FirebrickPharma

3 April 2023

ASX Announcement

Nasodine COVID-19 Trial Concludes Recruitment - Results in June 2023

- **Recruitment has closed in the Nasodine COVID-19 Phase 2 Trial**
- **Trial results expected to be announced in June 2023**

Firebrick Pharma Limited (ASX: FRE) (the **Company** or **Firebrick**) is pleased to announce that its Phase 2 COVID-19 trial of Nasodine® Nasal Spray ("Nasodine") has closed for recruitment.

Nasal swabs collected from all subjects have been forwarded to a specialist virology laboratory in the Netherlands for viral culture analysis, which will determine the results on the trial's primary endpoint. These results are expected to be available in June 2023.

The trial (designated FBP-007) commenced in April 2022 at five clinical sites in South Africa (see ASX announcement 26 April 2022). The study is a randomised, controlled Phase 2 study to assess the extent to which frequent daily Nasodine application can stop or reduce shedding of the COVID-19 virus (SARS-CoV-2) in patients with early COVID-19 symptoms.

The protocol involved application of Nasodine (or a placebo nasal spray) 8 times daily over 2.5 days (to a total of 20 doses). This compares with the 4 times daily over 5 days regimen used in the common cold clinical trials conducted by Firebrick to date.

"This frequent dosing was designed to definitively assess the potential for Nasodine to rapidly eliminate the SARS-CoV-2 virus from the nose, which is believed to be the primary site of infection and shedding," said Firebrick Executive Chairman, Dr Peter Molloy. "In addition, we hope the study results will support the safe use of more frequent dosing of Nasodine."

The trial was originally intended to enrol up to 210 subjects but has been abridged to 39 subjects due to the ongoing very low numbers of new cases of COVID-19 in South Africa.

"We are confident that the reduced number of subjects will not impact our ability to detect statistically robust outcomes on the primary and secondary endpoints," said Dr Molloy.

"COVID-19 will not be the last viral pandemic we face," said Dr Molloy. "If the trial results are positive, Nasodine could be at the front line of future pandemic defence strategies."

The Company owns an international patent application covering the use of intranasal povidone-iodine for a range of pandemic viral diseases, including COVID-19. The COVID-19 divisional of this patent has been granted in the US and is pending in other key markets (see ASX announcement 17 February 2022). The patent is titled "Prevention of infection by highly

pathogenic viruses using topical application of povidone-iodine on mucous membranes" and expires in 2040 (Patent No. US 11,246,887).

The main use protected by the US patent is the use of any povidone-iodine formulation in the nose for reducing the viral load of SARS-CoV-2 in people with COVID-19 and it is particularly aimed at healthcare workers involved in front-line pandemic defence roles.

"The results of the Phase 2 trial are very pertinent to this patent since the primary endpoint is to demonstrate reduction or elimination of nasal shedding of the SARS-CoV-2 virus," added Dr Molloy.

Other pandemic viral diseases applied for in the international patent, but not yet granted, include MERS, Ebola, pandemic influenza and any future emergent viruses (of as yet unknown origin and identity) that could cause a pandemic or be used as a bioterror agent.

The trial's overall structure and goals are summarised in the attached slide, which was presented at the Company's Annual General Meeting in November 2022.

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

- ENDS -

About Firebrick Pharma

Firebrick is a pharmaceutical company founded with the mission to commercialise a nasal spray treatment for the common cold based around the potential of povidone-iodine as a broad-spectrum antimicrobial agent. 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 and a second patent family covering the prevention of pandemic viral diseases, including COVID-19. The Company also has a third patent family covering the Nasodine formulation, which has been granted in Australia. Firebrick is currently completing a second Phase 3 trial for Nasodine, to confirm its efficacy as a treatment for the common cold and support international approvals. Positive Phase 3 trial results will also be important for securing regulatory approvals and partnerships in major markets outside Australia.

Media enquiries:

Heidi Cuthbert
+61 411 272 366
heidi.cuthbert@multiplier.com.au

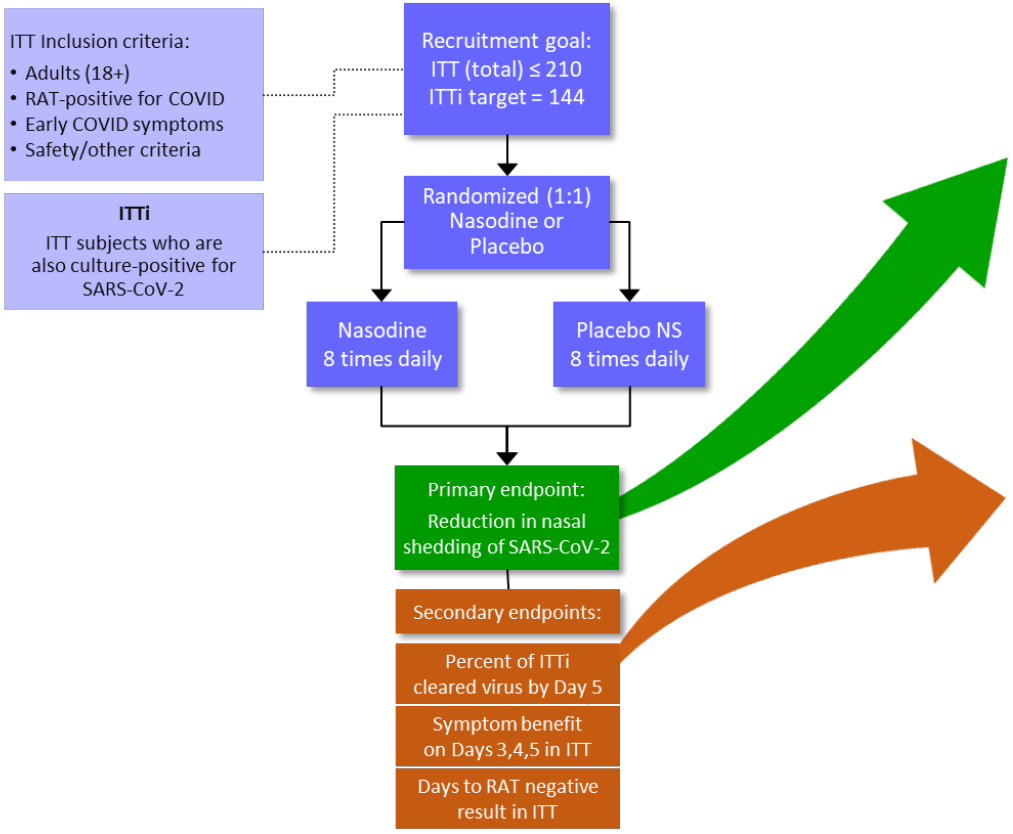
Investor enquiries:

Investors@firebrickpharma.com

FirebrickPharma

Phase 2 COVID-19 trial (FBP-007)

Reduction of nasal shedding of SARS-CoV-2 in COVID-19 positive patients by the use of Nasodine® (povidone-iodine 0.5%) Nasal Spray



Primary endpoint

(proof-of-concept study)

= Reduction in viral load[1] on Days 2-4 versus placebo nasal spray

- Primary study goal is to demonstrate that frequent Nasodine application (8 times daily) causes a significant reduction in viral shedding from the nose and throat (versus placebo nasal spray)

Secondary and Exploratory endpoints

- Does Nasodine treatment lead to faster viral clearance, measured as the percent of ITTi (culture-positive) subjects who clear the virus by Day 5?
- Is there a symptomatic benefit of Nasodine treatment, measured in the ITT (all subjects)?
- Is there a benefit of Nasodine treatment in the ITT in the time it takes to become RAT-negative?

[1] Based on TCID50 results in cell culture, adjusted for baseline