FirebrickPharma

1 March 2022

ASX Announcement

Firebrick to file appeal seeking immediate approval of Nasodine

Firebrick Pharma Limited (ASX:FRE) (**Company** or **Firebrick**) announced today that it had decided to file an appeal against TGA's initial decision not to approve Nasodine® Nasal Spray ("Nasodine") for sale in Australia, based on the existing clinical data.

If successful, the appeal could lead to approval of Nasodine sometime in 2022. If unsuccessful, the Company will re-submit to TGA at the end of the year upon completion of the already planned second Phase 3 trial to commence in the first half of this year.

"The potential for an appeal was telegraphed in our prospectus," said Firebrick Executive Chairman, Peter Molloy. "Today, we have decided to proceed with that appeal."

The Company's prospectus stated (Section 2.4.3, p.21) that Firebrick was waiting for a formal letter from TGA confirming its decision and the reasons not to approve Nasodine in Australia based on the existing data; and that upon reviewing those reasons, the Company would decide whether to file an appeal. Having recently received that letter, Firebrick has decided to proceed with the appeal and today appointed legal counsel experienced in prosecuting TGA appeals.

"Nasodine is clearly safe and has met all of the TGA's stringent quality and manufacturing requirements, with the TGA delegate's residual concern being whether there is sufficient proof of clinical efficacy as a treatment for the common cold," said Firebrick Executive Chairman, Peter Molloy.

"We believe that the first Phase 3 trial in 2019 sufficiently supports the clinical efficacy of Nasodine to allow approval in Australia, without additional studies," added Dr Molloy. "This appeal allows us to present our case to a new delegate and potentially achieve approval this year, while we also complete a second Phase 3 trial this coming winter."

The second Phase 3 trial was also outlined in the prospectus and is designed to confirm Nasodine's clinical efficacy as a treatment for the common cold. The trial was originally intended to support international regulatory approvals, but if the Australian appeal is unsuccessful, it will be used to support approval in Australia as well.

The appeal is technically referred to as a "Section 60" appeal, because it is provided for under Section 60 of the Therapeutic Goods Act. Under the Act, companies can appeal to the Minister of Health seeking reconsideration of a TGA decision not to approve a medicine. The Company has until 20 May 2022 to file its Section 60 appeal submission to the Minister of Health and thereafter, the Minister or a delegate has two months to reach a decision and advise the

Company. Refer “About Section 60 Appeals” below for more information on the appeals process.

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

- ENDS -

About Section 60 Appeals

Under section 60 of the Therapeutic Goods Act, a company can submit to the Health Minister a request for reconsideration of (i.e., appeal) an initial decision by the TGA. The Minister may either personally undertake the reconsideration or delegate it to an officer of the TGA. The Minister (or delegate) must give notice in writing of the reconsideration decision within 60 calendar days after receiving the request for reconsideration. More information is available on the TGA website at: https://www.tga.gov.au/reconsideration-reviewable-initial-decisions

About Firebrick (ASX:FRE)

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. During 2022, Firebrick is undertaking two major clinical trials: 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.

Media enquiries:

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

Investor enquiries:

Investors@firebrickpharma.com