FirebrickPharma

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ASX Announcement

Firebrick Investor Update

- **Investigation into Phase 3 trial results completes: Expert study points to inaccuracies in trial efficacy data and no efficacy conclusions can be drawn**
- **Firebrick to market Nasodine as a nasal antiseptic/disinfectant with sales expected to commence in 2024**

Firebrick Pharma Limited (ASX:FRE) (**Firebrick, Company**) is pleased to provide an update to investors on the Company's key projects relating to Nasodine® Nasal Spray (**Nasodine**):

(1) Phase 3 common cold clinical trial investigation

As noted in the Company's announcement of 3 October 2023 and the September Quarterly Activity Report (**QAR**), Firebrick has been continuing its investigation into the results of the 2022-2023 Phase 3 common cold trial (**2023 Trial**). Recently, the Company engaged an expert in data analysis and modelling to independently review the 2023 Trial data, and for comparative purposes, the data from the first Phase 3 trial (**2019 Trial**). The project scope was restricted to efficacy data from Australian sites only, as this permitted a direct comparison between the two trials, and because the Australian results of the 2023 Trial displayed the greatest deviation from expected outcomes.

The expert analysis assessed the data from the trials for their fit with a human model of respiratory illness recovery, which was built on Australian healthcare data over five recent years (2018-2022). The Company has now received the expert report, which concluded in summary:

(a) The 2019 Trial placebo results conformed strongly with the human model; the Nasodine results also conformed with the model but showed an accelerated and amplified wellness recovery pattern compared with both the model and the placebo. The expert concluded: "Overall, the 2019 modelling suggested that the data were robust and consistent with a positive therapeutic effect of the active."

(b) The 2023 Trial data – for both placebo and Nasodine – starkly contrasted this; the 2023 Trial data showed an incongruous convergence between the placebo and active, and both the placebo and Nasodine data showed a flattened recovery pattern that was inconsistent with both the human model and the 2019 Trial. The expert concluded: "The model outcomes strongly indicate major inaccuracies in the 2023 trial data, casting doubt on its reliability. This raises significant concerns about using the 2023 data to draw conclusions about the efficacy of the active versus placebo in that trial."

No conclusions could be drawn from the modelling or the Company's previous investigations as to the cause of the inaccuracies in the 2023 Trial data. However, the impact of the COVID pandemic on patient reported symptoms and quality of life measures used in the study could be a factor.

The Company emphasises that it has no concerns about the reliability or accuracy of the safety data from the 2023 Trial. Those data were collected independently, were consistent with the 2019 Trial and confirmed the favourable safety profile of Nasodine.

The modelling project brings to a close all investigations into the 2023 Trial. Firebrick will now proceed with all previously deferred trial closure activities (refer to QAR), including processing of all other (non-efficacy) patient data, database lock and preparation of a clinical study report.

As stated in the QAR, Firebrick remains committed to the development of Nasodine for the common cold but will now consider alternative study designs that could avoid the problems experienced in the 2023 Trial. There are no immediate plans to repeat the 2023 Trial.

"We firmly believe Nasodine works as a treatment for the common cold, if used at the first signs of a cold, but demonstrating that fact in a natural setting trial design is challenging," said Executive Chairman, Dr Peter Molloy.

(2) Marketing of Nasodine as a nasal antiseptic/disinfectant

In addition to its ongoing development for the common cold, Firebrick believes that there is an important early opportunity for Nasodine as a nasal antiseptic/disinfectant for elimination of microbial pathogens in the nasal passages.

Based on published literature, PVP-I has been shown *in vitro* to be highly active against MRSA and other nasal bacteria. Firebrick's recent COVID-19 Phase 2 study results (announcement 7 August 2023) also demonstrated that Nasodine emphatically reduces viral shedding in a clinical setting.

The Company is exploring further clinical studies to support registration opportunities as a nasal antiseptic/disinfectant. However, the Company now has regulatory advice that Nasodine can be legally marketed in several countries as a nasal antiseptic/disinfectant without further clinical studies. For commercial reasons, the Company cannot disclose which countries, but sales are expected to commence in 2024.

"This is an exciting new opportunity for Firebrick," said Dr Molloy. "Previously, we focused on securing Australian approval and exporting internationally; we have now moved to an international strategy, which achieves our goal of making Nasodine available and generating earlier revenues."

This announcement was authorised for release by the Board of 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 povidone-iodine nasal spray (www.firebrickpharma.com). The Company has successfully developed a povidone-iodine nasal spray, called Nasodine® Nasal Spray and filed international trademarks and multiple patents on the product, including a formulation patent and two use patents, some of which have already been granted in the US, Europe and Australia. The Company has also completed six clinical trials for Nasodine, including a Phase 1 study, three Phase 2 studies and two Phase 3 studies, which have affirmed the product's safety and generally supported its efficacy as an antimicrobial nasal spray with utility in a range of clinical settings.

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