FirebrickPharma

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ASX Announcement

Firebrick starts COVID-19 trial of Nasodine

- **Phase 2 trial of Nasodine in COVID-19 has started in South Africa**
- **Goal is to show that Nasodine regimen reduces SARS-CoV-2 viral load**
- **Other goals: determine if Nasodine accelerates viral clearance and reduces days to a negative RAT (versus placebo)**

Firebrick Pharma Limited (ASX:FRE) (**Company** or **Firebrick**) is pleased to announce that the first patient had been recruited into its Phase 2 clinical trial in South Africa of Nasodine® Nasal Spray ("Nasodine") for the management of COVID-19.

The trial is scheduled to recruit up to 210 adults who are COVID-positive by Rapid Antigen Test (RAT) to achieve a target treatment population of 144 subjects who will be confirmed by viral culture to be shedding SARS-CoV-2 virus. Depending on patient recruitment, the trial could be completed by August this year.

The study is a randomised, placebo-controlled Phase 2 trial, titled: 'Reduction of nasal shedding of SARS-CoV-2 in COVID-19 positive patients by the use of Nasodine® (povidone-iodine 0.5%) Nasal Spray.' The short title for the trial is 'Nasodine for Elimination of COVID-19 Shedding study' or 'NASO-ELOCS'. Details can be found on the SANCTR at: https://sanctr.samrc.ac.za/TrialDisplay.aspx?TrialID=5792

In 2021, Firebrick Pharma sponsored a pilot human study in South Africa, which showed that a single Nasodine dose (4 sprays per nostril, 1.12 mL per dose) led to an overall 79% reduction in viral shedding at one hour after the dose in six COVID-19 patients who were shedding the virus from the nose (https://sanctr.samrc.ac.za/TrialDisplay.aspx?TrialID=5360).

The current trial significantly extends that research by undertaking a multi-dose, placebo-controlled, Phase 2 trial looking at impact on viral load and other outcomes over several days.

The primary aim of the trial will be to show that frequent Nasodine application (every 2 hours, up to eight-times-daily) over three days leads to a significant reduction in nasal shedding of SARS-CoV-2 virus, compared with a placebo nasal spray.

Secondary aims will include whether Nasodine treatment (compared with placebo) reduces the number of days to a negative RAT and increases the percentage of subjects who have cleared the virus from the upper respiratory tract within 5 days, based on a combined throat and nasal swab.

"If the trial demonstrates that the Nasodine regimen reduces or eliminates viral shedding, it could point to a potentially important role for Nasodine treatment in anyone who has been recently diagnosed with COVID-19," said Firebrick Executive Chairman, Dr Peter Molloy.

Prior to gaining regulatory approval for any role in the management of COVID-19, Nasodine would likely need to undergo a confirmatory Phase 3 trial in a specific aspect of COVID-19 that is clinically relevant to the management of the disease.

Nasodine has already completed a Phase 3 clinical trial as a treatment for the common cold and Firebrick is preparing to start a second Phase 3 common cold trial this year, in order to support international regulatory approvals, and if the Australian appeal is unsuccessful (ASX announcement 1 March 2022), it will also be used to support approval in Australia.

“While secondary to our focus on the common cold, this Phase 2 COVID-19 trial is important because it may provide proof-of-principle for the reduction of SARS-CoV-2 nasal viral load in patients who are shedding the virus,” said Dr Molloy. “Demonstrating that an agent kills a virus in the laboratory is one thing; proving that it translates clinically is a big step, which we are now taking.”

This announcement was authorised for release by Dr Peter Molloy, Executive Chairman, Firebrick Pharma Limited.

- ENDS -

About the Trial: NASO-ELOCS

The Phase 2 trial was previously approved by SAHPRA (ASX announcement 1 February 2022) and recently also received ethics approval allowing the trial to start recruiting. All published trial details can be found on the South African National Clinical Trials Registry at: https://sanctr.samrc.ac.za/TrialDisplay.aspx?TrialID=5792

The study is a randomised, controlled Phase 2 study. Enrolled subjects will be randomised 2:1 to Nasodine treatment or placebo (Control) by household. The primary aim of the trial will be to show that frequent Nasodine application (every 2 waking hours, up to eight-times-daily) over 3 days leads to a reduction in nasal shedding from culture-positive COVID-19 patients, as measured by the reduction (versus baseline) in $\log_{10}$ of TCID50 titres on Days 2-4 compared with placebo.

Secondary objectives will be to determine if the treatment leads to: (a) people clearing the virus from their nasal passages more quickly based on culture; (b) reduction in the time to a negative RAT (rapid antigen test); (c) overall elimination of SARS-CoV-2 from the upper respiratory tract within 5 days, based on a combined throat/nasal swab; and (d) a beneficial impact on symptoms. The trial is targeted to recruit up to 210 adults, who are COVID-positive by RAT (rapid antigen test), to achieve a primary endpoint target population of 144 subjects who are confirmed by culture, to be shedding SARS-CoV-2 virus.

In addition, the trial will assess the safety and tolerability of applying Nasodine, at a dose of four sprays per nostril (1.12 mL per dose), 20 times over three days. This regimen compares with the treatment regimen tested for the common cold, which is a smaller dose (three sprays per nostril, 0.84 mL per dose), applied 20 times (four-times-daily) over five days.

The trial is being managed by OnQ Research in South Africa on behalf of Firebrick Pharma. Subjects will be recruited at 5 main clinical trial sites around Cape Town: Langeberg Medical

Centre (Dr JS Trokis, Principal Investigator), Tiervlei Trial Centre (Dr MMDV Basson, PI), Be Part Yoluntu Centre (Dr E Hellström, PI), Paarl Research Centre (Dr K Coetzee, PI) and TASK Applied Science (Dr Lee-Ann Davids, PI).

About Firebrick Pharma

Firebrick is a pharmaceutical company founded in 2012 to develop and commercialise a nasal spray treatment for the common cold based around the potential of povidone-iodine as a broad-spectrum antimicrobial agent. On 28 January 2022, Firebrick listed on the ASX under the code 'FRE'. The Company owns numerous granted and pending patents, including a core patent family that covers the use of intranasal povidone-iodine for the treatment and prevention of the common cold. The Company also owns a patent family that covers the use of intranasal povidone-iodine for the prevention of pandemic viral diseases, including COVID-19. During 2022, Firebrick is undertaking two major clinical trials: This Phase 2 trial of Nasodine in COVID-19 and a second Phase 3 trial for Nasodine, to confirm its efficacy as a treatment for the common cold and support international approvals.

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