



Kensana Health Agrees to Partner on Phase 3 Clinical Trial for Rare Disease

University of Sydney and Kensana Health Sign Research Support Agreement for Clinical Trial

Kensana Health, a Canadian based global biotechnology company, has come to agreement with the University of Sydney to enter their platform Phase 3 clinical trial “Better Evidence and Translation for Calciphylaxis” (BEAT-Calci), led by the NHMRC Clinical Trials Centre.

The aim of the study is to assess the effect of treatment in patients with kidney failure with newly diagnosed calciphylaxis. Calciphylaxis, also known as calcific uremic arteriolopathy (CUA) is a rare syndrome characterized by painful lesions. It is seen mostly in people with end stage kidney disease but can occur in earlier stages of chronic kidney disease, and on very rare occasions, in people with normally functioning kidneys.

Calciphylaxis is believed to affect 1-4% of all dialysis patients resulting in chronic and difficult to heal wounds with a typical life expectancy of less than one year.

Ken Clement, Founder and Executive Chair of Kensana Health said, “Kensana Health is very excited and honored to be included in this terrific initiative by the University of Sydney.” Clement went on to say, “Kensana Health is in a unique situation where we have been able to demonstrate both the safety and efficacy of our chronic wound therapy in clinical settings in Canada. It could revolutionize the sector. We are excited by the success we had in open label trials and look forward to conducting a definitive



LEFT: BEAT-Calci project team. RIGHT: Mark Bresciano, Director of Kensana Health, with Prof Meg Jardine, Director of NHMRC Clinical Trial Centre at the University of Sydney.

controlled trial with the University of Sydney. We anticipate that this trial will not only help with future treatments for the devastating disease of calciphylaxis but illustrate the potential the Kensana therapy has inside this Phase 3 trial for treating all chronic wounds.”

Kensana Health demonstrated wound closure in a small series of people with chronic wounds from Canada. The trial showed successful outcomes on many types of chronic wounds, including patients with calciphylaxis.

“We are very interested to see how the Kensana Health treatment performs inside a rigorous Phase 3 clinical trial with full double blinded placebo protocols” said Prof Meg Jardine, Director of the NHMRC Clinical Trials Centre at the University of Sydney. Prof Jardine went on to say, “There is a dire need for effective therapies for this rare and serious condition. We are excited to work with companies like Kensana Health that share our commitment to improving clinical outcomes.”

The BEAT-Calci multi-domain platform trial is designed to generate evidence for multiple potential therapies as efficiently as possible and has support from a competitive Australian government MRFF award, the University of Sydney and other industry sources. The trial is approved by the Sydney Local Health District (SLHD) Human Research Ethics Committee – CRGH (2019/ETH13630). It has already begun to recruit patients in Australia and New Zealand to its existing treatment domains. The team are continuing to work towards onboarding patients in multiple countries.

For further information about the **BEAT-Calci trial**, please go to <https://ctc.usyd.edu.au/our-research/research-areas/kidney-health/active-trials/beat-calci/> or contact the BEAT-Calci trial team at beat-calci.study@sydney.edu.au.

For further information about **Kensana Health** go to <https://kensana.health/> or contact Kensana Health at info@kensana.health.

About the University of Sydney

As Australia’s first university – founded in 1850 – the University of Sydney has a proud history of global leadership in education and research and inspiring people from all backgrounds to contribute to positive real-world change. We’re a world-renowned teaching and research institution – our research combines the expertise and talents of scholars from many disciplines.

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About University of Sydney, NHMRC Clinical Trials Centre

The NHMRC Clinical Trials Centre is a flagship centre of excellence at the University of Sydney, that designs and manages clinical trials. This includes responsibility for study coordination, monitoring, data acquisition and management and statistical analysis. Our health economics, biostatistics, systematic reviews and biomarker teams work with trial data and inform healthcare providers about best practice.

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