CSL Biotherapies

Press Release

For immediate release

September 18, 2009

PANVAX® H1N1 APPROVAL FOR REGISTRATION FOR USE IN AUSTRALIA* BY THE THERAPEUTIC GOODS ADMINISTRATION (TGA)

CSL Biotherapies, a subsidiary of CSL Limited, Australia's leading biopharmaceutical company, can today confirm that its vaccine against the pandemic (H1N1) 2009 influenza or 'swine flu' has been approved registration for use in people aged 10 years and over. The TGA assesses safety, efficacy and quality when arriving at the decision to register a medical product for use by the general public.

The TGA, Australia's regulator of drugs and medical devices, has registered the vaccine after an assessment of the clinical trial results demonstrating that a single standard 15mcg dose produces a strong immune response against the swine flu in over 95% of healthy adults, and that side-effects are similar to those experienced with the seasonal flu vaccine. The most commonly reported side effects were injection site tenderness, headache and injection site pain.1 This approval paves the way for a Government program to immunise Australians against the influenza pandemic.

'CSL as the only manufacturer of influenza vaccines in the Southern Hemisphere has had a huge responsibility to make a vaccine available against this pandemic as quickly as possible, and we have worked night and day to be able to achieve this' General Manager of CSL Biotherapies Mary Sontrop said today.

'Of a total of 21 million doses ordered by the Australian Government, we have manufactured 8 million, 5 million of which have been delivered to States and Territories in anticipation of the announcement of an immunisation program.' she said.

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[1] *Greenberg etal' Response after One Dose of a Monovalent Influenza A (H1N1) Vaccine – Preliminary Report' NEJM September 10, 2009*

Panvax® H1N1 vaccine has been manufactured using the same process as used for seasonal influenza vaccines, but it contains the influenza strain that has been determined by the World Health Organisation (WHO) as the strain responsible for the pandemic (H1N1) 2009 influenza. Australia had 36,173 confirmed cases of pandemic (H1N1) 2009 up to 16 September, and 171 people have died.

The vaccine has already been registered for use by the Food and Drug Administration in the US. Preliminary results of clinical trials to determine the most appropriate vaccine dose in children younger than 10 years are expected to be available in mid-to late October.

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*** Panvax® H1N1 has been licensed for use in the prevention of pandemic (H1N1) 2009 influenza; however its availability to the Australian public will depend upon the Department of Health and Ageing approving an immunisation program against the disease.**