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CSL

ASX Announcement

For immediate release

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CSL Biotherapies Statement on FDA Warning Letter for GMP issues at Australian Influenza Vaccine Facility

Today the US Food and Drug Administration (FDA) published a Warning Letter issued by its Office of Compliance and Biologics Quality to CSL Biotherapies, a division of CSL Limited. The FDA regulates the manufacture, marketing and distribution of CSL Biotherapies' influenza vaccine, Afluria®, in the US market.

The Warning Letter relates to the FDA's most recent annual inspection of CSL Biotherapies' influenza vaccine manufacturing facilities, processes and procedures at the Parkville, Australia site, in March 2011. The Letter is available on the FDA website[1].

At the completion of the March inspection, the FDA issued to CSL Biotherapies a list of observed deviations from current Good Manufacturing Practice (GMP). CSL Biotherapies submitted a written response to the FDA to address the observations, including details of corrective steps that had already been undertaken as well as further actions underway.

The Warning Letter states that CSL Biotherapies' response to the March inspectional observations did not provide sufficient detail for the FDA to fully assess the adequacy of CSL Biotherapies' corrective actions. The Letter lists a number of significant items that require prompt attention. These primarily relate to the methodology used by CSL Biotherapies to document and manage processes and investigations at its Parkville facility.

"CSL Biotherapies is committed to the highest standards of compliance in our quality systems and we are taking the Warning Letter very seriously. Our technical team is in the process of preparing more substantive details about our corrective actions to meet the FDA's requirements," said Dr Jeff Davies, Executive Vice-President CSL Biotherapies.

"We will work diligently with the FDA to resolve these GMP issues as quickly as possible while continuing to fulfil our commitments to public health programs in Australia and internationally," said Dr Davies.

[1] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm259888.htm

Background

CSL Biotherapies is a division of CSL Limited (ASX:CSL). In fiscal 2010, CSL Limited reported total revenues of $4.6 billion. In the same period, CSL Biotherapies' total worldwide sales of influenza vaccine amounted to $124 million, of which $53 million was generated in the US.

CSL is a global, specialty biopharmaceutical company that researches, develops, manufactures and markets products to treat and prevent serious human medical conditions. Headquartered in Australia with substantial operations in the United States of America, Germany and Switzerland, CSL has over 10,000 employees working in 27 countries.

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

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