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Press Release

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CSL DEMONSTRATES ROBUST IMMUNE RESPONSE FROM SINGLE (15mcg) DOSE OF MONOVALENT PANDEMIC (H1N1) 2009 INFLUENZA A VACCINE IN HEALTHY ADULTS

CSL Limited, Australia's leading biopharmaceutical company, announced today that preliminary data from the first study of its candidate pandemic H1N1 vaccine demonstrated a robust immune response in healthy adults after a single unadjuvanted15mcg dose.

The preliminary data, published today as an original article in the New England Journal of Medicine, showed that over 95% of participants receiving the single 15mcg dose of the vaccine achieved antibody levels that correlate with the prevention of influenza infection.[1]

The study also shows that the vaccine has a tolerability profile consistent with seasonal influenza vaccines.

In this single-centre observer-blind study, 240 healthy adults aged 18 to 64 were randomised into two dose groups. Each participant received an initial vaccination followed by a second vaccination three weeks later. The first group received 15mcg of vaccine, the standard dose used for a single strain in the trivalent seasonal influenza vaccine, and the second group received 30mcg of vaccine. Blood samples were taken three weeks after each dose.

Preliminary data after the first vaccination demonstrated that post-vaccination antibody titres of 1:40 or greater were achieved in 96.7% of participants receiving the 15mcg dose and in 93.3% of participants receiving the 30mcg dose. This immune response remains consistently strong irrespective of age. No deaths, serious adverse events or adverse events of special interest were reported. The most commonly reported solicited adverse events were injection site tenderness, headache and injection site pain.

[1] de Jong J C Haemaggutination -Inhibiting Antibody to Influenza Virus. Dev Biol 2003 vol 115, 63-73.

'The preliminary data obtained from this initial study show a promising result which gives us confidence that a vaccination program can be successfully carried out in adults using a single standard dose of the H1N1 vaccine. CSL currently has other studies underway that are examining the vaccine in children and older adults. We look forward to sharing these data when they become available' CSL Chief Scientific Officer Dr Andrew Cuthbertson said today.

'The results of our initial study provide critical information given that vaccine yields have been much lower than expected around the world. Knowledge of the likely effective dose will enable the available vaccine to go further'.

'CSL can also offer reassurance that no safety signals have been noted so far in any of our current studies We will, of course, continue to monitor safety through the clinical study process and with post-marketing surveillance', he said.

CSL has worked quickly to make the preliminary dose response and safety data available to public health and regulatory authorities around the world in order to inform policy decisions about how immunisation programs against pandemic H1N1 2009 influenza should be implemented.

The article is available at http://content.nejm.org/cgi/content/full/NEJMoa0907413

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