

## ASX ANNOUNCEMENT

Brisbane, 4 May, 2017

### ADMEDUS RELEASES RESULTS OF HSV-2 PHASE IIa STUDY

- Study meets primary endpoint in terms of vaccine safety
- Positive T-cell response in study subjects receiving vaccine

Admedus Limited (ASX: AHZ) today announced the final results from its Phase IIa Herpes Simplex (HSV-2) vaccine study. The trial reached its primary endpoint of safety, with a positive immune response to the vaccine seen in most subjects. The study enrolled a total of 44 subjects, and was not designed to look at statistical significance between the vaccine and placebo for any of the endpoints.

“This study is consistent with the findings from our first human study that the novel vaccine technologies that were protective in a published animal model of HSV infection appear able to induce immune responses in human subjects with HSV infection, and has provided support suggestive of a possible impact on HSV associated disease,” said Professor Ian Frazer, Chief Scientific Officer.

“The research provides a foundation for Admedus Limited to consider sponsorship possibilities for a study with a large enough population to determine the efficacy of the induced immune response against HSV-2. The results warrant examination of alternative delivery approaches and dosage variations to conclude whether there is a treatment benefit in a large population,” stated CEO Wayne Paterson.

An overview of results is included below. For additional data, please refer to the related webinar HSV-2 presentation slide deck. The Company is aiming to publish the complete data analysis in the future.

## **Results Overview**

A total of 44 subjects were enrolled in the study. Each subject received two intradermal injections of vaccine or placebo, in one of two group allocations. Group 1 received vaccination in each forearm and Group 2 received vaccination in one forearm. The subjects were equally allocated to the groups and 34 received vaccine while 10 received placebo. All adverse events related to – or probably or possibly related to – the vaccine were considered mild, except for one adverse event, which was considered moderate, and none of these resulted in any subjects withdrawing from the study. There were eight withdrawals from the study, one due to anxiety, one that was lost to follow-up and the rest for personal reasons. Two subjects withdrew after the first vaccination and the remainder after the third vaccination.

Although this was a small safety study not powered for efficacy, a number of encouraging trends on clinically relevant endpoints were observed.

The study found that there was a statistically significant 52% reduction in viral shedding rate for vaccine recipients, when the post-vaccine period was compared with pre-vaccine, and a non-significant 31% reduction in shedding was observed over the course of the study for the subjects receiving placebo. When the extent of reduction in shedding was compared between the vaccine and the placebo groups, however, the reduction associated with vaccine was non-significant.

The number of lesion outbreaks per year was compared between baseline screening, post-vaccination and post-booster periods. There were significant reductions in overall outbreak frequency observed post-vaccination and post-booster compared to baseline in the vaccine recipient group. However, no significant change in outbreak frequency was seen when the vaccine and placebo groups were compared.

The median time to first outbreak recurrence after immunisation was 6.6 months for the vaccine group, compared to 1.2 months for placebo group. However, the difference between groups did not reach statistical significance.

When comparing the subjects with no outbreaks over all the shedding periods, the vaccine group had 10 subjects with no outbreaks (29.4%) compared to one subject (10.0%) in the placebo group. There was no significant difference in viral load between vaccine and placebo groups at any time during the study period.

Given the study population consisted of HSV-2-infected individuals, gD2-specific antibodies were detected in all subjects prior to the first vaccination. Administration of the vaccine did not significantly increase antibody levels in any subject.

In contrast, approximately 35% of subjects in the vaccine group (compared to 0% of placebo subjects) displayed increases in gD2 peptide-specific CTL responses following the third vaccination. It is possible that some of the observed increases in CTL were the result of lesion outbreaks. However, it seems likely that the increases are primarily the result of the vaccine as many of the increases did not correlate with outbreaks, and there were outbreaks without accompanying CTL increases in both the vaccine and placebo groups.

Analysis of the punch biopsy taken from the injection site indicated that the vaccine strongly stimulated local inflammatory activity, including T cell recruitment. However, as the placebo did not contain control empty vector DNA, it is not possible to conclude whether the inflammatory response was specific to the gD2 antigen, or a response to the vaccine DNA backbone. Further testing will investigate the specificity of the local cellular response.

For more information, please contact:

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**About Admedus Limited**

Admedus (ASX: AHZ) is a specialist healthcare company. Our focus is on investing in and developing next generation technologies with world class partners, acquiring strategic assets to grow product and service offerings and expanding revenues from our existing, profitable medical sales and distribution business. The company has assets from research & development through clinical development as well as sales, marketing and distribution.

Admedus has commercialised its innovative tissue engineering technology for regenerative medicine in four continents. We also have a major interest in developing the next generation of vaccines with a Brisbane-based research group led by Professor Ian Frazer. The vaccine programmes target disease with significant global potential, such as Herpes and Human Papillomavirus.

More information about the company can be found online:

Website: [www.admedus.com](http://www.admedus.com)

Twitter: [@ADMEDUS](https://twitter.com/ADMEDUS)