2013 National Influenza Vaccine Summit Update

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Presentation

1. Rationale for Quadrivalent Vaccines
2. FluMist Quadrivalent Overview
3. FluMist Quadrivalent Availability and Educational Resources
Rationale for a Quadrivalent Influenza Vaccine

- Influenza B contributes significantly to seasonal epidemics in the United States*
  - 24% of all influenza infections reported by CDC from 2001-2011
  - Ranged from 1% in 2003-2004 season, to nearly 50% of all infections in 2002-2003
- Influenza B causes significant morbidity among children and adults
- Two genetically/antigenically distinct B lineages
  - Trivalent vaccines containing a single B lineage provide little or no cross-lineage protection
  - Frequent mismatch between B lineage chosen for the trivalent vaccine and the circulating B lineage

* CDC Surveillance Data

Frequent Mismatch Between Trivalent Vaccine B Lineage and Circulating B Lineage

<table>
<thead>
<tr>
<th>Year</th>
<th>Vaccine-Lineage Influenza B</th>
<th>Opposite-Lineage Influenza B</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001-02</td>
<td>10.0%</td>
<td>40.0%</td>
</tr>
<tr>
<td>2002-03</td>
<td>45.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td>2003-04</td>
<td>15.0%</td>
<td>25.0%</td>
</tr>
<tr>
<td>2004-05</td>
<td>10.0%</td>
<td>35.0%</td>
</tr>
<tr>
<td>2005-06</td>
<td>20.0%</td>
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<td>2006-07</td>
<td>25.0%</td>
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</tr>
<tr>
<td>2007-08</td>
<td>30.0%</td>
<td>30.0%</td>
</tr>
<tr>
<td>2008-09</td>
<td>35.0%</td>
<td>25.0%</td>
</tr>
<tr>
<td>2009-10</td>
<td>40.0%</td>
<td>20.0%</td>
</tr>
<tr>
<td>2010-11</td>
<td>45.0%</td>
<td>15.0%</td>
</tr>
</tbody>
</table>

% Influenza B Viruses (Proportion of All Characterized Influenza Isolates)
FluMist Quadrivalent is a 4-Strain Version of FluMist

- Same attenuated vaccine strains
- Same manufacturing process
- Same strain potency
- Same intranasal delivery
- Same preservative-free formulation
- Same indication (healthy non-pregnant persons 2 – 49 years of age)
- Comparable immunogenicity and safety profile

Potential Attributes of FluMist Quadrivalent

- Protection against both B lineages
- Immunologic priming against both B lineages
- No uncertainty about B strain selection
- Maintains increased manufacturing capacity
Complete Conversion to FluMist Quadrivalent

◆ There will be a total conversion to FluMist Quadrivalent in the US market for the 2013-14 season
  – Equal access to broader influenza B coverage
◆ Conversion will simplify manufacturing
◆ Conversion should simplify recommendations and implementation
◆ Conversion will not impact vaccine supply or timing

FluMist Quadrivalent Availability and Resources

◆ Pediatric offices
  – Field support deployed to address product inquiries and re-orders
◆ Pharmacies
  – National and regional pharmacy chains with a focus on adult vaccination
  – Comprehensive product training available to support pharmacists for upcoming season
◆ Schools
  – Continuing engagement in school-located influenza vaccine programs
  – Assistance with school-located influenza vaccine programs
  – Share knowledge of drivers and barriers of school vaccination programs
On-Line Educational Resources
www.MedImmuneAdvocacy.com

- Launched April 2012
- Available at no charge to non-profit organizations
- Contact: Christeen Moburg
  moburgc@medimmune.com

Participating partners include:

Materials Available In Spanish

Summary

- Approved by FDA on February 29, 2012
- Available for the 2013-2014 season
- 100% conversion from FluMist to FluMist Quadrivalent
- ~13-15 million doses for 2013-2014 season
- Shipping expected to begin in July – August 2013
- More information at www.flumistquadrivalent.com
FluMist® Quadrivalent (Influenza Vaccine Live, Intranasal)
Important Safety and Eligibility Information

FluMist® Quadrivalent is a vaccine indicated for active immunization of persons 2-49 years of age for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. FluMist Quadrivalent is for intranasal administration only.

FluMist Quadrivalent is contraindicated in persons who have had a severe allergic reaction to any vaccine component including egg protein, gentamicin, gelatin and arginine or after a previous dose of any influenza vaccine, and in children and adolescents receiving concomitant aspirin or aspirin-containing therapy.

In clinical trials, the risks of hospitalization and wheezing were increased in children <24 months of age who received FluMist® (trivalent Influenza Vaccine Live, Intranasal). Children <5 years of age with recurrent wheezing and persons of any age with asthma may be at increased risk of wheezing following FluMist Quadrivalent administration. FluMist Quadrivalent has not been studied in persons with severe asthma or active wheezing.

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FluMist® Quadrivalent (Influenza Vaccine Live, Intranasal)
Important Safety and Eligibility Information (cont’d)

If Guillain-Barré syndrome has occurred within 6 weeks of any prior influenza vaccination, the decision to give FluMist Quadrivalent should be based on careful consideration of the potential benefits and risks. FluMist Quadrivalent has not been studied in immunocompromised persons. The safety of FluMist Quadrivalent in individuals with underlying medical conditions predisposing them to wild-type influenza infection complications has not been established. FluMist Quadrivalent may not protect all individuals receiving the vaccine.

The most common solicited adverse reactions (occurring ≥10% in vaccine recipients and at least 5% greater than in placebo) reported after FluMist were runny nose or nasal congestion in all persons 2-49 years, fever >100˚F in children 2-6 years, and sore throat in adults 18-49 years. Among children 2-17 years who received FluMist Quadrivalent, 32% reported runny nose or nasal congestion and 7% reported fever >100˚F. Among adults 18-49 years who received FluMist Quadrivalent, 44% reported runny nose or nasal congestion and 19% reported sore throat.

Please see accompanying complete Prescribing Information for FluMist Quadrivalent, including Patient Information.