

31 May 2023

ASX Announcement

Nasodine Phase 3 Clinical Trial Surpasses 80% Recruitment

Firebrick Pharma Limited (ASX:FRE) (**Firebrick**) is pleased to provide an update on the progress of the confirmatory Phase 3 clinical trial of Nasodine® Nasal Spray (**Nasodine**) as a treatment for the common cold.

The study, which commenced in 2022, aims to recruit 196 subjects with early-stage colds who are confirmed by PCR to have a viral infection (other than SARS-CoV-2). These subjects represent the primary endpoint population for the trial, referred to as the ITT_i¹. At 30 May 2023, 160 ITT_i subjects have been enrolled, representing 82% of the final recruitment target.

In 2022, the trial ran for 26 weeks from 3 May 2022 to 31 October 2022 and recruited 224 subjects with colds (8.7 per week), of whom 45% (100) were virus-positive². The trial was then paused over the summer period and reopened on 21 March 2023³.

In the 10 weeks since it re-opened, another 113 subjects have already been enrolled (11.3 per week), of whom 53% are virus-positive (60), bringing the total ITT_i subjects to 160.

“Both the overall recruitment rate and the virus-positivity rate are significantly higher than we achieved in 2022,” said Dr Peter Molloy, Executive Chairman of Firebrick. “As a result, the weekly ITT_i recruitment has gone up from 3.9 subjects in 2022 to 6.0 subjects in 2023, an increase of 55%.”

“We are now very confident about reaching our target of 196 subjects well before the end of the current cold season,” said Dr Molloy. “As previously telegraphed, we expect to announce headline results during the third quarter.”

The trial results will be used primarily to support international regulatory filings for Nasodine, including a European approval submission.

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

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¹ The “ITT_i” (“Intent-To-Treat-*infected*”) population is to be used for assessment of the primary endpoint. It comprises any subjects that are PCR-positive for a respiratory virus other than SARS-CoV-2. The ITT includes all enrolled subjects and is used for assessment of secondary endpoints.

² Refer ASX announcement 31 October 2022 for trial details

³ Refer ASX announcement 21 March 2023

About Firebrick (ASX:FRE)

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.

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