

## Tolero Pharmaceuticals collaborates with AbbVie for AML trial

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Tolero Pharmaceuticals, Inc., a clinical-stage biopharmaceutical company focused on developing treatments for hematologic and oncologic diseases, has entered into a clinical research collaboration with AbbVie, a research-based global biopharmaceutical company, exploring the potential of combination therapy with AbbVie's venetoclax and Tolero's investigational agent, alvocidib, for the treatment of relapsed/refractory acute myeloid leukemia (AML).

Alvocidib is a small molecule inhibitor of cyclin-dependent kinase 9 (CDK9), which controls the expression of a survival factor, MCL-1. Venetoclax is a small molecule inhibitor of B-cell lymphoma-2 (BCL-2). Both MCL-1 and BCL-2 are key proteins used by certain cancer cells to avoid apoptosis, and non-clinical studies have shown that cancer cells can resist inhibition of BCL-2 by using MCL-1 to avoid cell death. Alvocidib is currently in Phase II development for the treatment of MCL-1-dependent AML.

"We are very pleased to announce our clinical research collaboration with AbbVie, as it marks an important step in the development of this novel agent for patients with relapsed/refractory AML," said David J. Bearss, Ph.D., Chief Executive Officer of Tolero. "Preclinical data suggest that the mechanisms of action for venetoclax and alvocidib may synergistically drive apoptosis in cancer cells. We hope to further investigate this hypothesis with our planned trial of this combination therapy in patients with relapsed/refractory AML."

"This is a unique opportunity to bring together and investigate two first and only in class compounds to help patients with AML," said Neil Gallagher M.D., Ph.D, Vice President, Head of Global Oncology Development, AbbVie. "There is an urgent need for new therapies, particularly in patients who either did not respond well to initial therapy or who subsequently relapsed. AML is a complex disease at the cellular level. Therefore, combining alvocidib with venetoclax, which have distinct but potentially complementary mechanisms for targeting the leukemia cells, makes a lot of sense from a scientific perspective."

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