

Accelerating Innovations into CarE – Market Access Program (AICE-MAP)



Phase 1 Trial of PCLX-001 in Relapsed/ Refractory Non-Hodgkin Lymphoma (NHL)

PROJECT FAST FACTS

PARTNERS: Pacylex Pharmaceuticals, Cross Cancer Institute, Alberta Health Services

AWARD: \$300,000

AWARD DATE: June 1, 2020

PROJECT DURATION: 24 months

THE PROBLEM

The four major hematological cancers account for almost 10% of new cancer cases and deaths. There remains a large need for new and effective treatments, especially for cases that do not respond to currently available therapies.

THE SOLUTION

Pacylex Pharmaceuticals is a pre-clinical trial stage pharmaceutical company founded in 2012. The company is developing a first-in-class, oral drug, PCLX-001, to selectively kill various types of cancer cells while leaving normal cells unharmed. Animal tests show PCLX-001 completely eliminates tumors in xenograft models of leukemias and lymphomas (Acute Myelogenous Leukemia; AML, Burkitt Lymphoma; BL, and Diffuse Large B Cell Lymphoma; DLBCL). PCLX-001 also kills many solid tumor cancer cell lines and slows tumor growth in models of human lung and breast cancer. Given the preclinical efficacy and safety results Pacylex has generated to date, we hypothesize that the inhibitory effect of myristoylation by PCLX-001 may be an effective therapy for relapsed/refractory (R/R) B-cell NHL, and that PCLX-001 will be safe and tolerable at doses expected to demonstrate clinical activity.

PROJECT OBJECTIVES

The Cross Cancer Institute, on behalf of Pacylex Pharmaceuticals, is conducting a Phase 1 Clinical Trial of PCLX-001. The goals of this trial are to:

1. Determine the maximum tolerated dose (MTD) and/or recommended Phase 2 dose, safety, tolerability, and pharmacokinetics of PCLX-001 in patients with R/R B-cell NHL.
2. Assess the preliminary anti-tumor activity of PCLX-001 and of its pharmacodynamic effects and mode of action. This will enable progression to Phase 2 studies to develop a novel lymphoma treatment.

"Alberta Innovates' support through this AICE-MAP project helps Pacylex ensure that PCLX-001 is tolerated in humans, a key first step to having this therapeutic in the market and helping patients." – Ryan Heit, COO, Pacylex Pharmaceuticals

ABOUT THE AICE-MARKET ACCESS PROGRAM

AICE - MAP is designed to accelerate health innovations that face evidentiary hurdles in achieving market access. The Program supports small to medium-sized enterprises and real-world testing sites in carrying out clinical trials and feasibility studies of innovative health technologies. Successful Projects are designed to generate key evidence that will facilitate commercial progression and market adoption. If you'd like to learn more, please check out our [AICE website](#).

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