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Promising results for new Western Australian-pioneered cystic fibrosis drug

- *A Western Australian-led international clinical trial for a new cystic fibrosis drug has successfully completed a Phase 1b study in patients and is now proceeding into a Phase 2a study*
- *The locally developed drug is a novel inhaled antibiotic combination, which has already shown to be effective in reducing infection and improving lung function in cystic fibrosis patients*
- *The Phase 2a study will be led in Australia by the Perth Children's Hospital and involve up to 20 other sites in Australia and the USA*
- *Potential for the drug to be used to treat lung infections in other indications in both children and adults*

16 October: Perth, Australia: Children with cystic fibrosis will be included in the next phase of a clinical trial of a promising new treatment for chronic lung infections pioneered in Western Australia.

Originally developed by researchers at The Kids Research Institute Australia (The Kids) and Perth Children's Hospital (PCH), the treatment, known as RSP-1502, uses an antibiotic booster to improve the effectiveness of treatment for *Pseudomonas aeruginosa* infections in people with cystic fibrosis.

Respirion Chief Scientific Officer, Professor Barry Clements said the Phase 1b study of RSP-1502 in cystic fibrosis patients had been successful in confirming safety. "We are now able to proceed into the Phase 2 study, which can include children aged 12 years and older who have cystic fibrosis". This follow-on Phase 2a study will test the efficacy of RSP-1502 in reducing bacterial infection and reducing biomarkers of underlying inflammation in the lung.

"With limited antibiotic options to address rising bacterial resistance, new options are urgently needed for treating lung infection in people with cystic fibrosis, and RSP-1502 represents a long-awaited breakthrough for this vulnerable population," said Professor Clements.

The Phase 2a study will involve PCH and eight other sites in Australia as well as additional sites in the USA, enrolling 40 children and adults with cystic fibrosis.

"We are very excited by the potential for RSP-1502 to solve the challenge of both chronic lung infection and inflammation in these patients," said Professor Clements. "Positive data from this Phase 2a study will support further development of the drug and represents a real inflection point for Respirion."

About RSP-1502 and Cystic Fibrosis

An early WA-based pilot study using RSP-1502 to treat chronically infected CF patients was published in the industry leading journal¹ and demonstrated an average 16 per cent improvement in lung function - compared to 5 per cent for those patients using a standard of care antibiotic treatment. Enhanced lung function is vital for patients, enabling them to engage more in normal activities such as moving around, participating in sports, enjoying improved quality of life and ultimately, increasing their overall life expectancy.

Cystic fibrosis is a genetic disorder that occurs in about 1 in 4,000 births, where the defect predisposes patients as young as one to lung infections with bacteria including *Pseudomonas aeruginosa*. Once established, these infections are difficult to clear with existing treatment options, and lead to progressive lung damage, decreased lung function, and eventually respiratory failure and death. With few effective options for the treatment of chronic lung infections in people with cystic fibrosis, RSP-1502 represents a potential breakthrough for this vulnerable population.

The promising results from the Perth pilot study led to RSP-1502 being developed by spinout company Respirion Pharmaceuticals Pty Ltd, supported with funding from Brandon Capital through the Federal Government's Biomedical Translation Fund and The Kids Research Institute Australia, as well as the US Cystic Fibrosis Foundation, Cure4CF, The Perth Children's Hospital Foundation, CUREator and other local West Australian investors.

The experienced team behind Respirion were instrumental in developing the current standard of care for cystic fibrosis infections (tobramycin) and have taken a number of drugs successfully through FDA approval and commercialisation globally. Together, with advisers from the US Cystic Fibrosis Foundation and their Therapeutic Development Network, Respirion is now taking RSP-1502 into the Phase 2a efficacy study in Australia and the USA.

Next steps for RSP-1502

With the successful completion of the Phase 1b study, RSP-1502 is now proceeding into a Phase 2a efficacy study in 40 cystic fibrosis patients. Recruitment for the Phase 2a study is currently underway and interested patients can find a local site and additional information about the Phase 2a study by accessing <https://clinicaltrials.gov/search?intr=RSP-1502>.

This Phase 2a study will bring the new drug closer to receiving international regulatory approval, thereby providing people with cystic fibrosis access to a more effective treatment which, if started early in childhood could slow disease progression. RSP-1502 has broader potential in other chronic lung conditions including Non-CF Bronchiectasis and COPD where new and effective antibiotics are needed as there are no FDA approved inhaled antibiotics for these conditions. Respirion has plans to expand testing RSP-1502 to these conditions and is actively seeking new investment to help fund that expansion.

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¹ Puvvadi R, Clements B. Tris-CaEDTA as an adjuvant with nebulised tobramycin in cystic fibrosis patients with *Pseudomonas aeruginosa* lung infections *J Cyst Fibros*. 2021 Mar 20(2):316-323



About Respirion Pharmaceuticals Pty Ltd

Founded in 2018, Respirion Pharmaceuticals is an early-stage biotechnology company focused on developing new treatments for respiratory disease. Respirion's lead product (RSP-1502) is an inhaled combination therapy for the life-threatening disease Cystic Fibrosis, has shown promising results in an early clinical study carried out in conjunction with The Kids Research Institute Australia and the Western Australian Department of Health. The Company has partnered with Australia's largest life science investment fund, the Medical Research Commercialisation Fund (managed by Brandon Capital), as well as the US Cystic Fibrosis Foundation, Cure4CF, The Kids Research Institute Australia and The Perth Children's Hospital Foundation, to conduct further clinical trials in Australia and the US.

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