

'G'day' for Pathway: \$7.5M for PWT33597 Cancer Phase I

By Tom Wall
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Pathway Therapeutics, Inc., a San Francisco-based company built largely on research from New Zealand and funding from Australia, raised \$7.5 million from two Australian venture investors and will advance its PWT33597 to a Phase I trial for treatment of patients with advanced solid tumors.

Pathway announced Wednesday that the FDA accepted its investigational new drug application for PWT33597, a selective, dual inhibitor of PI3K kinase alpha and mTOR. The company said it is the first agent with this profile to enter the clinic.

"PWT33597 is the first PI3k alpha selective/mTOR inhibitor to enter the clinic." Pathway President and CEO Julie Cherrington told *BioWorld Today*. "All of the other inhibitors of this pathway in the clinic inhibit all of the PI3K family members – alpha, beta, delta, gamma, so they are 'pan' PI3K inhibitors – and some inhibit mTOR as well. Alpha is by far the most critical in solid tumors. . . . There is little to no efficacy upside to inhibiting beta, gamma, delta in solid tumors and certainly anticipated higher toxicities if you inhibit these other family members. By selectively inhibiting PI3K alpha we believe we will be able to potently shut down the dysregulated signaling pathway in tumors and have an improved safety profile compared to other inhibitors under investigation."

PWT33597 also is a potent mTOR inhibitor, Cherrington said, noting that first-generation mTOR inhibitors have shown efficacy in renal cell carcinoma, sarcoma, lymphoma and neuroendocrine tumors.

The combination of selectively inhibiting PI3K alpha and mTOR could prove a winning combination from a safety and efficacy standpoint across a wide range of solid tumors, she said.

Cherrington said the company expects to dose the first patient in Phase I this summer. The Phase I trial will be a single agent study designed to evaluate the safety of escalating doses, while also providing pharmacokinetic and pharmacodynamic measurements and an early assessment of clinical activity.

The privately held company, which was founded in 2008, had previously raised about \$10 million in Series A financing.

The new \$7.5 million infusion came from two original investors: GBS Ventures, Australia's largest specialist life science venture capital investment group with offices in Melbourne and Sydney, and CM Capital Investments; and CM Capital Investments, of Brisbane, an Australian venture capital company focused on early stage life sciences companies.

CM Capital Investments and GBS Venture Partners jointly led a \$10 million Series A financing in June 2008, soon after Pathway was spun off from Auckland UniServices, the commercialization arm of the University of Auckland. Pathway's initial funding came from the Health Research Council of New Zealand and the University's Maurice Wilkins Centre, a New Zealand government funded Center of Research Excellence.

The company's drug development program is based on therapies developed at the Maurice Wilkins Centre and is based on the work of research groups led by cancer therapeutics and cell signaling specialists Bill Denny, director of the Auckland Cancer Society Research Centre and a founding scientist of biopharmaceutical company Proacta, of San Diego and Auckland, and Peter Shepherd, founding scientist of Symansis, of Auckland. They examined inhibitors of PI3 kinase, an enzyme involved in controlling cell growth and migration and a potential therapeutic target for cancer and inflammatory diseases.

The \$10 million Series A financing was also backed by the Trans-Tasman Commercialization Fund, of Melbourne, Adelaide and Auckland, an investment fund designed to help the early stage commercialization of intellectual property developed at the University of Auckland and four Australian universities; the Breast Cancer Research Trust, of Auckland; and the New Zealand Venture Investment Fund Limited, of Auckland.

Last July Pathway re-incorporated in the U.S. and opened headquarters in San Francisco – a strategy also used by other New Zealand biotechs. Cherrington said the move to the U.S. was necessary to build drug development capability beyond the very early stage discovery capabilities in New Zealand and also to access U.S. venture capital.

Cherrington said the company currently has five employees and relies on an extended project team of consultants. The majority of the work is outsourced although the company has biochemistry, cell biology and translational medicine capabilities at the bench internally in San Francisco.

In addition to PWT33597, Cherrington said Pathway has a second program for a PI3K delta selective inhibitor program in lead optimization, for application in leukemia and lymphoma as well as inflammatory diseases such as asthma, allergic rhinitis and COPD. ■