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PROBIOMICS TO COMMENCE TRIAL ON FLU VACCINE

Probiomics Ltd (ASX:PCC) today announced that it is to undertake a clinical trial examining the ability of PCC[®], its proprietary probiotic strain, to boost the immune response to influenza vaccine. If successful, the trial could have significant implications for any potential avian flu pandemic.

“This project will aim to test the hypothesis that oral consumption of a specific strain of PCC[®] is able to significantly enhance the immune response to a vaccine for influenza. If the trial demonstrates significant efficacy of PCC[®] in enhancing the immune response to influenza vaccine, we would then seek to test it using an H5N1 (avian flu) vaccine,” Professor Ron Penny, Director of Probiomics, said.

The Company has reached this decision based on preliminary data as well as a number of recent publications which demonstrated that:

- In experiments in rats, Probiomics’ probiotic strain PCC[®] enhanced the response to a bacterial antigen (*H. influenzae*), demonstrating the potential of PCC[®] to act as an effective adjuvant (a term used for substances which are co-administered with a vaccine to enhance the immune response).
- In clinical studies, PCC[®] has been demonstrated to significantly decrease the incidence of respiratory illness.
- certain probiotic strains can promote dendritic cells to regulate T cell responses toward T helper 1 pathways and therefore “could be particularly advantageous as vaccine adjuvants” (Proceedings of the National Academy of Sciences, February 2005, pp. 2880–2885)
- some strains of probiotics can reduce influenza virus titer when fed to mice (Clinical and Diagnostic Laboratory Immunology, July 2004, pp 675–679)

Furthermore, the concept of probiotics being potentially useful as vaccine adjuvants has existed for a number of years (e.g. Journal of Dairy Science, 1995) but to date the Company is not aware of any human trials which have examined this concept.

Probiomics will recruit 300 healthy volunteers aged 18-49 through Good Health Solutions Clinics, and test two doses of PCC[®] against a placebo capsule, in a randomised, double blind trial. All subjects will receive an influenza vaccine as part of the trial, and will take 1 capsule per day of PCC[®] or placebo for a period of 6 weeks. The response to the vaccine in the subjects will be tested by measuring the titre of haemagglutinin antibody inhibition.

The rationale is to test the ability to enhance the response to vaccines in humans. If successful, this would have major implications for improving the performance of poorly immunogenic vaccines, particularly the H5N1 vaccines.

In August 2005, the head of the US National Institute of Allergy and Infectious Diseases, Dr Anthony Fauci, revealed that to get a significant immune response to an unadjuvanted H5N1 vaccine, people needed to be given 90 micrograms of killed vaccine virus, in two doses four weeks apart. That is 12 times as much virus as is needed to make an effective vaccine out of an ordinary influenza virus. This was predicted, as several studies have shown that H5 on its own does not induce a strong immune response.

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Having to use so high a dose means that the world's vaccine-making capacity would only be able to produce 25 million doses a year, orders of magnitude below what would be required in a global pandemic.

To address this, new trials are underway using conventional adjuvants such as alum, which, if effective, would substantially increase the number of vaccine doses the world could produce per month. If PCC[®] can be demonstrated to be an effective 'bioadjuvant', it would have a number of advantages over alum and other chemical adjuvants in that it provides a systemic mucosal immune response, has no known adverse effects and has been demonstrated in its own right to reduce the number of respiratory tract infections in adults and infants. Additionally, as a 'bioadjuvant' its ability to persist within the body provides a potentially on-going effect.

"The potential for PCC[®] in providing a boost to the body's immune system to help fight respiratory infections, in combination with a vaccine, makes conducting such a trial an easy decision to make", commented Probiomics' chairman, Mr Brian Gardiner. "If this trial is effective, it could be that not only avian influenza, but also a large number of other vaccines may be targets for co-administration with PCC[®]."

The trial is planned to take four months.

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