FirebrickPharma

3 October 2023

ASX Announcement

Update on Nasodine Trial and Forward Plans

- **Preliminary investigation into Phase 3 common cold trial results completed**
- **Firebrick committed to the development of Nasodine for the common cold**
- **Potential opportunities beyond the common cold to generate early sales**

Firebrick Pharma Limited (ASX:FRE) (**Firebrick, Company**) announces that the independent preliminary investigation into the Phase 3 trial results of Nasodine Nasal Spray ("Nasodine") (refer ASX announcement 13 September 2023) has not revealed any systematic error or other data issue that could explain or disclaim the reported results. The preliminary investigation phase has now been closed to avoid additional costs, but further internal analysis supported by expert advice will continue.

The Company remains committed to the development of Nasodine for the common cold. This includes alternative study designs and/or other aspects of the illness that may accelerate regulatory approvals.

"We believe that the development of Nasodine as a treatment for the common cold ultimately will be successful," said Firebrick Executive Chairman, Dr Peter Molloy, "but proving this using a controlled clinical trial design is challenging." The recognised challenges are that there is no objective outcome measure for the common cold, it is difficult to recruit subjects early enough to demonstrate a difference in a rapidly self-resolving illness, and an intranasal placebo can obscure the treatment effects by impacting reported symptoms.

The current trial was designed mainly to support EU registration of Nasodine as a treatment for the common cold (refer ASX announcement 9 August 2023) and built upon the previous Phase 3 trial which generated several positive outcomes. The EU filing has now been deferred, pending decisions about a future common cold trial and assessment of alternative approval pathways in the EU and elsewhere. In Australia, the Company plans to continue its discussions with the TGA, while its AAT appeal remains ongoing.

In addition, the Company will also actively pursue opportunities beyond the common cold. For example, Firebrick's recent Phase 2 COVID-19 study (ASX announcement 7 August 2023) demonstrated 100% clearance of SARS-CoV-2 from the nasal passages, indicating Nasodine could play an important role as a nasal disinfectant in a future pandemic.

"We have a patented, high-quality product, that is manufacturing ready with a 2-year shelf life, and it is safe and well tolerated based on extensive human studies," said Dr Molloy. "It kills all respiratory viruses *in vitro* and human studies have demonstrated that it reduces the viral load in the nose and throat."

The Company believes that the product can be made available for uses other than the common cold and could potentially generate early sales in several markets, starting in 2024. The Company will provide more information on these plans when details are finalised.

In the meantime, the Company has taken action to reduce its cash expenditure to preserve funds to support its plans and expects to receive a substantial RDTI payment in the current month.

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 in 2012 with the mission 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 patents, know-how and other intellectual property around the use of intranasal povidone-iodine.

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

Investor enquiries:
Investors@firebrickpharma.com