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CSL to file Pandemic Vaccine Dossier with the Therapeutic Goods Administration (TGA)

CSL Limited, Australia's leading biopharmaceutical company, has today announced it has new data from its pandemic influenza vaccine clinical trial program. These results will enable submission of a dossier to the TGA for the registration of a pandemic influenza vaccine. The latest clinical studies confirm that two doses of 30 micrograms of antigen with the addition of an aluminium adjuvant or immune stimulant, are required to produce a strong immune response against the H5N1 bird flu virus.

The vaccine was found to be safe and well-tolerated in the study population of adults aged 18 to 65. Results of a subsequent study undertaken in infants, young children and the elderly are expected to be available later this year.

'CSL is delighted to reassure the community that the Australian Government will be able to respond with CSL's vaccine in the event that an influenza pandemic affects Australia.' Dr Andrew Cuthbertson, Chief Scientific Officer at CSL said today.

The Australian Government has contributed \$7.17 million towards the costs of CSL's pandemic vaccine development program including the vaccine trials.

CSL's future research and development Program for pandemic influenza is ongoing as part of its role as Australia's major supplier of influenza vaccines, and the only supplier based in the Southern Hemisphere.

'While CSL is encouraged by the results of its clinical program thus far, it is desirable we undertake research which will enable the maximum number of vaccine doses to be produced in the shortest possible time.' Dr Cuthbertson said.

'The ultimate goal of our research program is to develop a pandemic vaccine which uses the lowest dose of antigen, which can offer cross-protection against similar but non-identical bird flu strains, and which lasts as long as possible.' he added.

For more information about CSL Limited, visit www.csl.com.au

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