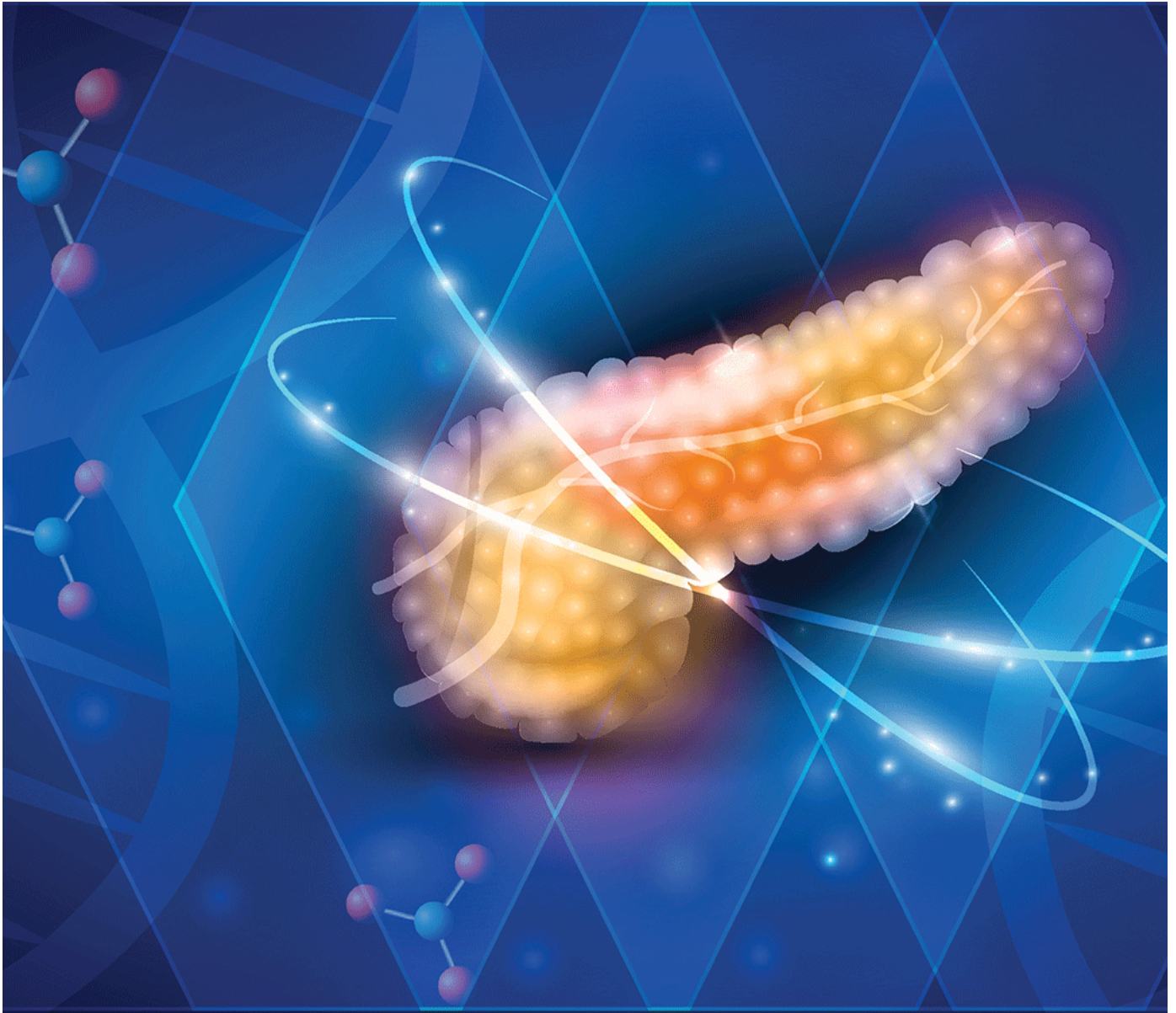


Phaim Pharma poised to trial drug that resets immune system to treat T1D



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By [Richard Staines](#)

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Now is a good time to be involved with type 1 diabetes (T1D) research, according to a U.K. biotech that hopes to reduce or cut the need for insulin injections to treat the condition.

According to London-based Phaim Pharma Ltd., the T1D tie-up [announced earlier this month](#) between Evotec SE and Sernova plc is evidence that pharma is becoming interested in finding a therapy or even a cure for the autoimmune condition to prevent the need for constant insulin injection.

In patients with T1D, the beta cells found within the pancreas that secrete insulin are destroyed by the body's own immune system, which mistakes them for foreign cells.

It's that process that Phaim is trying to target using a peptide that aims to reset the immune system so that it no longer sees the beta cells as the enemy.



Nara Daubeney,
chief operating
officer and co-
founder, Phaim

According to the firm's chief operating officer and co-founder, Nara Daubeney, the interest in T1D from the likes of Vertex Pharmaceuticals Inc., Viacyte Inc. and Sigilon Therapeutics Inc. could kickstart development of new therapies for the condition.

Phaim's approach is two-pronged, with a diagnostic tool to highlight people who could go on to develop the disease coupled with the currently unnamed peptide therapy.

This could be used in different ways: it could prevent patients in the early stages of the disease from progressing, or it could be used in tandem with a cell therapy to prevent the immune system destroying the transplanted cells.

Because Phaim hopes to modify, rather than suppress, the immune system, the combination therapy could allow production of insulin to resume within the body without knocking out the immune system and resulting in the side effects and risks that entails.

Daubeney, an adult and pediatric ENT surgeon by training, told *BioWorld*, "Having identified the correct self-antigens, you present it in the novel way to the immune system.

"As opposed to it driving a destructive T-cell response, it pivots to a tolerogenic T-cell response."

In 2020, Daubeney co-founded the company with her father, Tihamer Orban, a world-leader in the immunological mechanisms underlying T1D, who now serves as chief scientific officer, along with her husband, Piers Daubeney, an expert in drugs that promote child health, who serves as Phaim's CEO.

The team had been working on the project under a different guise since 2014, beginning an early seed investment round in early 2020, followed by another seed investment round last year that enabled manufacture of the therapeutic asset.

Ready for the clinic

After supportive preclinical results, Phaim is now ready to begin clinical studies with the support of the U.K.'s health care system and the Type 1 Diabetes U.K. Immunotherapy Consortium.

The latter was set up in 2015 with funding from the charities Diabetes U.K. and the Juvenile Diabetes Research Foundation Ltd (JDRF).

Daubeney said the company has already drawn up plans for a phase I/II rollover trial that is designed to run for three years.

Dosage will be determined in the first part of the trial, followed by a phase II part that could provide enough data for an accelerated approval.

The peptide is expected to be delivered by injection every two or three years and could be used in tandem with cell therapies under development as an alternative to a wide-ranging suppression of the immune system.

This is used to prevent graft-vs.-host disease in cell therapies but has its own risks and leaves patients vulnerable to infection from other diseases.

"The biggest challenge has been side effects of immunosuppression. If you are putting cells back in, you have to dampen down autoimmune response," Daubeney said.

That led to the company's plans to develop the new drug. The idea is to find a company whose product works in tandem with the therapy and partner up. "I don't think raising money is easy, but there is a focus on this disease," she said. "Having big players with deep products with the potential to cure or alleviate symptoms shows it's an area that's worthy of investment time and attention."

The company is now at that point where it is aiming to turn enticing preclinical trial results, including curing a mouse of T1D, into meaningful results in the clinic.

It hopes to do that in combination with a diagnostic tool, which could also one day help to identify those at risk of the disease before it develops.

"What we would like to do is either partner or license the asset or look for VC funding to take it into clinical trials after three years," Daubeney said. "We would like to use all the learning to pivot into the next disease, which is psoriasis."

Phaim also has other projects underway, including trials involving Bristol Myers Squibb Co.'s Orencia (abatacept) in type 1 diabetes.

Perhaps with the help of a big pharma partner already working in T1D, the company's bold ambition is to change the treatment paradigm for the disease.

"It's time the population had an alternative to insulin," Daubeney said.