FirebrickPharma

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ASX Announcement

Phase 3 Common Cold Trial Results

Firebrick Pharma Limited (ASX:FRE) (**Firebrick, Company**) announces that trial statisticians have completed their efficacy analysis of the headline results in the Phase 3 trial of Nasodine® Nasal Spray ("Nasodine") as a treatment for the common cold.

The analysis has shown that the trial did not meet its primary endpoint, which was the impact of Nasodine on overall cold severity (GSS) in subjects with a confirmed viral infection (ITTi). Based on the reported results, the placebo (sterile water) performed better than Nasodine. In the QoL ('quality-of-life') measure (functional impairment caused by a cold), the results were also in favour of the placebo in the ITTi. Similar enigmatic results were seen in other population subsets.

The results provided to the Company are shown in the table titled: **Trial Headline Results Summary**. These results are compared in summary form with the previous (2019) Phase 3 trial in the table titled: **Phase 3 Trial Comparisons on Key Endpoints.**

The 2019 trial used the same protocol and treatment regimen as the current (2022-23) trial and both trials were robust Phase 3 trials. The 2019 trial took place in Australia, so a comparison of the results with the current trial for Australian sites only has been undertaken (not shown in summary tables). In the 2019 trial, the GSS benefit of Nasodine in the viral-infected subjects (N=52) was 22.9% (p=0.048), but in the current trial, for Australian sites, the benefit was reversed, with the water placebo outperforming Nasodine by 22.7% in the ITTi (N=181), the result being statistically significant (p=0.024).

"Given that sterile water has no antiviral properties and povidone-iodine is a proven potent antiviral agent, the reported results of the current trial are inexplicable," said Firebrick Executive Chairman, Dr Peter Molloy. "They are scientifically confounding and completely at odds with everything we know about povidone-iodine and the results of the first Phase 3 trial."

The reported results also appear to conflict with the Company's recently reported Phase 2 COVID-19 trial, where Nasodine treatment led to 100% clearance of the SARS-CoV-2 virus from the nasal passages. That result was significantly better than the placebo (p=0.028), which was the same water placebo as used in the 2022-23 Phase 3 trial.

The Company is concerned that the results are so confounding, unexpected and at odds with previous data that there may be a systematic error or other issue in the data, and a detailed analysis is now underway to try to identify any causes of such an error. To that end, the Company is working with the Contract Research Organisation (CRO) responsible for trial governance and other service providers to thoroughly investigate the trial results. At this time, there is no evidence that the placebo and Nasodine treatments were switched during production, distribution or treatment.

The Company will keep investors informed once the investigation is completed, or otherwise as more complete information becomes available.

"We continue to believe in Nasodine and its utility in the treatment of the common cold and will pursue all available avenues to create value for this important asset," said Dr Molloy.

Trial Headline Results Summary

Outcome	Population subset[a]	Placebo N LSMean Change # (95% CI)	Nasodine N LSMean Change # (95% CI)	Difference * (95% CI)	p-value of difference
GSS (global severity score)	ITTi	123 -34.5 (-38.0, -31.0)	136 -30.0 (-33.3, -26.6)	4.53 (-0.4, 9.4)	0.069
	ITT	247 -32.6 (-35.2, -30.1)	250 -31.3 (-33.8, -28.8)	1.32 (-2.3, 4.9)	0.471
	ITT24	88 -30.4 (-34.9, -25.9)	90 -31.8 (-36.3, -27.4)	-1.42 (-7.8, 4.9)	0.659
QoL (Quality-of-Life score measuring functional impairment)	ITTi	123 -16.5 (-18.3, -14.7)	136 -13.6 (-15.3, -11.9)	2.91 (0.4, 5.4)	**0.024**
	ITT	247 -14.6 (-16.0, -13.3)	250 -13.5 (-14.9, -12.2)	1.10 (-0.8, 3.0)	0.256
	ITT24	88 -13.4 (-15.7, -11.0)	90 -13.5 (-15.8, -11.2)	-0.13 (-3.4, 3.2)	0.938

[a] ITTi = viral infected population; ITT = all subjects; ITT24 = subjects who started treatment within 24 hours of symptom onset
LSMean Change over Days 2-6 for GSS and QoL
* Difference is Nasodine LSMean – Placebo LSMean

Phase 3 Trial Comparisons on Key Endpoints

Outcome	Population subset	2022/23 Phase 3 Trial		2019 Phase 3 Trial	
		N	Nasodine % Benefit over Placebo	N	Nasodine % Benefit over Placebo
GSS	ITTi	259	-13.1%	52	**22.9%***
	ITT	497	-4.0%	260	12.6%
	ITT24	178	4.7%	29	**39.7%***
QoL	ITTi	259	**-17.6%***	52	**32.1%***
	ITT	497	-7.5%	260	**16.1%***
	ITT24	178	1.0%	29	37.1%

* Statistically significant

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 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 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