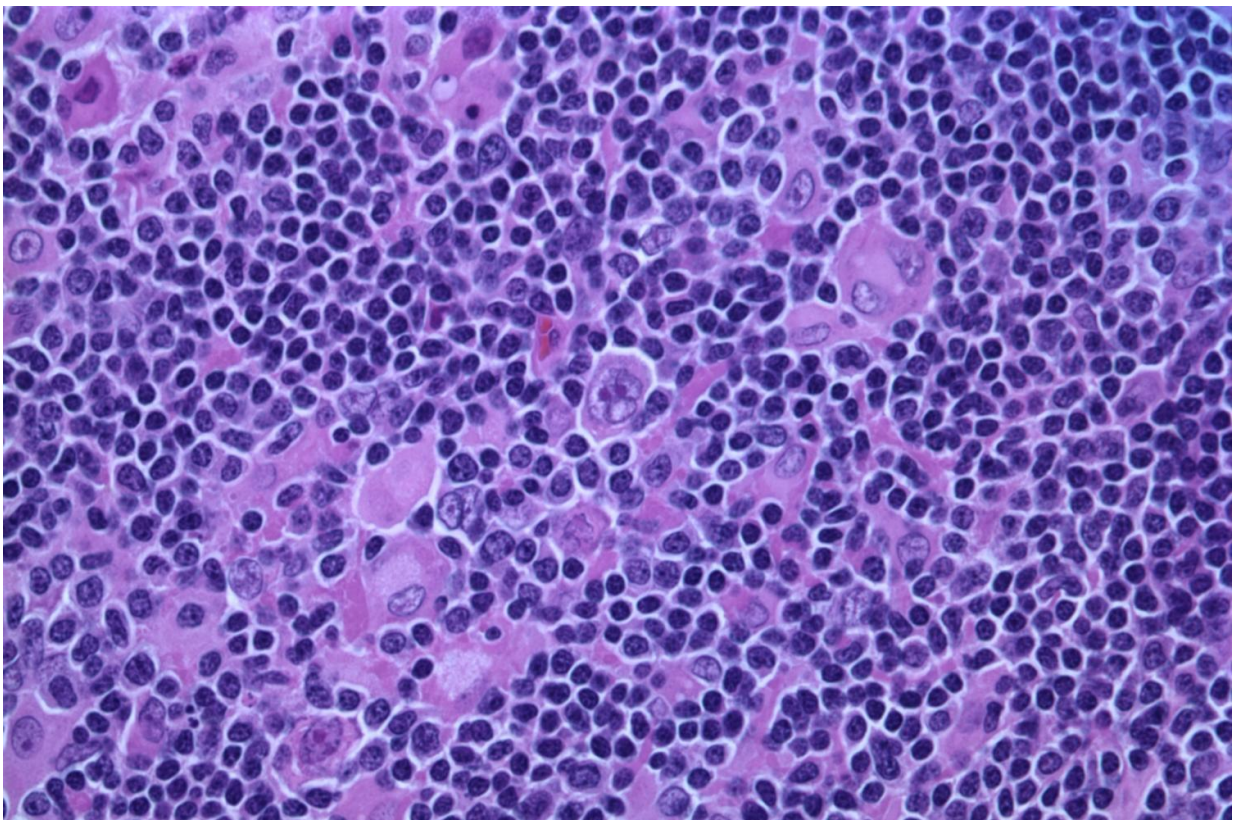
NK cells combined with bispecific antibody showed strong response for patients with lymphoma

April 10 2022



Hodgkin lymphoma, nodular lymphocyte predominant (high-power view) Credit: Gabriel Caponetti, MD./Wikipedia/CC BY-SA 3.0

Researchers from The University of Texas MD Anderson Cancer Center

showed that natural killer (NK) cells derived from donated umbilical cord blood, combined with a novel bispecific antibody known as AFM13 that targets CD16A and CD30, achieved effective responses in patients with pretreated and refractory CD30+ lymphoma. The study was presented today at the American Association for Cancer Research (AACR) Annual Meeting 2022.

There was an 89% overall response rate (ORR) in 19 patients, including 10 complete responses (CR). The progression free survival and overall survival rates across all three dose levels were 53% and 79%, respectively, after a median follow-up of 11 months and lead-in follow-up of 19 months. Expansion of NK cells occurred immediately after infusion and persisted for two weeks.

Dose level three (10^8 NK/Kg) was established as the recommend Phase II dose (RP2D). All 13 patients treated at this dose level had a response to therapy (100% ORR), including eight CR (62%).

"Patients with relapsed CD30+ lymphoma can sometimes be successfully treated with current regimens, but, if those treatments fail, the tumors develop treatment resistance and patients are left with few effective therapeutic options," said study presenter Yago Nieto, M.D., Ph.D., professor of Stem Cell Transplantation and Cellular Therapy and principal investigator on the trial. "Our preliminary results indicate promising activity and tolerability in this heavily pretreated patient population and warrant further investigation of this approach."

NK cells are a type of white blood cells that monitor the body for virus-infected and cancerous cells. The technology to isolate and expand NK cells from umbilical cord blood was developed at MD Anderson.

Affimed's AFM13 is a proprietary bispecific antibody designed to bind to CD16A on NK cells and CD30 on lymphoma cells, allowing NK cells

to eliminate cancer cells. Before infusion, the NK cells are activated with cytokines, expanded in the presence of artificial antigen-presenting cells, and finally complexed with AFM13. This combination approach was developed in the laboratory of Katy Rezvani, M.D., Ph.D., professor of Stem Cell Transplantation and Cellular Therapy. Affimed and MD Anderson are advancing the clinical development of AFM13 through a strategic collaboration agreement.

This single-center Phase I/II trial has enrolled 22 patients with relapsed or refractory CD30+ lymphoma. Most trial participants had been diagnosed with Hodgkin lymphoma and had received a median of seven prior lines of therapy. All patients had active progressive disease at enrollment and no bridging therapy was given. Patients were enrolled at three dose levels, and 19 patients completed both planned cycles. The racial breakdown of participants was 15 White (68.2%), 3 Hispanic (13.6%), 3 Middle Eastern (13.6%) and 1 Black (4.5%), with a median age of 37.

The treatment was well tolerated, with minimal side effects beyond the expected myelosuppression from the preceding lymphodepleting chemotherapy. There were no cases of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome or graft versus host disease. There were six infusion-related reactions in 110 infusions of AFM13 alone and no reactions to the AFM13-loaded NK cells.

Six patients received a stem cell transplant after a response to this treatment, which limits the evaluation of duration of responses.

"This data suggests that this new therapeutic option, either used as a bridge to stem cell transplantation or perhaps even as a curative treatment, offers an effective treatment option for patients with CD30+ lymphoma," Nieto said. "We are excited about these findings and the possibility of bringing this treatment to this patient population with a

large unmet need."

The trial was originally designed with short follow-up. To assess durability beyond two cycles, an amendment has been approved by the Food and Drug Administration to increase the length of treatment from two to four cycles, enabling longer follow up of patients.

More information: CT003—Innate cell engager (ICE) AFM13 combined with preactivated and expanded cord blood (CB)-derived NK cells for patients with refractory/relapsed CD30+ lymphoma, www.abstractsonline.com/pp8/#! … 7/presentation/20145

Provided by University of Texas M. D. Anderson Cancer Center

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