



ROCKEBY BIOMED TO LAUNCH AVIAN FLU TESTS

8 November 2005: Rockeby biomed (ASX:RBY) today announced it will launch two tests for avian bird flu, having signed a marketing and distribution deal with Pacific Biotech Co Ltd, Thailand for the exclusive rights to the test in Asia Pacific, Europe and South Africa.

Rockeby Avian Virus Antigen Test is a rapid one step test for qualitative detection of avian influenza virus antigen (H5N1). It will be used for veterinary diagnostic for on site testing of bird faeces, as well as clinical screening of bird blood and serum specimens. The test takes only 10 minutes to complete. Rockeby's veterinary test is sensitive, rapid and simple to use. The kit is stable for storage between about 2 and 30 degrees and has a long shelf life.

The Avian Virus Antigen Test was evaluated at Faculty of Veterinary Science, Chulalongkorn University, Bangkok, Thailand. It was found to be able to detect Avian Influenza Virus Ag, subtype H5N1 efficiently. These virus isolations were obtained from infected chicken and duck during avian flu epidemic in Thailand in 2004. The test kit required AIV Ag at least 10^7 ELD₅₀/ml to show positive result, whereas chick embryo technique, haemagglutination test and multiplex RT-PCR required virus at least 10^0 , 10^7 , and 10^4 ELD₅₀/ml, respectively.

The terms of the agreement between Rockeby biomed and Thai-based Pacific Biotech are:

- Rockeby Biomed has secured the exclusive rights to the tests in Asia, Asia Pacific, and Europe
- The tests will be manufactured by Pacific Biotech, and the license fee of the tests is incorporated as of the cost of the kits supplied to Rockeby.
- The tests will be branded and marketed under the Rockeby name.

The second test, Rockeby Influenza A Antigen test, is a rapid screening method that measures Influenza A proteins in samples taken from human nose or throat. It is an immunoassay test kit that can also be used for the quantitative detection of H5N1 in humans.

Both tests have been optimised to yield a result within 10 minutes of application of the sample to the testing device and both rely on immunological detection of the viral protein.

Bird flu subtype H5N1 has been shown recently to infect humans and trigger an aggressive clinical response, causing severe disease that often proves fatal, even in previously healthy adults and children.

Influenza experts worldwide are concerned that H5N1 has met two of the three criteria for a global outbreak of bird flu in humans, or so-called pandemic, with many believing that it is only a matter of time before such an outbreak occurs.

The two criteria are that H5N1 is a new form of virus and it causes serious disease in humans. At this stage, it is not highly infectious and readily transmitted between humans, but mutation may change that situation.

To date, the 100 or so people known to have been infected with bird flu have had direct contact with birds and their faeces.

"There is an urgent need for a quick, reliable test for avian flu. Compared to the H5N1 subtype isolated in 1997 and 2004, the 2005 variant is already more lethal to animals in laboratory testing and survives for longer in the environment," said Dr Sze Wee Tan of Rocheby.

"Domestic ducks have become 'silent' reservoirs of the virus. They shed a high number of viral particles in their faeces, but show no symptoms of the disease."

"We believe that Rocheby's product has substantial advantages over a new test announced by European company AJ Roboscreen GmbH, in mid-October. In particular, their test relies on laboratory testing by polymerase chain reaction (PCR) to detect viral particles, a method that requires specialised equipment and transport of samples from site of collection to the laboratory."

In its document *Responding to the avian influenza pandemic threat*, the World Health Organization (WHO) and other parties have identified the need for new methods for detecting the virus in environmental samples as one component of a multi-faceted approach to controlling a bird flu pandemic.

The WHO also noted the shortcomings of routine veterinary surveillance, describing it as "weak in most risk-prone countries", which highlights the need for a suitable new test such as Rocheby's Avian Virus Antigen Test.

About Rocheby biomed:

Rocheby biomed Limited is an ASX-listed (ASX: RBY) biotechnology company engaged primarily in the research, development and marketing of products for the diagnosis and treatment of fungal infections in humans. The company's main market is that of in-vitro diagnostic testing which covers serology tests in hospitals as well as point-of-care products for use by consumers or health professionals operating outside hospitals.

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