

## **bioCSL 2015-16 Season Update National Adult & Influenza Immunization Summit (NAIIS)**

***Where delivering vaccines is our  
mission -- protecting lives, our passion***

**Charles (Chip) Altman, MD, MBA**  
US Head, Medical Affairs & Vaccine Policy

**bioCSL™**

### **Agenda**

- **2014-15 Performance**
- **bioCSL: Increasing Vaccination Rates**
  - Focus on expanding adult flu immunization
- **bioCSL: Moving Forward**
  - 2015-16 Projections
- **Extending Reach & Influence of NAIIS**

2

**bioCSL™**

## bioCSL 2014-15 Flu Season for Afluria®

ANTICIPATED

▪ **13.5M**   doses in US

ACTUAL

- Indirect business model – key partnership with distributors
- Early, reliable delivery achieved; all commitments met
  - Initial doses delivered the week of August 5th
  - 60% delivered by August 31st
  - 90% by September 30th
  - **100% by October 20th**

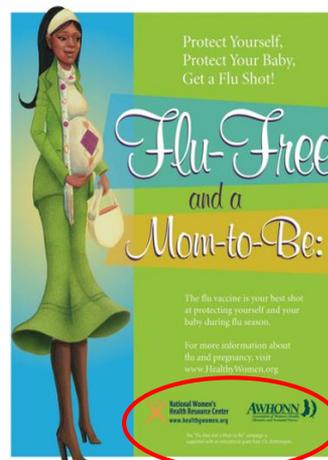


3

bioCSL

## bioCSL Focus on Advocacy: Increasing Vaccination Rates in Adults

- In 2008, bioCSL focused on increasing vaccination rates in pregnant women
  - Won Flu Summit award
  - Vaccination rates for pregnant women just **15%** prior to 2009; now rates approach **50%**
- Current unmet areas of focus
  - College-age patients
  - Needle aversion as barrier



4

bioCSL

## Innovative Advocacy Campaign to Promote Influenza Vaccination for College Students



- Partnered with Michigan Department of Health & Human Services, Families Fighting Flu, & Alana's Foundation
- bioCSL conducted data mining on social media to understand who influences college students to get a flu vaccine:
  - **Moms 61%**
  - **Friends 18%**
  - **Dads 8%**

bioCSL

## Addressing Needle-Aversion

- **Needle-free jet injection with Afluria®**
  - FDA-Approval August 2014
  - Patient Satisfaction data from 2014-15 flu campaigns (N=1,463)

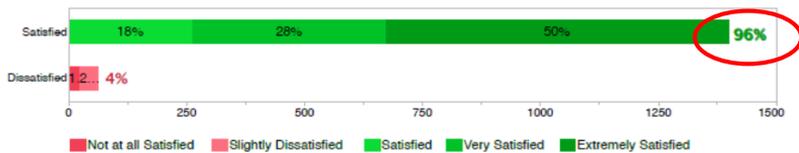


Figure 1: Satisfaction with needle-free injection.

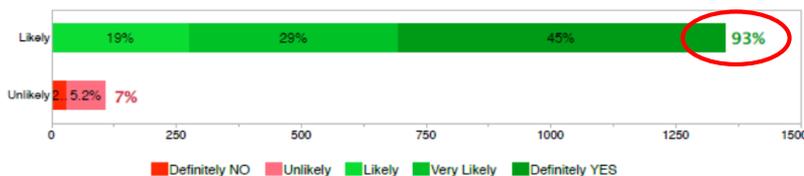


Figure 2: Likelihood of choosing a needle-free injection next year.

6

bioCSL

## bioCSL: Moving Forward in 2015 - 2016

- **100 yr anniversary of CSL (2016)**
  - Responded to pandemics from Spanish flu (1919) to H1N1 (2009)
- **QIV program currently in advanced Phase III**
- **Integration of Novartis flu vaccine business planned for completion by end of 2015**
  - Enhanced focus on influenza
  - Portfolio offering choices
  - Tailor vaccine to patient



7

bioCSL

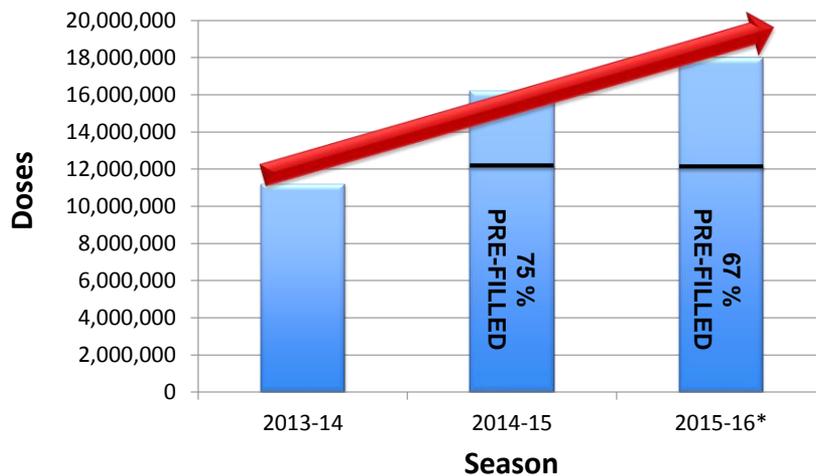
## bioCSL 2015 – 2016 Projections

- **TIV doses of Afluria in US**
  - Matching or exceeding last year's delivery performance
  - 2/3 Pre-filled Syringes
  - 1/3 Multi-dose Vials

8

bioCSL

## Growth in US Sales Volume of Afluria



\* Estimated Minimum

9

bioCSL

## Extending Reach & Influence of NAIIS

- **May, 2015 Internet Survey of Primary Care Physicians (N = 112)**
  - 83% rated flu vaccine 'very important' in everyone  $\geq$  6 mos
  - CDC/ACIP & AAFP highest rated
  - ~80% unaware of mission/agenda of NAIIS
- **Most compelling information to receive from Summit:**
  - Absolute # of hospitalizations & deaths related to flu
  - Priority list of who should receive earliest vaccinations
  - How to more effectively address importance of flu shots for healthy adult patients

10

bioCSL

## Important Safety Information



- AFLURIA<sup>®</sup>, influenza vaccine, 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. Administration of AFLURIA with a needle and syringe is approved for use in persons 5 years of age and older. Administration of AFLURIA with the PharmaJet<sup>®</sup> Stratis<sup>®</sup> Needle-Free Injection System is approved for use in persons 18 through 64 years of age only.
- 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.
- 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.

·11

bioCSL

## Important Safety Information



- 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.
- Antibody responses in persons 65 years of age and older were lower after administration of AFLURIA as compared to younger adult subjects.
- In children 5 through 17 years of age, most common injection-site adverse reactions observed in clinical studies of AFLURIA when administered by needle and syringe were pain, redness, and swelling. The most common systemic adverse events were headache, myalgia, irritability, malaise, and fever.

12

bioCSL

## Important Safety Information



- In adults 18 through 64 years of age, the most common injection-site adverse reactions observed in clinical studies of AFLURIA when administered by needle and syringe were tenderness, pain, swelling, and redness, itching. The most common systemic adverse reactions observed were muscle aches, headache and malaise.
- In adults 18 through 64 years of age, the most common injection-site adverse reactions observed in clinical studies with AFLURIA when administered by the PharmaJet Stratis Needle-Free Injection System up to 7 days post-vaccination were tenderness, swelling, pain, redness, itching and bruising. The most common systemic adverse events within this period were myalgia, malaise, and headache.
- In adults 65 years of age and older, the most common injection-site adverse reactions observed in clinical studies of AFLURIA when administered by needle and syringe were tenderness and pain.
- Vaccination with AFLURIA may not protect all individuals.
- Please see full prescribing information for AFLURIA.
- You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088.

bioCSL