

Second generation BTK inhibitor highly effective as solo therapy in adult leukemia

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Updated data on the first 134 chronic lymphocytic leukemia patients treated with single-agent acalabrutinib shows that the drug was well-tolerated in the majority of patients treated and responses were durable over time, according to researchers at The Ohio State University Comprehensive Cancer Center – James Cancer Hospital and Solove Research Institute (OSUCCC – James).

Acalabrutinib is a second-generation Bruton's [tyrosine kinase](#) (BTK) inhibitor, a newer class of drugs shown to improve the survival of [patients](#) with CLL and mantle cell lymphoma (MCL). All preclinical research and the first phase I study of the drug was completed by a team of researchers led by John C. Byrd, MD, at the OSUCCC – James.

Byrd will present updated data from the first 134 CLL patients treated with single-agent acalabrutinib in a phase I/II clinical trial led by the OSUCCC – James and conducted at 15 cancer centers in the United States as well as the United Kingdom and Italy.

Data shows that the treatment was tolerated well in the majority of patients, and responses were durable over time. For this trial, a total of 134 patients received treatment – 132 with CLL and two with small lymphocytic lymphoma (SLL). Overall [response](#) rate—which includes patients with both a complete and partial response—was 85 percent. Most patients (81 percent) remained on treatment at 19.8 months. The drug is being investigated in patients with relapsed/refractory CLL in two ongoing phase III studies, ACE-CL-006 and ACE-CL-309.

"This is a very promising drug that produces response rates just as good as the first-generation drug, ibrutinib. The exciting part is these responses appear to deepen with time and are also associated with fewer life-impacting side effects, such as atrial fibrillation," adds Byrd, who holds the D. Warren Brown Designated Chair in Leukemia Research and is a Distinguished University Professor at Ohio State.

In addition, combined data analysis from seven ongoing clinical trials testing the second-generation Bruton's [tyrosine kinase inhibitor](#) drug, acalabrutinib, shows the drug is well-tolerated by patients across various blood cancers. Patients were able to stay on the drug for longer periods without treatment-limiting side effects, according to Byrd.

In this analysis, researchers analyzed safety data from 610 patients who were treated with single-agent acalabrutinib. All patients had at least one dose of the [drug](#) to treat [chronic lymphocytic leukemia](#), follicular lymphoma, multiple myeloma, prolymphocytic leukemia, small lymphocytic lymphoma or Waldenstrom macroglobulinemia. Average median duration of treatment was 14.2 months. Adverse side effects led to discontinuation of treatment in only 6.1 percent of patients. Most reported side effects were low-grade and did not result in discontinuation of [treatment](#).

This data was presented in a poster session (Abstract #4326) on Monday, Dec. 11, 2017, at the American Society of Hematology annual meeting in Atlanta, Georgia.

Provided by The Ohio State University

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