National Influenza Vaccine Summit

Novartis Vaccines Presentation

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Objectives and Overview

- 2012-2013 Influenza Season Delivery Performance
- 2013-2014 Influenza Season Projections and Offerings
- Overview of Recently Approved Product
- Influenza Pipeline

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Novartis Supply Performance

- In 2012 Novartis completed the shipping of 36.1 million FLUVIRIN® *(Influenza Virus Vaccine)* doses
  - Delivered to all customers in full quantities
  - Expanded production from the initial forecast of 30 million doses to assist in meeting increased demand
  - Novartis provided approximately 25% of all influenza doses in the US for the 2012-2013 influenza season
- For the 2013-2014 Influenza Season Novartis plans to bring a minimum of 30 million doses of influenza vaccine
  - Shipping expected to begin in August and continue through October
  - Manufacturing proceeding well, no issues foreseen at this point

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Formulations to be Available for the 2013-2014 Influenza Season

- FLUVIRIN® (*Influenza Virus Vaccine)*
  - 4 + years of age
  - Pre-filled Syringe (preservative-free) or Multi-Dose Vial Presentations
  - CPT © code 90656 and 90658
- FLUCELVAX® *(Influenza Virus Vaccine)*
  - 18 + years of age
  - Pre-filled Syringe (preservative-free) Presentation
  - CPT© 90661

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FLUVIRIN® *(Influenza Virus Vaccine)*
Indication and Important Safety Information (1/2)

Indication and Usage for FLUVIRIN® *(Influenza Virus Vaccine)*

- Fluvirin ® (Influenza Virus Vaccine) is an inactivated influenza virus vaccine indicated for active immunization of persons 4 years of age and older against influenza disease caused by influenza virus subtypes A and subtype B contained in the vaccine.
- Fluvirin is not indicated for children less than four years of age because there is evidence of diminished immune response in this age group.

Important Safety Information for Fluvirin

- In clinical trials, the most common adverse events in adults following administration of Fluvirin were headache, fatigue, injection site reactions (pain, mass, redness, and induration) and malaise. These adverse events were generally mild/moderate and transient.

Novartis Vaccines Direct Web site. https://www.novartisvaccinesdirect.com/fluvirin/fluvirinabout. Accessed October 1, 2012.

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FLUVIRIN® *(Influenza Virus Vaccine)*
Indication and Important Safety Information (2/2)

- Fluvirin *(Influenza Virus Vaccine)* vaccine should not be administered to anyone with a history of systemic hypersensitivity to any component of the vaccine, including eggs, egg products, or thimerosal or to anyone who has had a life-threatening reaction to previous influenza vaccination. Fluvirin vaccine supplied in prefilled syringes includes a syringe tip cap which may contain natural rubber latex; and therefore, may cause allergic reactions in latex sensitive individuals
- Fluvirin vaccine is not indicated for use in children under the age of 4 years. Immunosuppressive therapy may result in a reduced immune response to Fluvirin. If Guillain-Barré syndrome has previously occurred within six weeks of receipt of influenza vaccine, the decision to use Fluvirin should be based on careful consideration of the potential benefits and risks. Individuals should consult with their healthcare providers if they are pregnant, nursing, and/or are taking other medications.
- Fluvirin vaccination may not protect all of the individuals who are susceptible to influenza.

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FLUCELVAX ® *(Influenza Virus Vaccine)*
Indication and Important Safety Information (1/2)

Indication and Usage for FLUCELVAX® *(Influenza Virus Vaccine)*

- FLUCELVAX® *(Influenza Virus Vaccine)* is indicated for active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUCELVAX is approved for use in persons 18 years of age and older.

Important Safety Information for FLUCELVAX

Contraindication

- Do not administer FLUCELVAX to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine.

Warnings & Precautions

- **Guillain-Barré Syndrome (GBS):** If GBS has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLUCELVAX should be based on careful consideration of the potential benefits and risks.
- **Latex:** The tip caps of the pre-filled syringes may contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals.

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FLUCELVAX ® *(Influenza Virus Vaccine)*
Important Safety Information (2/2)

- **Preventing and Managing Allergic Reactions:** Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.
- **Altered Immunocompetence:** After vaccination with FLUCELVAX, immunocompromised individuals, including those receiving immunosuppressive therapy, may have a reduced immune response.
- **Limitations of Vaccine Effectiveness:** Vaccination with FLUCELVAX may not protect all vaccine recipients against influenza disease.

Most Common Adverse Reactions

- The most common (≥10 %) solicited adverse reactions occurring in adults 18-64 years of age within 7 days of vaccination with FLUCELVAX were pain at the injection site, erythema at the injection site, headache, fatigue, myalgia and malaise. The most common (≥10%) solicited adverse reactions occurring in adults ≥65 years of age within 7 days of vaccination were erythema at the injection site, fatigue, headache and malaise.

Please see accompanying US Full Prescribing Information for FLUCELVAX.

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FLUCELVAX (Influenza Virus Vaccine) is the First Cell Culture–Based Influenza Vaccine in the United States

- Approved by the US-FDA on November 20, 2012
- Currently produced in Marburg, Germany
- Future manufacturing in the US at the Holly Springs, North Carolina Novartis manufacturing facility
- Cell Culture will be the development platform for Novartis's quadrivalent influenza vaccine.

FLUCELVAX®
Influenza Virus Vaccine

FLUCELVAX [prescribing information]. Cambridge, MA: Novartis Vaccines and Diagnostics, Inc; 2012:1-13.

US-FDA, United States-Food and Drug Administration.

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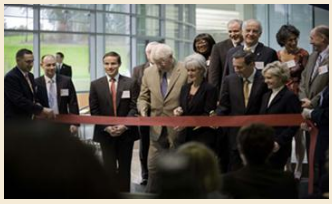
Novartis / HHS-BARDA Partnership

Pre-Pandemic Preparedness

Holly Springs, North Carolina



- Collaboration between US Department of Health and Human Services (USHHS) and Biomedical Advanced Research and Development Authority (BARDA)
  - capital investment
  - US commitment to annual pre-pandemic stockpile purchases
- Site will have seasonal, pre-pandemic, and pandemic vaccine capability (150m doses within 6 month of declaration of influenza pandemic)
- Construction of US-based flu cell-culture site began in 2007
  - Ready to respond to pandemic as early as 2011
  - Full-scale commercial production by 2013
- Construction of the facility represents a financial commitment of nearly USD 1 billion for Novartis and HHS

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Future Directions: Adjuvanted Vaccines

Goal: Bring solutions that increase vaccine efficacy for populations with a high burden of disease

MF59 Adjuvanted Influenza Vaccines – Elderly*

- First licensed with MF59 in EU in 1997 for adults ≥65 years
- Approved in 30 countries; >50 million doses distributed

MF59 Adjuvanted Influenza Vaccines – Pediatrics*

- Ongoing clinical trials in pediatric populations.

Path forward for adjuvanted vaccines for both populations is under discussion with the FDA

*Not licensed in the US

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Summary and Conclusions

- 36 million doses delivered for the 2012-2013 influenza season (25% of US production)
- Fluvirin® *(Influenza Virus Vaccine)* and Flucelvax® *(Influenza Virus Vaccine)* to be available for the 2013-2014 influenza season
- Vaccine Production for the 2013-2014 season on time, minimum of 30 million doses
- Future Directions:
  - Adjuvanted Vaccines to help provide protection to children and the elderly under development

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