Novartis Vaccines Update

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Novartis: Committed to U.S. Influenza Prevention

Legacy, Commitment, Future

- Long-term partnership with private & public spheres to combat influenza
- More than 20 years of distribution of seasonal influenza vaccine in the United States
- Able to increase supply to help support universal recommendation
  - Significant investment in updating existing manufacturing sites
- Ongoing partnership with HHS on H5N1 vaccine development and manufacturing program
- Working to develop novel H1N1 vaccine for current pandemic
  - First lots of cell culture based H1N1 vaccine ready for clinical trials
  - Adjuvanted and unadjuvanted formulations
- Building state of the art cell culture manufacturing facility in NC
  - When licensed, 150 million dose pandemic capacity; also planning production of seasonal vaccine and adjuvant

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Novartis Trivalent Influenza Vaccine – Fluvirin®

Supply for 2009-2010 season

- Supply
  - Production expected to provide ~30 million doses
    - Volumes produced this season aligned with projected demand; sufficient to meet all pre-booked demand
  - BLA submitted to CBER for Agriflu
    - Thimerosal free, egg based vaccine
- Timing
  - Expectations for one third of supply to be available by August 30th
  - Most doses should be available by September 30th
- Presentation
  - Multi-dose vials and pre-filled Luer-Lok syringes
    - Mix determined by customer demand

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Novartis Novel Influenza A (H1N1) Vaccines in Development

- Prior experience with Aflunov (H5N1 adjuvanted vaccine)
- Novartis awarded two supply contracts by HHS
  - H1N1 production based on Fluvirin egg-based platform licensed in US
  - MF59™ (oil-in-water adjuvant used for seasonal vaccine in EU)
- In addition, Novartis is working with other H1N1 antigen production platforms which may be relevant to US
  - Agrippal* egg-based platform approved in EU and BLA filed US
  - Cell culture-based production: Optaflu approved in EU, IND in US
- Proposed clinical development programs
  - Unadjuvanted and adjuvanted formulations with FDA/EMEA guidance
  - Dose-finding studies in adult and pediatric populations
  - Clinical trials to be conducted in the US, Europe & Latin America

*Agrippal filed as Agriflu in US

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Provisional Novel Influenza A (H1N1) Clinical Trials

Fluvirin platform with and without MF59

- Two parallel dose-finding trials in adults or children
  - Intent to provide safety and immunogenicity data to support EUA/BLA
  - Design includes both antigen- and adjuvant-ranging treatment groups, including antigen sparing arms with MF59
- Three target populations: adults 18-64, elderly ¡ 65 and children 3 to <9
  - Number of subjects planned, >2000 adults/elderly, >1000 children
  - Adult and pediatric studies to run in parallel, in line with CBER guidance
  - Extended safety follow-up requested by CBER
- Proposed start of trials, summer 2009
- Data from influenza cell culture trials in Europe may be available earlier

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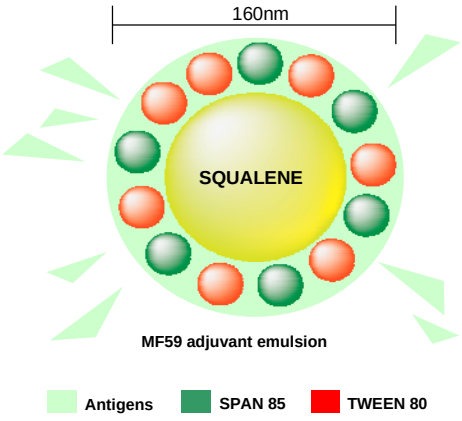
MF59: An Established Adjuvant in a European Licensed Seasonal Trivalent Vaccine

- Oil-in-water emulsion adjuvant **licensed for use in seasonal influenza vaccine FLUAD®* since 1997**
  - More than 40 million commercial doses distributed
- Adjuvanted vaccine **provides heterologous responses to drifted strains**
- Clinical trial data on **>25,000** subjects
  - No safety signals in either pharmacovigilance database or meta-analysis of clinical trial database with 6 month subject follow-up (filed with CBER)
- Ongoing pediatric efficacy trial in 3,000 subjects
- Not currently licensed in the US



Source: FLUAD® is a registered trademark of Novartis. FLUAD is not licensed in the United States

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Cell Culture Based Influenza Manufacturing Capability

Project progressing well & on schedule

- Novartis producing a cell culture based A(H1N1) vaccine at its facility in Germany
- Holly Springs cell culture facility supported by $486 mn HHS grant
- When online, will have 150 million dose monovalent capacity
- Commercial production of pre-pandemic, adjuvant, and seasonal flu vaccines planned

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Novartis: Committed to U.S. Influenza Prevention

Seasonal and Pandemic

Legacy

- Over 20 years of distribution of seasonal influenza vaccine in the United States
- Ongoing partnership with HHS on H5N1 vaccine development and manufacturing program

Commitment

- Meet pre-booked demand in 2008
- Able to increase supply to help support universal recommendation
- Working to develop novel H1N1 vaccine for current pandemic

Future

- Cell culture platform & manufacturing facility in NC

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