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Opportunity

To support funding of stage 1/2 clinical trials - ready human mAb with potent activity against SARS-CoV-2 Omicron strains, contact:

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Monoclonal antibodies against COVID-19

Human monoclonal antibodies against COVID-19 with potent activity against the Omicron strains

The Technology

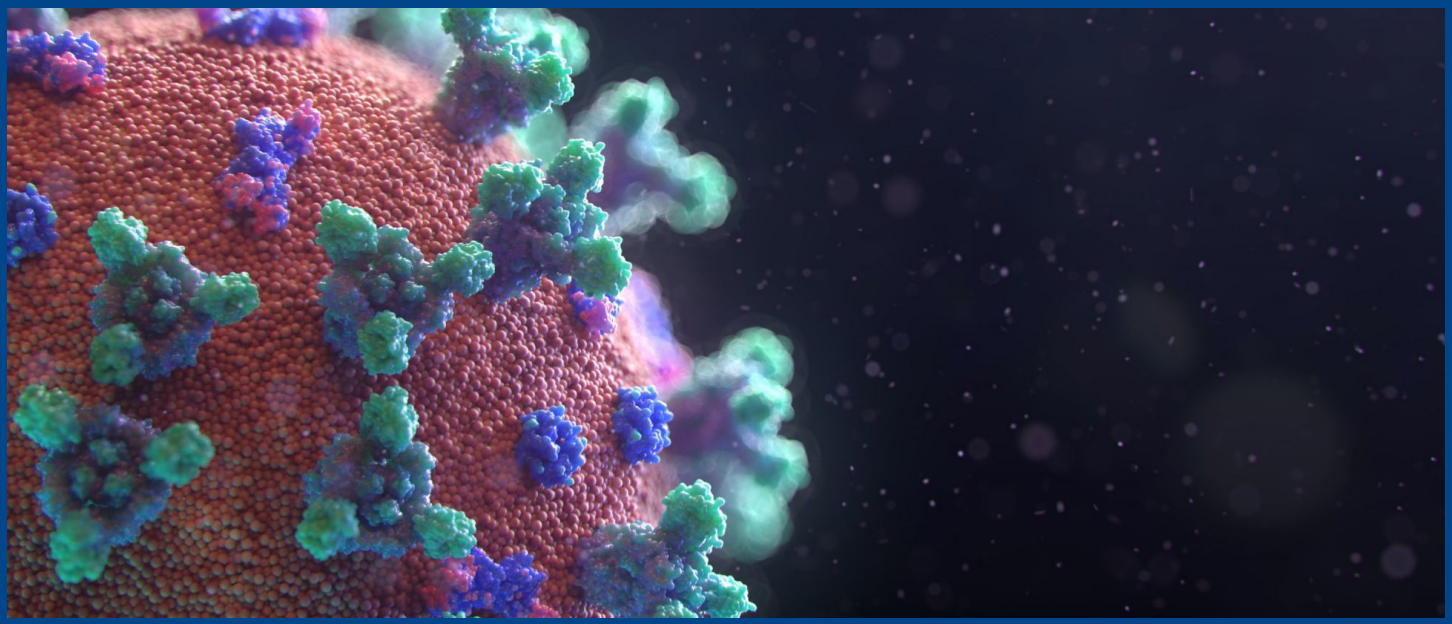
- Human monoclonal antibodies developed by the University of Melbourne (UoM) researchers displayed high binding affinity and have exhibited potent and broad neutralization against all major SARS-CoV-2 variants, including Alpha, Beta, Gamma, Kappa, Delta, and Omicron (BA.1, BA.2, BA.4 and BA.5) strains.

Market Need

- The SARS-CoV-2 Omicron variant shows substantial resistance to neutralization by infection- and vaccination-induced antibodies, highlighting the demands for development of broadly neutralizing antibodies (bnAbs) that can be used to treat severe cases of COVID-19 disease.

Technology Status

- The UoM human monoclonal antibodies are highly effective against SARS- CoV-2 variants in vitro and in animal models. The monoclonals are effective against Omicron strains *in vitro*.



Market Need

The COVID-19 pandemic caused by SARS-CoV-2 has infected over 609 million people, claimed more than 6.52 million lives, and adversely affected global economies. Most existing of the COVID-19 monoclonals on the market have reduced efficacy against the Omicron strain.

Monoclonal antibodies were the first treatment to arrive since the start of the pandemic and were considered the first line of defence against severe COVID-19 disease. Antibody drugs can prevent infection and/or reduce the severity of the disease in people who have recently been exposed to the SARS-CoV-2 virus. Antibodies against COVID-19 remain an important therapeutic option, particularly for individuals with immunodeficiencies who are unable to develop adequate immunological response to vaccines.

As the COVID pandemic evolved, the new SARS-CoV-2 variants have rendered ineffective all but one of the FDA- approved antibody treatments and have significantly reduced efficacy of many of the COVID vaccines on the market. Therefore, scientific and clinical experts agree that monoclonal antibodies are going to continue playing a role in treatment and prophylaxis in vulnerable groups. There is a need for antibodies that are active against the new COVID variants.

Solution

Prof Stephen Kent and Dr Adam Wheatley at the Doherty Institute for Infection and Immunity have developed human monoclonal antibodies with high affinity binding to SARS-CoV-2 and potent neutralising protection against SARS- CoV-2 variants Alpha, Beta, Gamma, Kappa, Delta, and Omicron (including BA.1, BA.2, BA.4 and BA.5 strains), as shown in live virus neutralisation assays.

Validation Data

	IC50 (ng/ml)			
mAb	D614G	BA.1	BA.2	BA.4
REGN 10933	157	1000	1000	1000
PDI 204 (lead candidate)	253	598	314	157

means no neutralisation/ total loss of activity

Table 1. Head to head comparison of the abilities to neutralise SARS-CoV-2 variants of concern for the lead UoM antibody candidate against the Regeneron REGN 10933 antibody. Presented are the IC50 values from the microneutralisation assay

Technology and IP Status

Prof Stephen Kent and Dr Adam Wheatley have identified a panel high affinity (single digit nM) and high potency antibodies that have proven efficacious in spike/ACE2 binding assays, live virus neutralization assays and in pre-clinical animal models. The antibody panel has been screened against the off target reactivity and has undergone stability and manufacturability assessment. The antibody candidates were further selected based on their ability to effectively neutralise Omicron strains (including BA.1, BA.2, BA.4 and BA.5). Manufacture of the lead monoclonal antibody suitable for phase I clinical trial is currently underway.

PCT Patent application has been filed claiming composition of matter and methods of treating and/or preventing diseases associated with coronavirus (PCT/AU2021/051553, filed on 30 July 2022, priority date 23 December 2020).

Tech name and number	2020-059 Hu-mAbs against COVID-19
Researchers	Prof Stephen Kent, Dr Adam Wheatley
Publications	Wheatly et al. Landscape of human antibody recognition of the SARS-CoV-2 receptor binding domain. Cell Reports 2021. DOI: https://doi.org/10.1016/j.celrep.2021.109822
Patents	PCT application PCT/AU2021/051553 filed on 30 July 2022
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