

ZUCERO THERAPEUTICS ANNOUNCES PROMISING COVID-19 VIRUS LABORATORY RESULTS

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"	LABORATORY RESULTS
Zucero is very excited to report that #pixatimod is active in lab studies against SARS-CoV-2, the virus responsible for #COVID19 bioRxiv viewer" <i>Founder Chris Burrell</i>	 Zucero's clinical-stage drug candidate pixatimod demonstrates potent antiviral activity against the COVID-19 virus in laboratory studies. Potency well within the safe therapeutic dose range of pixatimod as previously recorded in oncology patients in phase I studies. Results provide strong rationale for the clinical

THERAPEUTICS ANNOUNCES PROMISING COVID-19 VIRUS

investigation of pixatimod as a new multimodal therapeutic for the current COVID-19 pandemic.

Zucero Therapeutics Limited (Zucero), an Australian biotech company based in Brisbane, is pleased to announce promising laboratory-based findings relating to its lead clinical candidate, pixatimod, and SARS-CoV-2, the virus responsible for the COVID-19 pandemic.

Originally developed for infectious disease and cancer, pixatimod (formerly PG545) is a first-inclass innate immunomodulatory small molecule, which has been tested in Phase I clinical oncology studies in 83 patients to date. Zucero, now possessing a Phase 2 ready clinical asset with an acceptable safety profile, made the decision earlier this year to pursue a dual track antiviral/oncology development pathway for pixatimod.

The company announced plans on 20 March 2020 to undertake investigations on the wellestablished antiviral properties of pixatimod in relation to SARS-CoV-2. Over the past three months, Zucero has been working with national and international academic collaborators who have been assessing pixatimod's antiviral properties, including in a number of in vitro live virus infectivity studies. This includes collaborators from institutions such as the University of Liverpool (UK), Keele University (UK), Public Health England (UK), the University of Gothenburg (Sweden), Queensland University of Technology and The University of Queensland.

Zucero is now pleased to advise the in vitro studies clearly demonstrated that pixatimod binds directly to the SARS-CoV-2 spike protein S1 receptor binding domain (RBD) which alters its conformation, a finding that confirms predictions from in silico modelling data. Moreover, a number of independent laboratories used different methods with different SARS-CoV-2 isolates to report the effective concentration of pixatimod required to block host cell infection of live virus by 50% (EC50).

The mean EC50 values for the three different SARS-CoV-2 isolates tested were 2.7 μ g/mL, 8.0 μ g/mL and 8.1 μ g/mL. Importantly, the maximum plasma concentration following pixatimod (100mg dose) in cancer patients is 30 μ g/mL (Dredge et al, British Journal of Cancer 2018), indicating that antiviral activity can be achieved at clinically relevant doses.

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Dr Keith Dredge, Chief Scientific Officer said: "These robust and reproducible results highlight a new therapeutic approach to directly inhibit the SARS-CoV-2 virus and clearly support further testing of pixatimod for use in the treatment and prevention of COVID-19."

Pixatimod is currently in Phase 1b clinical trials for advanced cancer in Australia, and given the company has an open Investigational New Drug (IND) with the USFDA, this is anticipated to expedite clinical testing in the United States. Pixatimod was also recently selected as a Priority Group 1 asset for laboratory testing by the CSIRO/Doherty Institute as part of the SARS-CoV-2 Antiviral and Antiseptic Screening Program. The company is currently in contract discussions with the CSIRO relating to this testing program.

Zucero is also delighted to announce it is a recipient of the Therapeutic Innovation Australia voucher- based scheme designated Pipeline Accelerator COVID-19. This will co-fund critical bioanalytical and pharmacokinetic studies by TetraQ, at The University of Queensland, to support the progression of pixatimod into the clinical for COVID-19.

Zucero's Chairman, Chris Burrell, commented on the announcement saying "In this rapidly changing environment, Zucero has responded quickly and is applying its internally-designed, proprietary innovative technology to address this global public health challenge with very encouraging results."

"On the back of this new COVID-19 data and the emerging data from our Phase 1b oncology trial, we are seeking to accelerate our antiviral and oncology development programs with the aim of initiating Phase 2 clinical trials in the US later this year." Mr Burrell said. The data from the laboratory studies have been published on the preprint server bioRxiv and can be accessed via the following URL https://biorxiv.org/cgi/content/short/2020.06.24.169334v1

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Zucero Therapeutics is an Australian, Brisbane-based clinical stage drug development company. Our scientific and research team has been working together for several years, and are world leaders in the design and product development of modified sugar compounds as therapeutic agents.

Zucero Therapeutics' purpose is to help eradicate the world of serious disease. In pursuit of this endeavour, our focus is on the development of small molecule drugs designed to target viruses and modulate the immune system to enhance its response to disease.

For further information, visit <u>www.zucero.com.au</u>

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