National Adult & Influenza Immunization Summit (NAIIS)
2014-15 Season Update

Judith Wolf, MD
Director, Medical Affairs
bioCSL Inc.

Agenda

- bioCSL and AFLURIA® (Influenza Virus Vaccine) Sales & Marketing Update
- 2013-14 Performance & 2014-15 Planning
- NAIIS Actions to Consider

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bioCSL- New Name, Long-standing Heritage and Commitment to Public Health

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Indication & ACIP Recommendation for AFLURIA

- AFLURIA is an inactivated influenza 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.
- ACIP / CDC recommends vaccination with AFLURIA for patients 9 years of age and older
  - ACIP's recommendation is based on 2010 increased reports in Australia of febrile reactions in children aged 6 months through 8 years of age, that occurred with an associated vaccine (FLUVAX®)

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2013-14 Market Performance & 2014-2015 Planning

- 2013-14: 11.1 MM AFLURIA® doses distributed to U.S. market
  - Early delivery achieved, with consistent weekly shipping
  - Initial doses the week of August 5th and first U.S. supplier to complete shipping September 23rd
- 2014-15: ~13.5 MM doses, matching delivery performance of prior season
  - ~ 9.5 MM pre-filled syringe doses (TIV)
  - ~4 MM multi-dose vials doses (TIV)

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Afluria® + Stratis®

- sBLA filed with FDA: October, 2013
- Approval action date: August, 2014
- A new needle-free option for caregivers and patients to help increase immunization rates

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Current Company Activities

- PIVI donation
  - More than 700,000 doses to Laos
- AE 2010 investigation
  - Major contributing factors identified
- QIV development program

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Extending Reach and Impact of the NAIIS

- As a stakeholder group, our worst enemies are complacency and procrastination
  - "We have enough supply"; REALLY?
    - ➥Healthy People 2020 objectives: 70% of ≥18 year old cohort
    - ➥Reality: ~40% immunization rate
- Actions for Consideration
  - Can the Summit enhance social media presence focusing on key social media vehicles to reach key cohorts?
  - Pandemic preparedness is still not perfect - can more be done?
  - Many flu vaccine choices- we must educate caregivers and patients and personalize options in order to increase vaccination rates
  - Influenza Immunization Week in December is too late - consider one week per month beginning in September to highlight awareness

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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.

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Important Information About AFLURIA® (Influenza Virus Vaccine)

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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