

Media Release

Preventative nasal spray shown to reduce viral replication by up to 96% in COVID-19 challenge study

- New preventative nasal spray treatment that could protect people from COVID-19 infection and prevent transmission announced
- Novel therapy developed by Australian biotech company, Ena Respiratory, shown to significantly reduce COVID-19 virus levels in the nose and throat, in a gold-standard animal study
- *Reduced COVID-19 replication by up to 96%, study performed by Public Health England (PHE) scientists*
- Mode of action complementary to COVID-19 vaccines, with easy nasal administration, delivered once or twice a week
- Potential to be used to prevent infection in at-risk populations, including healthcare workers and the elderly
- Ready to progress to human clinical trials within four months
- Company has raised AU\$11.7m and is seeking additional investment

Melbourne, Australia, 28 September – A novel nasal treatment developed to boost the natural human immune system to fight common colds and flu, has proved remarkably successful in reducing COVID-19 viral replication test results, released today, reveal.

The novel product, INNA-051, being developed by Australian biotech company, Ena Respiratory, reduced viral replication by up to 96 percent in a gold-standard animal study led by Public Health England's (PHE) Deputy Director, Professor Miles Carroll and published today on biomedical prepublication research site, bioRxiv.

The INNA-051 compound works by stimulating the innate immune system, the first line of defence against the invasion of pathogens into the body. By boosting the immune response in this way with INNA-051 prior to infection, the ability of the COVID-19 virus to infect the animals and replicate was dramatically reduced the PHE study showed. The study provides evidence that INNA-051 can be used as a stand-alone method of antiviral preventative therapy, complementary to vaccine programs.

"We've been amazed with just how effective our treatment has been," says Ena Respiratory Managing Director, Dr Christophe Demaison. "By boosting the natural immune response of the ferrets with our treatment, we've seen a rapid eradication of the virus."

"If humans respond in a similar way, the benefits of treatment are two-fold. Individuals exposed to the virus would most likely rapidly eliminate it, with the treatment ensuring that the disease does not progress beyond mild symptoms. This is particularly relevant to vulnerable members of the community. In addition, the rapidity of this response means that the infected individuals are unlikely to pass it on, meaning a swift halt to community transmission." Ena Respiratory has raised AU\$11.7m from Australian investors and, subject to successful toxicity studies and regulatory approval, the company could be ready to test INNA-051 in human trials in less than four months.

The capital raise was led by the Brandon Capital managed, Medical Research Commercialisation Fund (MRCF) and a coalition of investment partners. These include the Australian Government through the MRCF Biomedical Translation Fund, four leading superannuation funds – AustralianSuper, HESTA, Hostplus, Statewide Super – and biotech giant, CSL. University commercialisation fund, Uniseed also participated.

The company is urgently seeking additional funding to accelerate the nasal spray's clinical development and global distribution.

Dr Chris Nave, CEO of the MRCF and co-founder of Brandon Capital, says these extremely promising results means INNA-051 is an exciting frontrunner in the battle to beat COVID-19. "We are doing all we can to support Ena Respiratory and its quest to secure additional investment to accelerate the development and testing of the therapy in humans. While a vaccine is ultimately the key solution to combatting COVID-19, governments need to be developing different treatment approaches to ensure they have a range of options, in the event that a vaccine proves elusive or takes longer to develop."

INNA-051 is a synthetic small molecule and would be self-administered via an easy-to-use nasal spray, taken once or twice a week, with the treatment taking almost immediate effect. If human trials are successful and, given the unprecedented need for drugs to combat COVID-19, this prophylactic immune modulation therapy could be rapidly manufactured at scale and be available for use soon.

"This is a significant development as the world races to find a solution to halt COVID-19 transmission and infection of at risk-populations," says Professor Roberto Solari a respiratory specialist, advisor to Ena Respiratory and visiting Professor at Imperial College London. "Most exciting is the ability of INNA-051 to significantly reduce virus levels in the nose and throat, giving hope that this therapy could reduce COVID-19 transmission by infected people, especially those who may be presymptomatic or asymptomatic and thus unaware they are infectious," Professor Solari says.

INNA-051 offers real hope to those in the frontline fight against COVID-19, says Dr Chris Smith, Ena Respiratory Board Director, and Senior Investment Manager at Brandon Capital. "The treatment offers significant potential to protect the most vulnerable, including those with pre-existing respiratory conditions and the elderly, where vaccines can be less effective."

INNA-051 was in development before the outbreak of COVID-19 to promote resistance towards broader respiratory viral epidemics. Unlike vaccines which are targeted to a specific strain, INNA-051, is designed to be effective for all types of respiratory infections.

"Our nasal treatment has amazing potential for combatting COVID-19 and future pandemics," continues Dr Smith. We know that vaccinations are often the most attractive approach in combating respiratory virus epidemics, but this method often comes with challenges as vaccines trigger a specific response in the adaptive immune system which might not be effective against future mutations of a virus. INNA-051 utilises the non-specific innate immune response meaning it is effective against a broad spectrum of viruses."

"As an original investor alongside Uniseed, the MRCF saw great potential in INNA-051, before the COVID-19 era, to manage respiratory viral outbreaks, exactly like we are currently experiencing,

although our initial focus was against influenza," Dr Nave continues. "We are now thrilled to be able to redirect the effort toward the fight against COVID-19. The treatment has significant potential, not only against this pandemic but also to play a key role in future viral respiratory outbreaks."

The authors of the study include scientists from Public Health England (PHE), Ena Respiratory, and leading Australian research organisations, the Hunter Medical Research Institute, Newcastle and the University of Melbourne.

Uniseed CEO Dr Peter Devine added, "These are very exciting results and demonstrate the potential clinical utility of the Ena drug in the treatment of COVID-19 which will likely require multiple treatment approaches. It also underlines the value of facilitating early-stage commercialisation of research, which can go on to create a global impact."

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Notes to Editors

If you would like a copy of the PHE study, or to arrange an interview please contact:

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About Ena Respiratory

Ena Respiratory is a wholly-owned subsidiary company of Ena Therapeutics, aiming to transform the treatment and prevention of respiratory infections in at-risk populations.

Ena Respiratory is developing novel, synthetic innate immunomodulators for the prevention of respiratory viral and bacterial infections. The company is based in Melbourne and Sydney, Australia. Ena Therapeutics has secured a Series A investment from the Brandon Capital managed Medical Research Commercialisation Fund (MRCF) and Uniseed.

https://enarespiratory.com

About INNA-051

Ena Respiratory's lead candidate, INNA-051 is a synthetic, pegylated TLR2/6 agonist. INNA-051 is developed for topical delivery to the airways (via nasal spray once/twice a week) in order to target the primary site of most respiratory virus infections, including COVID-19, influenza and rhinovirus. Topical respiratory administration of Ena Respiratory's pegylated TLR2/6 agonists result in the activation of several key, innate immune defence mechanisms involved in antiviral prophylaxis. INNA-051 is based on discoveries made by Professorial Fellow David Jackson and his team. Professor Jackson heads the laboratory at the Department of Microbiology and Immunology at the Peter Doherty Institute for Infection and Immunity, University of Melbourne.

The broad antiviral effectiveness of Ena Respiratory's pegylated TLR2/6 agonists has been demonstrated in animal preclinical models of respiratory viruses, including influenza and rhinovirus (common cold) and secondary bacterial infection models.

INNA-051 efficacy against COVID-19 has been confirmed in a ferret challenge model by the team led by Professor Miles Carroll at Public Health England. In this study, INNA-051 was administrated as prophylaxis. In the optimal dose regimen, after 5 days post-exposure to COVID-19, INNA-051 treated animals had statistically significant reduction of virus in throat swabs (96% reduction) and nasal washes (93% reduction) compared to untreated animals, despite very high levels of virus exposure (about 5 million virus particles were administrated in these studies).

About the Medical Research Commercialisation Fund (MRCF) and Brandon Capital Partners

Brandon Capital Partners is a venture capital firm that manages the Medical Research Commercialisation Fund (MRCF), Australia and New Zealand's largest life science investment fund. The MRCF is a unique collaboration between major Australian superannuation funds, the Australian and New Zealand governments, Australian state governments and more than 50 leading medical research institutes and research hospitals. The MRCF supports the development and commercialisation of early-stage biomedical discoveries originating from member research organisations, providing both capital and expertise to guide the successful development of new therapies. The MRCF has supported more than 45 start-up companies to date, most of which were founded by the MRCF.

For more information about the MRCF visit: https://www.mrcf.com.au/

For more information about Brandon Capital Partners visit: www.brandoncapital.com.au

About Uniseed

Uniseed is Australia's longest running early stage commercialisation fund that makes investments in research emanating from five of Australia's leading research organisations – The University of Queensland, The University of Sydney, The University of New South Wales, The University of Melbourne and the CSIRO. Uniseed is a mutual fund, owned by research organisations, for research organisations. The fund facilitates the commercialisation of its research partners' most promising intellectual property and secures targeted investment in resulting products and technologies. Uniseed has supported 57 start-up companies to date, being the seed investor in most of these.

For more information, visit: <u>www.uniseed.com</u>