

National Influenza Vaccine Summit 2011-2012 Season Update

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Merck and CSL Seasonal Influenza Vaccine Agreement

- ▶ In September 2009, Merck entered into an exclusive agreement with CSL Biotherapies, a subsidiary of CSL Limited, to market and distribute AFLURIA® (Influenza Virus Vaccine) in the United States
 - 2010-2011 season through 2015-2016 season

Our Partnership

- ▶ CSL has had more than 40 years of experience in manufacturing seasonal influenza vaccine
- ▶ Merck is committed to maintaining a robust portfolio of pediatric and adult vaccines
- ▶ CSL and Merck have been partners in vaccine development and marketing since 1980



About AFLURIA[®] (Influenza Virus Vaccine)

Indications and Usage

- ▶ AFLURIA is an inactivated influenza virus vaccine indicated for active immunization of persons ages 6 months and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine.
- ▶ This indication is based on the immune response elicited by AFLURIA; there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with AFLURIA.
- ▶ Administration of CSL's 2010 Southern Hemisphere influenza vaccine has been associated with increased postmarketing reports of fever and febrile seizures in children predominantly below the age of 5 years as compared to previous years.



2010 Southern Hemisphere Events

- ▶ In 2010 CSL's Southern Hemisphere's influenza vaccine was associated with an increase in postmarketing reports of fever and febrile seizures in children predominantly below the age of 5 years.
- ▶ Based on the available information, ACIP recommended the following for the 2010-11 influenza season in the United States:
 - AFLURIA[®] (Influenza Virus Vaccine) should not be used in children aged 6 months through 8 years.
 - If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5 to 8 years who has a medical condition that increases the child's risk for influenza complications, AFLURIA can be used; however, providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with AFLURIA before administering this vaccine.
 - AFLURIA may be used in persons aged ≥ 9 years.



2010 Performance

- ▶ Supplied ~ 7 MM doses of pre-filled syringe of AFLURIA® (Influenza Virus Vaccine) to the US market
 - Shipments began in August and concluded in early October



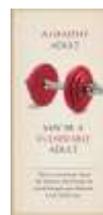
2011 U.S. Production Update

- ▶ ~15 MM doses will be available for the 2011-2012 season
 - AFLURIA® (Influenza Virus Vaccine) is available in two presentations
 - ~55% of doses will be pre-filled syringe, preservative-free
 - ~45% of doses will be multi-dose vials
- ▶ CSL's vaccine filling and packaging facility in Kankakee, IL, which includes a high-speed, single-dose vaccine syringe filling line, will primarily provide filling and packaging services for influenza vaccine supply to the US market.
- ▶ CSL will supply AFLURIA to Merck upon CBER release of the product
 - Shipping estimated to begin in August and be completed in October 2011



Merck's Commitment to the Vaccine Market

- ▶ Long-term commitment to the vaccine market
 - 9 out of 10 of the recommended vaccines for appropriate adults in the US
 - 9 out of 12 of the recommended vaccines for appropriate children in the US
 - New vaccines in development
- ▶ Continued commitment to helping to improve vaccination rates



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Important Information about AFLURIA® (Influenza Virus Vaccine)

Select Safety Information

- ▶ AFLURIA is contraindicated in individuals with hypersensitivity to eggs, neomycin, or polymyxin, or in anyone who has had a life-threatening reaction to previous influenza vaccination.
- ▶ If Guillain-Barré syndrome (GBS) has occurred within 6 weeks of prior influenza vaccination, the decision to give AFLURIA should be based on careful consideration of the potential benefits and risks.
- ▶ If AFLURIA is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.
- ▶ AFLURIA should be given to a pregnant woman only if clearly needed.
- ▶ AFLURIA has not been evaluated in nursing mothers. It is not known whether AFLURIA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when AFLURIA is administered to a nursing woman.



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Important Information about AFLURIA® (Influenza Virus Vaccine) (Cont.)

Select Safety Information (cont.)

- ▶ Antibody responses in geriatric subjects were lower after administration of AFLURIA in comparison to younger adult subjects.
- ▶ In adults, the most common local (injection-site) adverse reactions observed in clinical studies with AFLURIA were tenderness, pain, redness (erythema), and swelling. The most common systemic adverse reactions observed were headache, malaise, and muscle aches (myalgia).
- ▶ In children, the most common local (injection-site) adverse reactions observed in a clinical study with AFLURIA were pain, redness, and swelling. The most common systemic adverse reactions observed were irritability, rhinitis, fever, cough, loss of appetite, vomiting/diarrhea, headache, muscle aches and sore throat.
- ▶ Safety and effectiveness of AFLURIA in children below 6 months of age have not been established.
- ▶ Vaccination with AFLURIA may not protect all individuals

Before administering AFLURIA, please read the Prescribing Information available at this presentation.



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