



## **CSL Biotherapies announces FDA marketing approval of Afluria®**

***New influenza vaccine available  
for distribution in time for the 2007/2008 season***

*Global biopharmaceutical company with strong vaccine heritage  
affirms commitment to help address critical U.S. public health need*

**King of Prussia, PA – September 28, 2007 – CSL Biotherapies**, a subsidiary of one of the world's leading manufacturers of influenza vaccine, announced today that the U.S. Food and Drug Administration (FDA) has approved Afluria® (influenza virus vaccine) for active immunization of persons age 18 years and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. Today's approval marks the company's first entry into the U.S. vaccine market.

Afluria will be made available in both single-dose, thimerosal-free, pre-filled syringes and in multi-dose vials to provide choice and convenience to caregivers who administer it. CSL Biotherapies intends to deliver all shipments to the U.S. before the end of October 2007, an objective that affirms the company's commitment to helping address a critical U.S. public health need.

"CSL Biotherapies is proud to bring our 40-year heritage in influenza vaccines to the U.S. market, where boosting the supply of available flu vaccine and increasing vaccination rates is a priority public health goal," said Paul Perreault, Executive Vice President of CSL Biotherapies Worldwide Commercial Operations. "In addition, we are particularly pleased to be offering Afluria in a thimerosal-free formulation in pre-filled syringes, representing a greater degree of choice for patients and healthcare professionals."

"Health authorities continue to emphasize the importance of flu vaccination as a front-line defense against a common and serious public health threat that still claims lives every year in the U.S.," said Kathryn M. Edwards, MD, of Vanderbilt School of Medicine in Nashville, Tennessee, and principal investigator in the National Institutes of Health-funded clinical trial that assessed the CSL influenza vaccine in the U.S. "With today's approval of Afluria, we welcome the expanded diversity of vaccine suppliers and applaud CSL Biotherapies' efforts to increase the availability of thimerosal-free flu vaccine in the U.S. Now, healthcare professionals have the

ability to offer flu vaccination to more people and significantly decrease the burden of this preventable disease in America.”

### **About Afluria**

The Afluria market application was granted priority review status by the FDA in April, 2007. CSL-branded influenza vaccines are approved and marketed in 16 countries worldwide. The company also provides bulk antigen for influenza vaccine sold in 24 countries.

CSL’s influenza vaccine is a purified, inactivated, trivalent influenza vaccine propagated in embryonated chicken eggs. Each dose contains the required dose of influenza virus hemagglutinin antigens from the influenza strains recommended and prioritized by FDA’s Vaccine and Related Biological Products Advisory Committee for the 2007-2008 flu season. Previous international flu vaccine studies sponsored by CSL Limited, and a clinical trial conducted by the National Institutes of Health (NIH), formed the basis for CSL Biotherapies’ biologics licensing application submission.

The NIH-supported clinical trial that led to U.S. licensure enrolled 1,357 volunteers at nine clinical sites in the U.S. in a pivotal, Phase III, randomized, double-blind, placebo-controlled study. The study evaluated the safety, tolerability and immunogenicity of thimerosal-free and thimerosal-containing formulations of influenza vaccine in healthy adults aged 18 to < 65 years.

Last year, CSL, parent company to CSL Biotherapies, announced a \$60 million (U.S.D.) investment in plant and equipment to double the manufacturing capacity of the company’s Melbourne facility to 40 million doses per season, making it one of the largest vaccine manufacturing plants in the world. Recently, CSL also announced its intention to expand its fill and finish activities with installation of a new facility in Illinois.

### **Important Safety Information**

Afluria® is indicated for active immunization of persons age 18 and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. The indication is based on the immune response elicited by Afluria; no controlled clinical studies have demonstrated a decrease in influenza disease after vaccination with Afluria.

Afluria should not be administered to individuals with hypersensitivity to eggs or chicken protein or other components of Afluria, and in anyone who has had a life-threatening reaction to previous influenza vaccination. The most common injection-site adverse reactions were tenderness, pain, redness and swelling. The most common systemic adverse reactions were headache, malaise and muscle aches. Vaccination with Afluria may not protect all individuals. Immunocompromised persons may have a diminished immune response. If Guillain-Barré

syndrome has occurred within six weeks of receipt of prior influenza vaccine, the decision to give Afluria should be based on careful consideration of the potential benefits and risks. Full prescribing information on Afluria can be found at [www.Afluria.com](http://www.Afluria.com).

### **About Influenza**

The “flu” is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death. According to CDC’s Advisory Committee on Immunization Practices (ACIP), the single best way to prevent the flu is by getting vaccinated every year.

### **About CSL Biotherapies**

The U.S. headquarters of CSL Biotherapies are located in King of Prussia, Pa. Its parent company, CSL Limited, in Melbourne, Australia, operates one of the world’s largest influenza vaccine facilities for global markets. CSL Biotherapies, which shares its U.S. headquarters with its sister company, CSL Behring, is commercializing influenza vaccine products globally. At CSL Biotherapies, delivering vaccines is our mission, protecting lives our passion. The CSL Group, which also includes CSL Research & Development, CSL Bioplasma, and CSL Behring, has more than 8,500 employees and operates in 21 countries worldwide. For more information, visit us at [www.csلبiotherapies-us.com](http://www.csلبiotherapies-us.com), or call 1-888-435-8633.

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