



## National Influenza Vaccine Summit

CSL Biotherapies Update  
2009-2010 Season

Robert Lefebvre

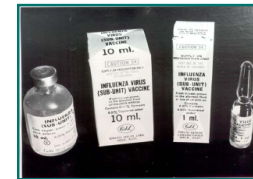
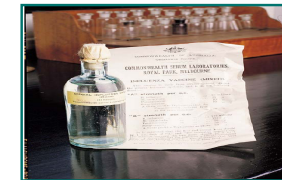
Vice President and General Manager, CSL Biotherapies  
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## Heritage and Commitment to Flu Prevention

- 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



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## 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  - Thimerosal withdrawn from bulk manufacturing in 2002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)



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



- Close working relationship with WHO -CC<sup>1</sup> and TGA<sup>2</sup>
- 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 (NYMC<sup>3</sup> and NIBSC<sup>4</sup>)
  - Yield improvement studies on candidate vaccines
  - Produce master and seed lots
  - Produce/provide reference reagents (no charge) early

<sup>1</sup>WHO Collaborating Centers (4) , <sup>2</sup>Therapeutic Goods Administration , <sup>3</sup>New York Medical Center

<sup>4</sup>National Institute for Biological Standard and Control (UK)

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## 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

Same as 2008-09 NH  
Same as 2009 SH  
New strain

\* A 'reassortant' produced at CSL : CSL has supplied ALL H1N1 reassortants for seasonal flu in the last 10 years

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## 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

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## 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

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## 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)

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Thank you

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