FirebrickPharma

31 October 2022

ASX Announcement

Firebrick update on Nasodine Phase 3 trial

- **Nasodine Phase 3 common cold trial achieves >50% recruitment**
- **Trial to be paused over summer and resumed in early 2023**

Firebrick Pharma Limited (ASX:FRE) (**Company** or **Firebrick**) is pleased to provide an update on its Phase 3 clinical trial of Nasodine® Nasal Spray ("Nasodine") in the treatment of the common cold (ACTRN12621000604808).

As at 31 October, the trial has so far successfully recruited 224 subjects with early-stage colds into the ITT ('Intent-To-Treat' population), with an estimated 100 qualifying for the primary endpoint population of those with confirmed viral infection (ITT_i)[1], based on PCR of a throat and nasal swab.

This represents at least 51% of the trial's full recruitment target of 196 subjects in the ITTi.

The primary endpoint for the trial is the benefit of Nasodine treatment on overall cold severity[2] in the ITT_i. In the previous Phase 3 trial, Nasodine produced a statistically significant benefit in the 52 subjects who had confirmed viral infection (see p. 20 of the Company's Prospectus).

The current Phase 3 trial was designed to support international registration of Nasodine and if completed by mid-2023, the EU application for approval could be filed by the end of calendar 2023. The US application will require a further Phase 3 trial to be conducted in the US.

"The trial protocol has been executed well and we feel confident in the quality and robustness of the study for international regulatory purposes," said Firebrick Executive Chairman, Dr Peter Molloy.

With summer approaching and to avoid unnecessary trial running costs, Firebrick intends to pause recruitment at all sites from 1 November 2022 and restart in March 2023, with expected completion of recruitment by mid-year.

"The pause over summer will allow us to review site performance and prepare for optimum recruitment at all sites as soon as the cold season starts again next year."

Further details about the trial are included in a Q&A at the end of this announcement.

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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] Overall cold severity is measured by the Global Severity Score (GSS) from the WURSS-21 (Wisconsin Upper Respiratory Symptom Survey, 21 item), which Firebrick has used in its previous Phase 2 and Phase 3 studies.

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

- ENDS -

About the Trial: Q&A

Q. Where can I find details about the trial?

A. The trial is registered on ANZCTR and all details can be found at the following URL: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=381767&isReview=true

Q. Why has the trial only recruited 50% of the targeted number of subjects?

A. The Adelaide site (CMAX) started recruitment in early May 2022 and recruited 50 subjects into the ITT_i, which was 125% of their recruitment target of 40.

Due to HREC approval delays in Victoria, the two Victorian sites (Geelong and Ballarat) did not start recruitment until mid-July; thereafter, recruitment at the two sites was disappointing, collectively contributing 14 subjects to the ITT_i or 18% of their recruitment target of 78.

The Victorian HREC delays also caused minor protocol amendments that delayed the start of recruitment in South Africa until mid-July. Despite this, the South African sites performed well, collectively recruiting an estimated 36 ITT_i subjects or 46% of their target of 78.

When the trial resumes in 2023, the Company intends to continue with the site in Adelaide, three sites in South Africa, and operate a single site in Victoria. It is expected that remaining recruitment will be completed by mid-year in calendar 2023.

Q. What are the aims and endpoints of the trial?

The primary aim (and endpoint) of the trial will be to show that compared with a placebo nasal spray, Nasodine treatment (3 sprays per nostril, 4 times daily for 5 days) leads to a significant reduction in overall cold severity in people who have a confirmed viral cold.

Overall cold severity is measured by the Global Severity Score (GSS) obtained from the WURSS-21 cold survey completed by each participant. GSS is the same measure used as a secondary endpoint in the first Phase 3 trial, against which Nasodine produced positive results in all subsets and statistically significant results in those with a confirmed viral infection and those who started treatment within 24 hours of symptom onset.

Secondary objectives will include:

- Improvement in GSS (versus placebo) in the whole population of enrolled subjects (ITT population) regardless of confirmed viral infection. The ITT represents the population likely to use the product and therefore GSS performance in this population is important.

- Improvement in GSS in ITT24[3]: The ITT24 is those subjects who started treatment within 24 hrs after symptom onset; based on the first Phase 3 study, we expect the GSS benefit in this group to be higher.
- Improvement in Quality of Life (QoL) in ITTi and ITT24: QoL measures the extent to which a cold interferes with daily activities and is an important measure of clinical effect. Nasodine had a consistently strong benefit on QoL in the first Phase 3 trial and we expect the QoL benefit to be greater in the confirmed viral-infected subjects and those who started treatment within the first 24 hours of symptoms.

Q. Will there be an interim analysis conducted on the results for the subjects already recruited?

A. No, the efficacy assessment will be conducted upon completion of the trial. An interim analysis was not provided for in the statistical plan for the trial and on the advice of the Company's statistician experts, any unblinding of results at this stage for the purposes of an interim efficacy analysis would compromise the results for international registration purposes.

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. 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. Firebrick is undertaking two major clinical trials in 2022: 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. Both trials have commenced recruitment.

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[3] "ITT" refers to 'Intent To Treat' population, which is the total population of subjects enrolled in the trial; the "ITTi" refers to those people within the ITT who are shown (post-enrolment) to have a viral infection; only the ITTi is being used for the primary endpoint assessment in this study, with the ITT used for one secondary endpoint and another subset, referred to the "ITT24" (those ITT subjects who started treatment within 24 hours after symptom onset) for other secondary endpoints.