American Latex Allergy Association

FDA Approves New Flu Vaccine

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October 5, 2006 GSK?s New Flu Vaccine, FluLaval(TM), Provides Americans With a New Option for Fighting the Flu

GlaxoSmithKline?s Expanded Influenza Vaccine Portfolio Will Help Ensure Adequate U.S. Supply for the 2006/2007 Flu Season and Beyond

PHILADELPHIA, Oct. 5 /PRNewswire-FirstCall/ ? GlaxoSmithKline (NYSE:GSK) announced today that the U.S. Food and Drug Administration (FDA) has approved FluLaval(TM) [Influenza Virus Vaccine] for the active immunization of adults 18 years and older against influenza disease, commonly known as the flu, caused by influenza virus types A and B contained in the vaccine. The approval of FluLaval is another major step towards increasing the influenza vaccine supply in the United States, following the introduction of GSK?s Fluarix(R) [Influenza Virus Vaccine] prior to last year?s flu season.

?While the threat of pandemic influenza rightly has received a lot of attention, it is important to remember that seasonal flu poses a real and serious risk to public health each year,? said William Schaffner, MD, Chairman of the Department of Preventive Medicine, Vanderbilt University School of Medicine, Nashville, TN. ?Getting an annual flu vaccine is the best way to protect against seasonal flu and its severe complications which kill too many Americans each year.?

GSK added FluLaval to its portfolio of flu products when it acquired the Canadian vaccine manufacturer ID Biomedical Corporation in December 2005. FluLaval, which will be available in 10 dose multi-dose vials, was granted fast track review status by the FDA in July 2005. It is marketed in Canada under the name Fluviral(R).

?Prevention of diseases like influenza not only helps people avoid getting sick, but is also one of the most effective ways to control healthcare costs,? said Chris Viehbacher, President, U.S. Pharmaceuticals, GlaxoSmithKline. ?We are expanding our seasonal flu vaccine offerings to include FluLaval, and we are investing heavily in new technologies and facilities to develop tomorrow?s vaccines to protect people from both seasonal and pandemic flu.?

About Influenza (Flu)

Many respiratory diseases occur every winter, but the flu can be one of the most severe. The illness is easily passed from one person to another through the air by tiny droplets released when an infected individual coughs or sneezes. Influenza is a highly contagious and potentially deadly virus that affects five to 20 percent of the total

U.S. population during each influenza season. Each year, more than 200,000 Americans are hospitalized and about 36,000 die from flu-related complications. Most deaths occur in people who are 65 or older. In 1918, before a flu vaccine was available, a flu pandemic killed an estimated 20-50 million people worldwide.

According to the Centers for Disease Control and Prevention (CDC), the single best way to prevent flu is to get vaccinated each fall. Groups who are at risk of serious complications include the very young, people 50 years of age or older, the chronically ill, and women who will be pregnant during influenza season. Additionally, people who live with or care for persons at high-risk of complications (including all healthcare workers) should get vaccinated to help them stay healthy and avoid infecting others.

The beginning, severity and length of the flu season can vary widely from year to year. While October or November is the best time to get vaccinated, getting the flu vaccine later can still be beneficial in most years because influenza activity usually peaks between December and March.

About FluLaval(TM)

FluLaval is indicated for active immunization of adults (18 years of age and older) against influenza disease caused by influenza virus subtypes A and B contained in the vaccine. This indication is based on immune response elicited by FluLaval and there have been no controlled trials demonstrating a decrease in influenza disease after vaccination with FluLaval. FluLaval is not indicated for use in children.

The FDA reviewed data from clinical trials that studied FluLaval in 1,000 healthy adults in the United States aged 18 to 64 and in 658 subjects 50 years of age and older in Canada. The results of the randomized, controlled, comparative trials showed FluLaval to be safe and to stimulate an immune response.

FluLaval should not be administered to anyone with known systemic hypersensitivity reactions to egg proteins (eggs or egg products), chicken proteins, or any component of FluLaval. FluLaval should not be administered to anyone who has had a life-threatening reaction to previous administration of any influenza vaccine, or to anyone with an acute evolving neurologic disorder. If Guillain-Barre syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FluLaval should be based on careful consideration of the potential benefits and risks. FluLaval should not be given to individuals with bleeding disorders such as hemophilia or thrombocytopenia, or to persons on anticoagulant therapy, unless the potential benefit clearly outweighs the risk of administration. If the decision is made to administer FluLaval to such persons, steps should be considered to control the risk of hematoma following the injection. If FluLaval is administered to immunocompromised persons, including individuals receiving immunosuppressive therapy, the expected immune response may not be obtained. FluLaval contains non-infectious killed viruses and cannot cause influenza. Coincidental respiratory disease unrelated to influenza vaccine can occur after vaccination. In comparator-controlled clinical trials with FluLaval, the most common adverse events were pain, redness, and/or swelling at the injection site and headache, fatigue, myalgia, fever, and malaise. Most adverse events in clinical trials were mild and self-limited. (See adverse reactions section of the Prescribing Information for FluLaval for other potential adverse events.) Vaccination with FluLaval may not protect 100% of susceptible individuals.

GlaxoSmithKline: A Leader in Flu

GlaxoSmithKline has an active research and development program targeted at both seasonal and pandemic flu and has recently invested more than $2 billion to expand capacity for manufacturing its flu vaccines Fluarix and FluLaval and its antiviral flu medication Relenza(R) (zanamivir for inhalation). GlaxoSmithKline ? one of the

world?s leading research-based pharmaceutical and healthcare companies ? is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For company information, visit GlaxoSmithKline at **www.gsk.com** [1].

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