

## **ASX ANNOUNCEMENT**

### **Interim HSV-2 Phase II clinical trial data encouraging**

- No safety issues noted
- Study ongoing; interim analysis on un-blinded data expected during Q3 2016
- Average rate of viral lesions in patients who completed dosing versus baseline decreased
- Study shows reduction in average number of days HSV-2 detected in patients versus baseline

### **Brisbane, Australia 4 March 2016**

Admedus Limited (ASX: AHZ) today announced the results of a scheduled, blinded, pooled analysis of data from the first 20 patients to receive at least three vaccinations in the randomised, placebo-controlled HSV-2 vaccine Phase II study.

The data showed that:

- No safety issues have been noted in this cohort of patients. The data remains blinded to protect the integrity of the trial.
- Study participants had a marked decrease in viral lesions (outbreaks) with a drop of over 90% in the monthly rate versus baseline.
- The average number of days HSV-2 was detected in patients was reduced versus baseline.

“We are encouraged by the results of this planned review of blinded data from our placebo controlled HSV-2 Phase II clinical trial. The decrease in the rate of outbreaks compared to the baseline following administration of the booster, and the reduction in the number of days the virus was detected in patients, is very important for this interim review. In addition, no safety issues were noted, which is the primary endpoint of the Phase II trial. We look forward to the next scheduled analysis, which will be more extensive and will be performed on unblinded data, giving us further insight into the data set. We anticipate this will be completed in the Q3 2016,” said Admedus CEO Mr Lee Rodne.

This prospectively designed, double blinded, placebo-controlled trial has randomised 44 patients (above the 40 prospectively defined number) to receive the Company’s COR-1 HSV-2 vaccine or placebo in a 3:1 ratio. The patients are divided into two treatment Groups; Group 1 (22 patients) receives a double inoculation split across both arms and Group 2 (22 patients) receives the double inoculation into one arm. The primary endpoint of the study is safety with secondary and investigative endpoints including various virological and immunological assessments such as occurrences of outbreaks (lesions), viral shedding, viral load, T-cell and antibody counts as well as safety. Post vaccination/booster virological assessments occurred over a time period of 45 days

commencing seven days after the third administration (booster administrations) respectively. This data is compared to the baseline virological assessments of each patient occurring for a period of 45 days prior to any vaccination.

“The initial data appears encouraging and we look forward to additional data from this study being released later this year,” said Professor Ian Frazer.

In this scheduled blinded review announced today, data from the first 20 patients to have received three vaccinations (14 had also received the booster) were analysed in a blinded, pooled fashion. Patients were assessed for monthly viral outbreaks and percentage of days where HSV-2 was detected in swabs taken from the patients relative to analogous pre-vaccination measurements as a baseline.

At this point the data remains blinded and therefore no definitive conclusions can be made. The Company plans an analysis of the unblinded data from these 20 study participants to be performed during Q3 2016. This will include assessment of the immunological endpoints including T cell response, as well as clinical and virological data. To date, six patients have withdrawn from the trial for reasons unrelated to vaccine safety, some of whom received their vaccination. Admedus anticipates all study groups to have completed their dosing, including booster, by Q4 2016 and full trial analysis data to be available by Q2 2017.

Figures released by the World Health Organisation (WHO) in October 2015 stated that 417 million people in the 15-49 age group are living with HSV-2. As a result, a successful HSV-2 vaccine could potentially address a market worth more than US\$6 billion.

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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.

Further information on the company can be found on [www.admedus.com](http://www.admedus.com)

### **About Admedus Immunotherapies**

Admedus Immunotherapies was founded in 2000 by the founder inventor Professor Ian Frazer as a private unlisted company, to develop and commercialise patented technology for improving immune responses to DNA vaccines licensed by UniQuest Pty Ltd and developed at the University of Queensland. The company has laboratories within the Translational Research Institute at the Princess Alexandra Hospital in Brisbane. The company's overall objective is to utilise its unique optimisation technology to produce prophylactic and/or therapeutic DNA vaccines for a range of infectious diseases and cancers in humans.

### **About Admedus Immunotherapies' optimised technology**

Admedus Immunotherapies has 6 granted US patents protecting its codon optimisation DNA technology, which enhances protein expression in the cell or tissue targeted and results in an improved humoral response. The second component of the technology, also patent protected, is to use a mixture of DNAs encoding ubiquitinated and non ubiquitinated proteins. This strategy enhances the degradation of the protein and optimises T cell responses, while preserving structural epitopes necessary for B cells responses, resulting in vaccines with prophylactic and therapeutic potential.

### **About Genital Herpes**

This disease often results in recurrent painful sores in the genital area. HSV-2 is the major causative agent of genital herpes. As well as pain and discomfort to infected individuals, the virus can have serious health implications for babies born to infected women. Herpes is also believed to aid in the transmission of HIV. Current herpes treatment involves the use of antiviral drugs which can reduce, but not eliminate, outbreaks and shedding and therefore do not prevent spread of the disease. According to research reported in Biomed Central's journal BMC Infectious Diseases, the economic burden of genital HSV infection and resulting complications has been estimated to be greater than \$1 billion annually in the USA alone.