

Triple drug treatment combo shows promise in adult leukemia

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A triple-drug targeted therapy approach could offer an effective new treatment option for chronic lymphocytic leukemia (CLL) that reduces the risk for the long-term side effects experienced with chemotherapy and is given for a limited time, not as a daily lifetime drug therapy.

Led by Kerry Rogers, MD, researchers at The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC – James) conducted a phase IB/II clinical trial combining the two most effective targeted drug agents available for CLL (ibrutinib, pronounced "eye BROO ti nib"and marketed as IMBRUVICA, and venetoclax, pronounced "ven ET oh klax" and marketed as Venclexta) with a monoclonal antibody drug (obinutuzumab, pronounced "OH bi nue TOOZ ue mab"and marketed as Gazyva) to treat patients with never-treated CLL and patients whose disease had relapsed and required additional treatment.

Initial data shows that the treatment is safe, well-tolerated and highly effective, with more than 96 percent of patients remaining on treatment at the study midpoint (eight months.)

Side effects were similar to single-agent treatment and manageable. In addition, patients experienced no incidences of the most severe side effect of venetoclax therapy alone, a potentially life-threatening metabolic disorder called tumor lysis syndrome, where many cancer cells are killed off at the same time by treatment, releasing their contents into the bloodstream.



This is first data reported on use of a triple-combination treatment in CLL patients who have not previously undergone treatment. The trial also evaluated a time-limited dosing strategy with targeted agents. Current standard of care for the targeted therapies used alone is to remain on therapy until the patient's cancer no longer responds to the treatment. In this study, patients received treatment for a total of 14 months.

"There are also many potential benefits to patients achieving cancer control with a time-limited treatment strategy because—despite its effectiveness and reliable increases in patient survival—we know that exposure to chemotherapy puts patients at increased risk for resistance to the agents, infections and other long-term side effects," says Rogers. "If we can find a targeted treatment approach that produces similar benefits in cancer control, we are improving quality of life for our patients. A time limited strategy could also reduce the cost of overall cancer therapy, an issue many patients are very concerned about."

Treatment response was measured through blood tests at eight months into treatment and two months after treatment completion.

"The majority of patients had virtually no detectable circulating tumor cells, which is a very promising indicator of durable <u>cancer control</u> in patients treated with chemotherapy. We are optimistic that the same will be true for patients treated with this targeted <u>therapy</u> drug regimen," adds Rogers.

She reported findings (Abstract #431) at the American Society of Hematology annual meeting in Atlanta, Ga., on Sunday, Dec. 10, 2017.

Researchers are continuing to follow <u>patients</u> enrolled to the trial through the end of treatment. Final treatment data will be available in May 2018, and the researchers will report end of treatment response rates.



Provided by The Ohio State University

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