and 78% of responding patients were projected to remain in remission at the one-year mark. The treatment is reasonably tolerated with common side effects, including cytokine release syndrome, cough, diarrhea, fatigue, a decline in blood counts and infections.

"Multiple myeloma is still incurable, and the majority of patients will eventually succumb to the cancer that keeps relapsing and no longer responds to treatment, particularly in the group that has already exhausted other meaningful therapy," said Suvannasankha, an associate professor of clinical medicine in the Division of Hematology and Oncology at Indiana University School of Medicine.

"In this very difficult-to-treat group of patients where remaining choices are so limited and average survival may be as short as six to nine months, to say that remission may continue at one year at such a high rate is pretty phenomenal," she added.

The study used a bi-specific antibody immunotherapy called REGN5459. The antibody attacks cancer cells with two grabbing arms—one that grabs onto a protein called BCMA on myeloma cells and the other grabs onto a protein called CD3 on T cells (a type of immune cell) to force those cells to kill off cancer cells.

"What's unique about this molecule is that it grabs onto the T cells lightly compared to other agents. The purpose for this is to try and stimulate the T cells but slow down the inflammation that this immune reaction may cause," Suvannasankha explained.

This type of immunotherapy can cause a life-threatening side effect called cytokine release syndrome (CRS) that can cause systemic inflammation, including fever and other symptoms. Data suggest that the design of REGN5459 might reduce CRS, and 93% of patients in the study either experienced no CRS or Grade 1 (mild reactions, such as a fever) cases of CRS.

Suvannasankha is part of the multiple myeloma research group at the IU Simon Comprehensive Cancer Center, which includes more than a dozen experts in the rare blood cancer. In addition to clinical trials such as this one and the Indiana Myeloma Registry, the cancer center's robust laboratory research works to understand the complicated biology of myeloma better.

"We are committed to providing novel treatments to our patients with myeloma who deserve better treatment choices, to live longer and it is our aspiration to hopefully contribute to finding a cure for this disease,"

she said. "Clinical trials like this one not only can provide direct benefit to patients, but also, we learn from every patient being treated on the clinical trial; and it helps us to be even better. We are so incredibly grateful to our patients who put their trust in us."

Additional sites for this study were Mayo Clinic Comprehensive Cancer Center, University of Michigan Rogel Cancer Center, Icahn School of Medicine at Mount Sinai, Medical College of Wisconsin, Simmons Comprehensive Cancer Center at UT Southwestern Medical Center and The University of Texas MD Anderson Cancer Center.

Provided by Indiana University School of Medicine

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