

20 June 2023

ASX Announcement

## Firebrick Pharma Investor Update on Key Projects

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- **Nasodine Phase 3 clinical trial reaches 100% of recruitment target; trial recruitment to continue through July**

**Firebrick Pharma Limited (ASX:FRE) (Firebrick, Company)** is pleased to provide the following update on the Company's key projects, which will be provided verbally by the Executive Chairman at a General Meeting of Shareholders, today.

- (1) Phase 3 clinical trial of Nasodine® Nasal Spray (Nasodine): This trial started in 2022 and is a pivotal trial of Nasodine as a treatment for the common cold; the primary purpose of the trial is to support international registrations and partnering. The target recruitment is 196 subjects with cold symptoms and a confirmed viral infection, referred to as the ITTi (the 'Intent-To-Treat-infected' population).

On 31 May 2023, we announced that 160 ITTi subjects had been recruited, equivalent to 82% of the recruitment target for the trial. Since then, the recruitment rate has accelerated and on 18 June 2023, we reached the original target of 196 ITTi subjects.

Given the outstanding recruitment rate this year and the statistical benefits associated with larger patient numbers, we intend to continue recruiting beyond the original target of 196 subjects. No amended ITTi target has been set, but at this stage, we expect to complete recruitment by the end of July, which is in line with our previously announced completion schedule.

In addition to this change in the target recruitment, we have been advised by our statistical experts to make minor modifications to the descriptions of certain endpoints in the trial protocol. These minor amendments to the protocol have been submitted to the relevant ethics committees in South Africa and Australia and has been approved in Australia and South African approval is expected to be forthcoming.

As previously indicated, we expect to announce headline results from the trial before the end of the third quarter (i.e., before 30 September 2023).

- (2) Phase 2 COVID-19 shedding study of Nasodine: This is a study of the impact of the frequent use of Nasodine (8 times daily over 3 days) on nasal shedding of SARS-CoV-2 in people with COVID-19. As noted in our announcement of 3 April 2023, the recruitment phase of this study has concluded and we have been awaiting the final results from viral culture analyses. The blinded results have now been received, and subject to satisfactory completion of a statistical analysis plan, we expect to announce headline results in the next two weeks.

- (3) Administrative Appeals Tribunal (AAT) process: This appeal seeks to overturn TGA's decision not to approve Nasodine based on the existing Phase 3 data. If successful, it could lead to approval of Nasodine in Australia. As noted in our announcement on 29 May 2023, the conciliation meeting, previously scheduled for 30 May, has been deferred due to the unavailability of the originally nominated AAT Member. The new conciliation date will be announced once it is agreed between the Parties.

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

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### **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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