National Influenza Vaccine Summit
CSL Biotherapies Update
2009-2010 Season
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Heritage and Commitment to Flu Prevention

- Produced first vaccine to combat 1918 ‘Spanish Flu’ pandemic
- 3 million doses made by hand between October 1918 and March 1919
- Seasonal flu egg-processing method commenced at CSL in 1944
- 20,000 eggs were inoculated manually and harvested every day
- Modern egg-processing was first licensed in 1968
Global Flu Vaccine Manufacturing

- CSL flu vaccines licensed and sold in 27 Countries
  - Afluria®: 2007/US
    2008/Germany and China

- World class facilities:
  - Thimerosal withdrawn from bulk manufacturing in 2002
  - Capacity expanded in 2007 ($60MM investment):
    → Approximately 80 million doses per annum
    → FDA, TGA, EMEA 'GMP compliant'
  - Filling lines in Australia, Germany and US (2009)

- Facility containment (license to BL2+):
  - Manufacture clinical trial material in an expedited fashion
  - Manufacture bulk pre-pandemic antigen stockpiles
  - Panvax® licensed by TGA in Australia (2008)

Key Role in Seasonal Flu Vaccine Production for Both NH and SH

- Close working relationship with WHO-CC¹ and TGA²
- Adapt viruses to grow in eggs (A and B strains)
  - CSL plays an integral role in vaccine preparedness, funding its own ‘High Growth Reassortant’ laboratory
    → Collaborates closely with the 2 other labs (NYMC³ and NIBSC⁴)
  - Yield improvement studies on candidate vaccines
  - Produce master and seed lots
  - Produce/provide reference reagents (no charge) early

¹WHO Collaborating Centers (4), ²Therapeutic Goods Administration, ³New York Medical Center
⁴National Institute for Biological Standard and Control (UK)
2009-10 NH Yield Update

- WHO/FDA selection:
  - A/Brisbane/59/2007, IVR-148* (H1N1)
  - A/Uruguay/716/2007, NYMC X-175C (H3N2) (an A/Brisbane/10/2007-like strain)
  - B/Brisbane/60/2008

- CSL did not meet any difficulty in growing any of these strains
- Completed manufacturing and filling/finishing of majority of supply
- First market deliveries for seasonal flu vaccine expected early August, pending annual strains licensure

Afluria 2009-2010 Seasonal Flu Overview

- Our goal is to supply over 8 million doses to the US
  - Majority in thimerosal-free, single-use, pre-filled syringes
  - Maximize new fast filling line in Kankakee, Illinois
    - At full capacity, fill and finish 20 million prefilled, single-use syringes for US population
  - Patient advocacy, educational programs to underscore the importance of influenza prevention
    - Focus on populations where rate of immunization are low: pregnant women, college students, healthcare workers

* A 'reassortant' produced at CSL : CSL has supplied ALL H1N1 reassortants for seasonal flu in the last 10 years
Vaccine Development Approach for Novel H1N1 Virus

- Working against two timelines to deliver H1N1 vaccine to Australia, New Zealand and the United States
  - Started development of H1N1 ‘egg-adapted’ antigen first week in May
  - Australian clinical trials (adult and pediatric) to begin in July 2009
  - Contract with US HHS to supply bulk novel H1N1 antigen – minimum $180MM USD commitment with option for filling/finishing services in Kankakee, Illinois and Marburg, Germany

Flu Vaccine Priorities

- Afluria® pediatric indication: clinical studies in progress
- Participate in new development to improve vaccine efficacy:
  - Adjuvant/ISCOMATRIX™: Phase II clinical study completed (early onset, strong, broad and long-lasting T-cell response, good safety profile, dose sparing potential); cross-protection in animal model (ferret)
- ‘Novel H1N1’ vaccine contract with HHS: bulk in Melbourne (Australia), filling and packaging in Kankakee (US) and Marburg (Germany)
Thank you