

Combination therapy for B-cell Cancers

Invention Summary

Combination therapy for B cell cancers with BTK inhibitors and CDK4 inhibitors, such as ibrutinib and palbociclib.

Technology Overview

Bruton's tyrosine kinase inhibitors have revolutionized treatment of B cell cancers. However, cancers can mutate to become resistant to these drugs.

Investigators at Cornell helped identify some of these mutations and have been conducting research to overcome them.

CDK4 is essential for driving the cell cycle, and CDK4 inhibitors including palbociclib, ribociclib, and abemaciclib have been approved for combination therapies with aromatase inhibitors or fulvestrant to treat breast cancers and have been investigated in other cancers.

Supported by good preclinical research results using ibrutinib and palbociclib, Cornell investigators organized an open label Phase I trial of 27 people with previously treated mantle cell lymphoma (NCT02159755). The study found that combination was relatively safe. The overall and complete response rates were 67% and 37%, and with a median

follow-up of 25.6 months, the 2-year progression-free survival was 59.4% and the 2-year response duration was 69.8%. The results were published in *Blood* in 2019. A Phase II trial is ongoing (NCT03478514).

Potential Applications

Treatment of B cell cancers including mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), small lymphocytic lymphoma (SLL), diffuse large B-cell lymphoma (DLBCL), activated B-cell diffuse large B-cell lymphoma (ABC-DLBCL), germinal center diffuse large B-cell lymphoma (GCB DLBCL), double-hit (DH) DLBCL, primary mediastinal B-cell lymphoma (PMBL), Burkitt's lymphoma, follicular lymphoma, and others.

Advantages

Prevent cancers from escaping treatment with BTK inhibitors alone and extend the utility and market for both drug classes.

Publications

Issued US patent 10,314,842 and published US patent application 20200061066.

Inventors:

Selina Chen-Kiang and Maurizio DiLiberto

Patents:

Filed

Licensing Contact:

Brian J. Kelly (646) 962 - 7041 bjk44@cornell.edu

Cornell Reference:

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