FirebrickPharma

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ASX Announcement

FRE files EU Paediatric Investigation Plan for Nasodine

- **Firebrick files Paediatric Investigation Plan (PIP) in advance of planned European marketing application for Nasodine**
- **PIP anticipates expansion of Nasodine use to children**

Firebrick Pharma Limited (ASX: FRE) (the **Company** or **Firebrick**) is pleased to announce that the Paediatric Investigation Plan (**PIP**) for Nasodine® Nasal Spray (**Nasodine**) has been filed with the European Medicines Agency (**EMA**) Paediatric Committee (**PDCO**), in preparation for filing for marketing approval of Nasodine in Europe later this year.

A Paediatric Investigation Plan or 'PIP' is a development plan aimed at ensuring that the necessary data are obtained through studies in children, to support the authorisation of a medicine for use in children and not just in adults. The PIP must be accepted by the PDCO prior to filing a European Marketing Authorisation Application (MAA) for use of a medicine in adults.

"The PIP can often take up to nine months to be accepted by the PDCO, so filing it at this time was critical to achieving our planned filing of the Nasodine MAA later this year, after we have the results of our second pivotal common cold trial in adults," said Firebrick Executive Chairman, Dr Peter Molloy.

The PIP addresses the development program for Nasodine in children, which will take place after Nasodine is approved in Europe for adult use. The PIP anticipates two pivotal clinical trials – the first in adolescents (children aged 12-17) and the second in children aged 6-11.

The PIP proposes that the trials focus on safety and compliance only, because efficacy as a treatment for the common cold can be extrapolated from the results of the adult Phase 3 trials, the second of which is expected to be completed this year.

The PIP also proposes that for children aged 6-11, a Nasodine 'junior' product form will need to be developed, incorporating a smaller spray device and bottle; however, adolescents 12-17 would use the same product form and dosage as adults.

If the proposed paediatric studies are accepted and then successfully completed, Firebrick would seek approval for use of Nasodine in both paediatric subsets in Europe as well as in Australia.

"As every parent knows, children suffer a much higher frequency of colds than adults and often pass on the infection to other family members," said Dr Molloy. "Having Nasodine approved for use in children would be a boon for parents everywhere, and a significant expansion of the addressable market for Nasodine."

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

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About Firebrick Pharma

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. Firebrick is completing 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. Positive Phase 3 trial results will also be important for securing regulatory approvals and partnerships in major markets outside Australia.

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