Sanofi Pasteur Influenza Vaccine Update

National Influenza Vaccine Summit
June 29 – July 1, 2009

Sanofi Pasteur’s Pandemic Preparedness

- Sanofi Pasteur is in close contact with health authorities and stands ready to support their public health efforts
  - HHS\(^a\) placed an initial order for a vaccine against novel influenza A (H1N1) virus on May 22
  - Sanofi Pasteur received the seed virus to begin production on May 27

- The FDA\(^b\) license of a new influenza vaccine manufacturing facility will increase production capacity to approximately 150 Million doses
  - New Facility: H1N1 production
  - Existing Facility: balance of seasonal production

\(^a\) US Department of Health and Human Services
\(^b\) Food and Drug Administration
Influenza A (H1N1): Production Update

• Large-scale production of influenza A (H1N1) began in newly licensed facility
  - Influenza vaccine production typically takes 4-5 months
  - Clinical trials to determine dosing and schedule
    - Trials to include adjuvanted and un-adjuvanted vaccine
  - In contact with FDA to determine the regulatory process

• Decision to implement a vaccination campaign has still not been made by the Federal Government
  - Ordering & distribution of monovalent vaccine is expected to be controlled by the HHS
  - Recommendations and educational efforts to be determined

Sanofi Pasteur Production Update for 2009-2010 Fluzone®, Influenza Virus Vaccine

• Production of 50 Million doses remains on track for the 2009-2010 season
  - Reservation process closes for all presentations except 0.25mL Pediatric Dose

• Expected to ship 50% of seasonal Fluzone vaccine doses in August and be completed in October
  - 2 US manufacturing facilities provides for earlier and increased availability of no preservative presentations
  - Capacity exists to significantly increase production of No Preservative Fluzone vaccine
    - Increased production of No Preservative Fluzone Vaccine for the 2009-2010 season
    - Full conversion to no preservative presentations is contingent on provider demand
While the Pandemic Has Raised Concerns, Cannot Lose Focus on Seasonal Influenza

- Seasonal influenza remains a serious public health threat
  - 36,000 deaths and 226,000 hospitalizations in the US each year
  - “More kids die from influenza than all other vaccine-preventable diseases combined” – Andrew Kroger, CDC
  - 4 out of 5 Americans are recommended to be immunized against seasonal influenza

- Patient anxiety over influenza A (H1N1) will likely drive earlier and increased demand for seasonal vaccine

- Key challenge:
  - Need to utilize the seasonal vaccine early (August – October) due to unknown distribution, immunization process, and timing of influenza A (H1N1)

Expanded Immunization Recommendations Provide More Influenza Vaccination Opportunities

39 Million (69%) 5 through 18 year-olds had one or more visits to a primary care physician during the 2007 influenza season

(As of July 31, 2007 the US Census Population Estimate for the 5-18 year age group is 57,692,196)

Sanofi Pasteur’s Commitment to the Future

• Robust R&D program investigating product innovations that:
  – Address the special medical needs of specific populations
  – Provide enhanced delivery methods

• On the Horizon: Fluzone High-Dose (IM)
  – High-dose trivalent, inactivated split influenza virus vaccine candidate formulated with no preservative or adjuvant
  – 0.5mL dose in a pre-filled syringe
  – Proposed indication is for active immunization against influenza disease for older adults