FirebrickPharma

**21 March 2023**

ASX Announcement

# Firebrick Pharma's Phase 3 Trial of Nasodine Resumes

- **Phase 3 Trial of Nasodine for the common cold reopens on schedule**
- **All ethics approvals are in place to resume recruitment at all sites**
- **Recruitment open at 2 Australian sites; 3 South African sites to open next week**
- **Target completion of recruitment is in July 2023**

**Firebrick Pharma Limited** (ASX: FRE) (the **Company** or **Firebrick**) is pleased to announce that its Phase 3 clinical trial of Nasodine Nasal Spray ("Nasodine") as a treatment for the common cold has received the necessary ethics approvals to re-open for the 2023 common cold season.

Two clinical sites in Australia are now open for recruitment and three sites in South Africa will be open in the next week.

This trial was 50% recruited in 2022 and then paused over the summer months, with the stated goal of re-opening in March 2023 (see ASX announcement 31 October 2022, "Firebrick update on Nasodine Phase 3 trial"). This target has been achieved.

The primary endpoint population for the trial is 196 adult subjects with confirmed viral colds. The trial enrolled 100 subjects with confirmed viral colds in 2022, so the goal in 2023 is to enrol the remaining 96 subjects and then report trial results.

"Nasodine works by killing viruses, so establishing its performance in people with actual viral infections is a pivotal proof of efficacy," said Firebrick Executive Chairman, Dr Peter Molloy.

"Typically, the common cold season starts in Autumn, so we expect to see recruitment escalate over the next several months and continue through the winter, with trial completion expected in July."

In Australia, the trial is taking place at Barwon Health (Geelong) and CMAX (Adelaide). Any adult (18+) in Adelaide or Geelong who would like to participate, can find out more information, including eligibility criteria and contact details, via www.firebrickpharma.com/nasodine-common-cold-clinical-trial/

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 completing two major clinical trials: A Phase 2 trial of Nasodine in COVID-19 and a 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.

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# Phase 3 common cold trial (FBP-006)

**Confirmatory Phase III study of Nasodine Nasal Spray (povidone-iodine 0.5%) as a symptomatic treatment for early stage common cold in the natural setting**

ITT[1] Inclusion criteria:
- Adults (18+)
- RAT negative
- <36hrs >symptom onset
- Moderate symptoms
- Safety/other criteria

ITTi Inclusion criteria:
Virus-positive by PCR, excluding SARS-CoV-2

[1] 'Intent To Treat' population

Enrolled subjects
ITT (total) ≤ 500
**ITTi target = 196**

Assumes 43.6% virus positive by PCR of swab on Day 1

Randomized (1:1)
Nasodine: Placebo

Nasodine
ITT ≤ 225

Placebo
ITT ≤ 225

Primary endpoint:
GSS benefit in ITTi Nasodine Vs Placebo

Secondary endpoints:
- GSS in ITT
- GSS in ITT24
- QoL in ITT24
- QoL in ITTi
- QoL in ITT

**GSS = overall cold severity**
Sum of 19 measures
(10 symptom and 9 QoL)

**QoL = quality-of-life**
9 items that measure interference of the cold with daily activities

## Primary endpoint
(primary/definitive measure of efficacy)

= GSS benefit of Nasodine treatment over placebo in subjects with viral infection, i.e., infected ITT ("ITTi")

➢ In the first Phase 3 trial, Nasodine achieved a statistically significant GSS benefit in the viral-infected subjects, despite the small number of subjects (52) and the use of saline as placebo

## Secondary endpoints
(supportive/additional measures of efficacy)

➢ ITT reflects the population likely to use the product (regardless of actual viral infection); therefore GSS and QoL performance in this population is important

➢ ITT24 (treatment started within 24 hrs after symptom onset) reflects the expected usage by most consumers; we expect the GSS and QoL benefit to be higher in this group

➢ QoL in the ITTi is also assessed; if the primary mode of action is by killing viruses, the QoL benefit should be greater in the confirmed viral-infected subjects