



## **PRESS RELEASE**

# **Fibrotech announces positive Phase Ia results for anti-fibrotic FT011**

## ***Immediate start to new Phase Ib trial of FT011***

**Melbourne, Australia- 10th March 2014** – Fibrotech, an Australian biopharmaceutical company developing a new class of drugs to prevent a massive health burden associated with fibrosis, today announced that its lead anti-fibrotic compound FT011 has successfully completed a Phase Ia trial in healthy volunteers demonstrating safety and tolerability up to doses of 1000mg. At the same time Fibrotech announced the commencement of a Phase Ib trial involving patients with diabetic nephropathy associated with Type 1 or Type 2 diabetes. Both trials have been and will be conducted in Australia.

The Phase Ia study was a double blind, randomised, placebo-controlled, dose-escalating study of the safety, tolerability, food effect and pharmacokinetics of single and repeat doses of FT011 administered orally to healthy volunteers. There were three stages in the study. In the first stage, 40 healthy volunteers received single doses of FT011 (10, 30, 100, 300 and 1000 mg). In the second stage, 8 healthy volunteers were given a 100mg dose under fed rather than fasting conditions to examine food effects. In the third and final stage healthy volunteers were administered daily doses of FT011 (250 or 500mg) for 14 days. All stages of the study demonstrated the safety and tolerability of FT011 with a once daily pharmacokinetic profile and no food effects or any observed adverse events.

The Phase Ib study about to begin will be a double blind, randomised, placebo-controlled, dose-escalating, multiple dose study involving 24 healthy male volunteers and up to 16 patients with Type 1 or Type 2 diabetes-associated nephropathy. As well as confirming the safety and tolerability of FT011 this second Phase I trial will also look for key biomarkers in the patient group.

Prof. Darren Kelly, CEO of Fibrotech commented:

"These Phase Ia results confirm our preclinical findings that FT011 is well tolerated and we keenly await the results of the Phase Ib trial. Patient recruitment has already begun and we expect first dosing to begin tomorrow, on March 11. It is very exciting to be making such progress in developing a compound with real promise to benefit patients with diabetic nephropathy and delay the progression of this disease."

Professor Darren Kelly, CEO of Fibrotech will be attending BIOEurope Spring in Turin on 10<sup>th</sup> and 11<sup>th</sup> of March and will be happy to meet with interested journalists and other parties there.

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### **About Fibrotech Therapeutics Pty Ltd**

Fibrotech is an Australian biopharmaceutical company developing a new class of drugs to prevent a massive health burden associated with fibrosis (tissue scarring). The Company develops novel anti-fibrotic drug candidates for the treatment of the fibrosis prevalent in such chronic conditions as chronic kidney disease, chronic heart failure, pulmonary fibrosis and arthritis. Fibrotech's lead product FT011 is an antifibrotic to prevent the tissue fibrosis associated with diabetic nephropathy and is currently undergoing safety testing in a Phase I clinical trial. Diabetic nephropathy is the leading cause of end-stage renal disease, a severe medical condition that can only be managed with dialysis or kidney transplantation. There are several products in preclinical development selected from over 150 analogues, many of which are novel chemical entities and are markedly improved antifibrotic agents. Fibrotech was founded in 2006 and is located in Melbourne Australia.

Further information on Fibrotech can be found at [www.fibrotech.com.au](http://www.fibrotech.com.au)

**Contact:**

Fibrotech Therapeutics	Instinctif Partners
Prof. Darren Kelly T: +61 (0)3 9657 0705 <a href="mailto:dkelly@fibrotech.com.au">dkelly@fibrotech.com.au</a>	Dr. Douglas Pretsell T: +61 (0)466 925 966 <a href="mailto:douglas.pretsell@instinctif.com">douglas.pretsell@instinctif.com</a>

**Notes for editors**

Fibrotech's proprietary compounds are novel and improved analogues of tranilast (Rizaben®), a known antifibrotic agent which is off patent and is approved for the treatment of asthma, allergic rhinitis and atopic dermatitis in humans in Japan. Fibrotech has synthesized over 150 analogues of tranilast, many of which are novel chemical entities and are markedly improved antifibrotic agents.

FT011 is Fibrotech's lead anti-fibrotic compound currently in clinical development for diabetic nephropathy. Kidney failure in diabetes occurs as a result of kidney fibrosis (scarring). This fibrosis is in turn due to the long term damage from excessive sugar levels in the blood.

In preclinical testing FT011 was effective at preventing kidney fibrosis in animal models of diabetic kidney disease. Specifically, these studies found that F011:

- More potently attenuates TGF- $\beta$  induced collagen synthesis in cultured kidney mesangial cells and cardiac fibroblasts in comparison to tranilast.
- Has high oral bioavailability in the rat, similar to tranilast.
- Shows no evidence of toxicity when administered to rats at three times its therapeutic dose.
- Prevents the development of fibrosis and albuminuria in a well-characterised and clinically predictive rat model of diabetic nephropathy.
- Halts the progression of late stage diabetic nephropathy in a head-to-head comparison with tranilast, while at the same dose tranilast failed to slow progression.
- Delays the progression of fibrosis and renal failure in a non-diabetic model of chronic kidney disease.
- Preserves systolic and diastolic function in both a diabetic and non-diabetic model of heart failure in rodents.