

ASX ANNOUNCEMENT

ADMEDUS ANNOUNCES POSITIVE UNBLINDED HSV-2 PHASE II INTERIM DATA

- 58% decrease in viral shedding in those receiving vaccine
- No safety issues relating to the vaccine
- Immune responses were generated only in the vaccine group
- Unblinded analysis on first 20 patients (15 vaccine, 5 placebo)
- Recommendation, following independent review, to progress vaccine
- Full results from the completed study are expected in 1H 2017

Brisbane, Australia 19th October, 2016

Admedus Limited (ASX: AHZ) today announced positive headline results from an interim analysis of unblinded data from the first 20 patients, enrolled in the Herpes Simplex (HSV-2) Phase IIa study. This follows a press release dated 4 March 2016 announcing encouraging data from an earlier blinded interim analysis of this study.

Of the 20 patients analysed, 15 received a vaccine while 5 received a placebo. In the vaccine group, a lower virus shedding rate was observed in post vaccination and post booster periods when compared with baseline screening. There was a 58% reduction in viral shedding rate in post booster when compared with baseline. No significant viral shedding rate reduction in post vaccination and post booster periods was not observed in the placebo group (see Figure 1 below).

“The data seen from the first 20 patients, which has been independently reviewed, is very encouraging when compared to results seen from other similar vaccines in the clinic and continues to support further development of the product. It also provides us with clinical proof-of-concept data around the core technology which has been developed by Professor Ian Frazer,” said Admedus Chair and interim CEO, Mr Wayne Paterson.

Whilst not formally reviewed as part of the full analysis of the unblinded pool data, there have been no safety issues for the first 20 patients or for any of the patients that have entered the study to date. All patients in the study have now completed vaccinations. It is expected that full results from the completed trial will be available in 1H 2017.

“The shedding rates look encouraging and I look forward to seeing the complete data in 2017,” said Professor Ian Frazer, CSO Admedus Immunotherapies.

The number of lesion outbreaks per year was compared between baseline screening, post vaccination and post booster. For the vaccine group, the overall outbreak frequency was reduced by 52% post vaccination compared with baseline. Further, an 81% reduction in overall outbreak frequency was observed post booster compared to baseline. However, a similar trend was also observed in the placebo group.

The recommendation following an independent expert review of this data, relative to results seen in other HSV-2 vaccine studies currently in the clinic, is to continue to progress the development of the vaccine.

Additional Study details

Study Design

This prospectively designed, double blind, placebo-controlled trial randomised 44 patients (8 patients subsequently withdrew from the study to date with none relating to issues from the vaccine) to receive the Company's COR-1 HSV-2 vaccine or placebo in a 3:1 ratio. The patients were divided into two treatment Groups; Group 1 (22 patients) received a double inoculation split across both arms and Group 2 (22 patients) received the double inoculation into one arm. Following baseline assessments each patient received three doses of vaccine or placebo (two vaccinations per dose) four weeks apart and a booster at 6 months post the 1st vaccination. A final follow-up and assessment was conducted after an additional 6 months. All patients enrolled in the study have received all doses.

The primary endpoint of the study was safety, with secondary and investigative endpoints including various virological and immunological assessments such as occurrences of viral shedding, viral load, outbreaks (lesions), 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 data reviewed and announced today relates only to the first 20 patients that entered into the study. Individual patient data will be received in 2017 and will include not just the first 20 but all patients in the study and will enable review of individual vaccine responses.

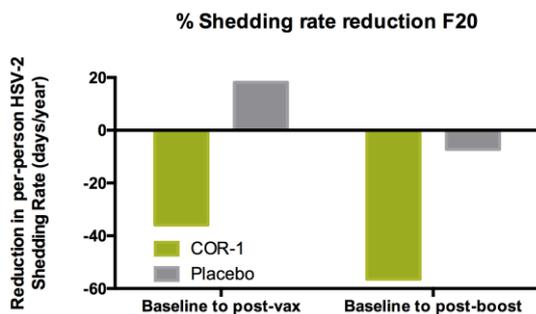
Safety Data

The primary endpoint of the study is safety and to date no safety issues have been reported relating to the vaccine. The vaccine is given by injection into the subdermal layer, with each vaccination requiring two injections per dose. Some study participants reported some pain during vaccination which resolved immediately.

Viral shedding data

Throughout the course of treatment the vaccine treated patients saw a steady decline in viral shedding compared with no change in the patients on placebo (see Figure 1 below).

Figure 1. Average viral shedding rate measured post the initial vaccine treatment (doses) and post booster compared to the baseline. No error bars have been included as the study is not powered for statistical significance.



Immune response

The anti gD2 antibody and the T-cell responses increased in the vaccine recipients, especially post boost. The Company will have more detailed data with the full data set in 2017 once the data for individual study participants is unblinded. The technology is particularly focused on activation of T-cells and as such the responses post vaccination is encouraging. These responses were not observed in the placebo group.

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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

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. 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.