



#### Key Points:

- Diabetes-related fibrosis is the leading cause of end-stage kidney disease
- There are no products to prevent or reverse diabetes-related fibrosis
- Phase II clinical trials of lead compound, and genetic testing, will start within a year

# Certa Therapeutics

## The precision-medicine company is developing a new treatment for chronic kidney disease

### The outcome

Precision-medicine company Certa Therapeutics launched in June 2018 to develop a treatment for patients with chronic kidney disease. Melbourne-based Certa is slated to start Phase II clinical trials within a year.

The treatment is based on FT011, a lead compound identified by University of Melbourne researchers, combined with genetic testing to identify patients most likely to respond.

The potential market is large. Diabetes causes 3.7 million deaths worldwide annually, 2.2 million of which are from diabetes-related cardiovascular and kidney disease. As FT011 targets the fibrosis, or kidney scarring, responsible for more than 90 per cent of the deaths in this latter group, it could be used to treat millions of people worldwide.

Since its discovery, the treatment has attracted investments of more than US\$550 million from the pharmaceutical industry and over \$30 million in venture capital funding.

### The need

There are currently no products to prevent or reverse fibrosis, including the fibrosis triggered by diabetes-related high blood glucose. Diabetes-related fibrosis is the leading cause of end-stage kidney disease, which is treatable only with dialysis or a kidney transplant. Preventing fibrosis will reduce or remove the need for these expensive treatments.

Fibrosis is also a key factor in diabetes-related heart disease and chronic lung disease.

Diabetes affects more than 400 million adults around the world, and its prevalence is increasing. It is estimated to account for 12 per cent of global health expenditure, or US\$612 billion each year.



There are 2.2 million diabetes-related cardiovascular and kidney disease deaths worldwide each year. Picture: Shutterstock

## The science

Compounds that slow fibrosis in the kidneys and heart were discovered by Professor Darren Kelly and his colleagues at the University of Melbourne's Faculty of Medicine, Dentistry and Health Sciences, the University's Bio21 Molecular Science & Biotechnology Institute, and St Vincent's Hospital Melbourne.

The team went on to identify a lead compound, FT011, which delays kidney disease and heart failure in people with diabetes.

The team has also developed DNA testing protocols to identify patients more likely to suffer from fibrosis and thus to respond to FT011.

## Technology development history

The researchers patented their discovery in 2006 and launched pharmaceutical start-up Fibrotech Therapeutics in the same year, with Professor Kelly as CEO. In addition to the researchers, the University of Melbourne, Bio21 and St Vincent's Hospital each took a stake in the company.

In 2008, Fibrotech received \$7 million investment from three venture capital funds: Melbourne-based Brandon Capital Partners, Australia's Medical Research Commercialisation Fund (MRCF) and university fund Uniseed. This funding supported animal studies and Phase I clinical trials for FT011, which were completed successfully in 2014.

Global biopharmaceutical company Shire acquired the technology when it bought Fibrotech in 2014. The acquisition agreement included an upfront payment of US\$75 million and milestone payments of US\$482.5 million. Shire developed the technology further, but subsequently decided to divest it, enabling it to be brought back to Australia.

This led to the launch in 2018 of Certa Therapeutics, whose stakeholders include the founding stakeholders of Fibrotech. The new company has received \$22 million from the Australian Government's Biomedical Translation Fund, managed by MRCF, and \$3 million from Uniseed, some of which it used to acquire the intellectual property originally transferred in the Fibrotech sale, in addition to other related technology. As part of the deal, Shire takes an 18 per cent stake in Certa Therapeutics and will receive royalties on global sales when products reach market.

Professor Kelly is the CEO of Certa Therapeutics. Having completed safety trials of FT011, the company is now focusing on developing FT011 and DNA testing for fibrosis susceptibility for later stage clinical trials.

## Players, publications and patents

**Company:** Certa Therapeutics Pty Ltd

**Researchers:** Professor Darren Kelly

**Patents and key publications:** Kelly DJ, Williams SJ, Zammit S. 2008. Australian Patent No. 2008341010. Woden, ACT: IP Australia.  
Zammit SC, Cox AJ, Gow RM, Zhang Y, Gilbert RE, Krum H, Kelly DJ, Williams SJ. 2009. Evaluation and optimization of antifibrotic activity of cinnamoyl anthranilates. *Bioorg Med Chem Lett* 19(24):7003-6. doi: 10.1016/j.bmcl.2009.09.120  
Williams SJ, Stapleton D, Zammit S, Kelly DJ, Gilbert RE, Krum H. 2007. Australian Patent No. 2007271734. Woden, ACT: IP Australia.

