FirebrickPharma

9 September 2024

ASX Announcement

Nasodine European Marketing Application filed and passed validation

- **Firebrick has filed an application for marketing of Nasodine in Europe, seeking approval for use as a nasal antiseptic.**
- **The application has now passed validation and entered the evaluation phase.**
- **The initial evaluation phase could be completed by 19 December 2024.**

Firebrick Pharma Limited (ASX:FRE) (**Firebrick, Company**) is pleased to announce that it has filed a Marketing Authorisation Application ("MAA") in Europe for the approval of Nasodine® Nasal Spray ("Nasodine") as a nasal antiseptic. The MAA has successfully passed validation and has now entered the evaluation phase.

The application was filed via a decentralised procedure, where one EU member state, referred to as the Reference Member State ("RMS"), leads the review of the application. Other EU member states, called the Concerned Member State ("CMS"), conduct a parallel assessment. For this MAA, Sweden serves as the RMS, with the Medical Products Agency ("MPA") leading the review. Iceland is the CMS, with the Icelandic Medicines Agency ("IMA") conducting a parallel assessment. Following approval in these 'States', approvals in other EU countries could proceed under the mutual recognition procedure.

The Company has received advice from both the MPA and the IMA that the dossier is valid and is now under evaluation. While this validation indicates that the dossier is complete and ready for review, it does not reflect the likelihood of approval.

Based on the timetable provided by the MPA, the initial evaluation phase could be completed by 19 December 2024 (Australian time) at which time Firebrick may address any questions raised by either Member State. Final approval, if granted, is unlikely to be earlier than mid-2025.

Should approval be obtained, or a positive outcome appears likely, the Company will move forward in line with its strategy as outlined in the Annual Report for the year ended 30 June 2024, to seek one or more marketing partners in Europe. These partners would be responsible for manufacturing, distribution and marketing to all target markets, including consumers, doctors, hospitals and government.

"Filing for approval in Europe is an important step forward in our strategy to make Nasodine widely available as a nasal antiseptic," said Dr Peter Molloy, Executive Chairman of Firebrick. "Approval success of this application will initiate access to the 27 countries of the EU."

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

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About Firebrick (ASX:FRE)

Firebrick Pharma is a pharmaceutical innovator focused on developing and commercialising novel formulations and uses of povidone-iodine (PVP-I). The Company has successfully developed a PVP-I nasal spray (Nasodine® Nasal Spray) and filed international trademarks and multiple patents on the product. The Company has also completed six clinical trials that have affirmed the product's safety and generally supported its efficacy as an antimicrobial nasal spray with utility in a range of clinical settings. Firebrick is now commercialising Nasodine in international markets, with the product already launched in the United States and Singapore.

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