Trilaciclib Improves Chemo's Effectiveness Against Small Cell Lung Cancer, Study Finds

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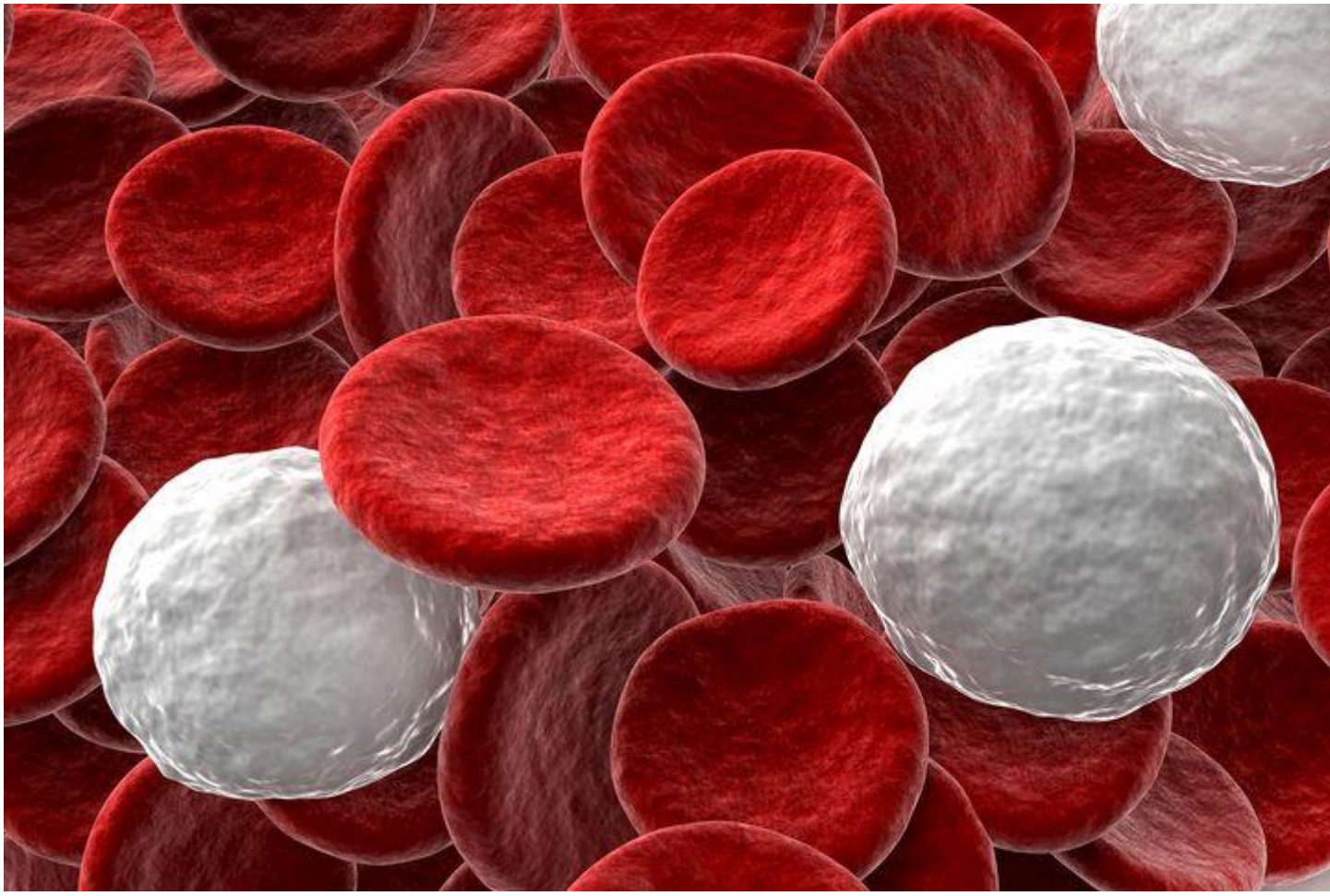

Adding the CDK4/6 inhibitor trilaciclib to chemotherapy can generate significant benefits for patients with advanced small cell lung cancer (SCLC), according to a Phase 1b/2a clinical trial.

Trilaciclib preserved blood stem cells and immune system function during chemotherapy, reduced chemo side effects, and improved patients' outcomes, the researchers said.

The therapy's developer, G1 Therapeutics, collaborated with several U.S. cancer centers on the trial (NCT02499770).

The researchers will present their findings at the American Society of Clinical Oncology's annual meeting in Chicago, June 2-6. The poster-session presentation is titled "Trilaciclib (G1T28): A cyclin dependent kinase 4/6 inhibitor, in combination with etoposide and carboplatin (EP) for extensive stage small cell lung cancer (ES-SCLC)—Phase 1b results."

While chemotherapy offers significant benefits to SCLC patients, it damages the immune system and both blood stem cells and the progenitor cells that produce blood cells. This not only reduces the immune system's ability to work with the chemotherapy to eliminate tumor cells, but it also makes patients more susceptible to infection.

Researchers wondered if using trilaciclib to increase chemotherapy's punch against tumors, while minimizing immunosuppression, could improve patient outcomes.

Chemotherapy affects rapidly proliferating cells. Researchers believed that using trilaciclib to stop blood stem cells from dividing could prevent chemotherapy from killing them.

Trilaciclib inhibits the CDK4/6 proteins that blood stem cells need to proliferate. Preclinical-trial studies have shown that it makes the cells resistant to chemotherapy-related toxicity.

Researchers gave advanced-stage SCLC patients trilaciclib before one of two chemotherapies — etoposide, marketed under the brand name Ethopophos and other labels, or Paraplatin (carboplatin).

The Phase 1b part of the trial was an open-label, dose-identifying segment. It covered 19 newly diagnosed SCLC patients with normal organ function. The patients' cancer had not spread to their brain, and they had not received chemotherapy.

Researchers gave 1o of the patients 200 mg/m2 of trilaciclib plus chemotherapy, and the other nine 240 mg/m2 of trilaciclib plus chemotherapy. The combo

treatment was well-tolerated. Three patients experienced dose-limiting toxicity, and one thrombocytopenia, or low blood platelet count.

The team was able to evaluate 17 of the 19 patients. One of the 17 achieved a complete response after chemotherapy, 14 had partial responses, and one patient's disease became stable. This translated to an overall response rate of 88% and a clinical benefit rate of 94%. A clinical benefit rate is the percentage of patients who receive some benefit from a treatment.

The combo regimen was well tolerated, the researchers wrote. "Early activity results are promising, with a confirmed objective response rate of 88%," they added. "This novel approach allowing the administration of chemotherapy while preserving HSPC [blood stem cells and progenitor cells] and immune system function could potentially improve treatment outcomes for SCLC patients."

Patients are now being enrolled in the Phase 2a part of the trial. It will randomize patients to receive either trilaciclib or placebo before chemotherapy.