

National Influenza Vaccine Summit 2013–2014 Season Update

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Merck and CSL Seasonal Influenza Vaccine Agreement

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 forged and maintained a strategic alliance in vaccine development and marketing since 1980
 - CSL in AU and NZ promote Merck's vaccines portfolio
 - Merck and CSL continue to explore opportunities to collaborate in the research and commercial space



CSL-Merck Distribution Agreement Update

- ▶ 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
 - However, Merck and CSL jointly agreed to terminate agreement after the 2013–2014 season
 - CSL Biotherapies will resume distribution of AFLURIA in the United States for the 2014–2015 season by initiating the prebooking of the vaccine late 2013
 - Merck and CSL Biotherapies have agreed to a transition plan during which teams from both companies will strive to provide the highest levels of customer service



ACIP Recommendation for AFLURIA® (Influenza Virus Vaccine)

- ▶ The ACIP/CDC recommends vaccination with AFLURIA for patients 9 years of age and older.
- ▶ Although AFLURIA is indicated for patients as young as 5 years of age, the ACIP's recommendation is based on increased reports in Australia in 2010 of febrile reactions in children aged 6 months through 8 years that occurred with an associated vaccine.



2012 Performance

- ▶ Supplied ~11 MM doses of AFLURIA® (Influenza Virus Vaccine) to the US market
 - 5 MM pre-filled syringes
 - 6 MM multi-dose vials
- Shipments to prebook customers began in August and concluded in early September
- Supply of AFLURIA was sold out in January 2013



2013 US Production Update

- ▶ ~10 MM doses will be available for the 2013–2014 season
 - AFLURIA® (Influenza Virus Vaccine) is available in 2 presentations
 - ~50% of doses will be pre-filled syringes, preservative-free
 - ~50% of doses will be multi-dose vials
- ▶ CSL maintains vaccine filling and packaging facilities in Kankakee, IL, which include a high-speed, single-dose vaccine syringe filling line, and Marburg, Germany, for multi-dose vial filling and packaging services. Both locations will continue to be utilized 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 2013



Important Information About AFLURIA® (Influenza Virus Vaccine)

AFLURIA is an inactivated influenza virus vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. AFLURIA is approved for use in persons 5 years of age and older.

Select Safety Information

AFLURIA is contraindicated in individuals with known severe allergic reactions (eg, anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine.

Administration of CSL's 2010 Southern Hemisphere influenza vaccine was associated with postmarketing reports of increased rates of fever and febrile seizures in children predominantly below the age of 5 years as compared to previous years; these increased rates were confirmed by postmarketing studies. Febrile events were also observed in children 5 to less than 9 years of age.

Guillain-Barré Syndrome (GBS) has occurred following vaccination with AFLURIA. If Guillain-Barré Syndrome (GBS) has occurred within 6 weeks of previous 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.



Important Information About AFLURIA® (Influenza Virus Vaccine) (cont)

Select Safety Information (cont)

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.

In children 5 through 17 years of age, the most common injection-site reactions observed in clinical studies with AFLURIA were pain, redness, and swelling. The most common systemic adverse events were headache, myalgia, malaise, and fever.

In adults 18 through 64 years of age, the most common injection-site adverse reactions observed in clinical studies with AFLURIA were tenderness and pain. The most common systemic adverse reactions observed were headache, malaise, and muscle aches.

In adults 65 years of age and older, the most common injection-site adverse reactions observed in clinical studies with AFLURIA were tenderness and pain.

Vaccination with AFLURIA may not protect all individuals.

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

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