

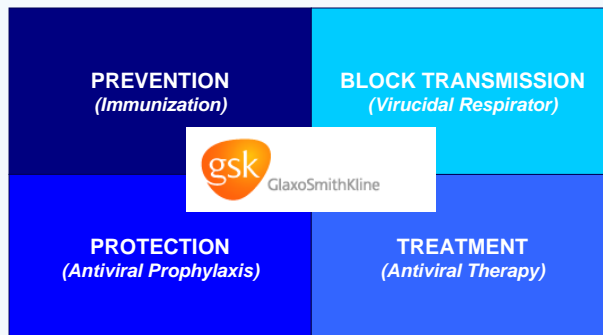


# National Influenza Vaccine Summit

Tosh Butt  
Executive Director- Influenza Franchise

## GSK's Commitment to the Influenza Market

*GSK is the partner for public health in delivering solutions across the broad spectrum of influenza needs*



## GSK Influenza vaccines

- ❖ GSK manufactures inactivated influenza virus vaccines in:
  - ❖ Dresden, Germany
    - *Fluarix*® - seasonal TIV
    - *Prepandrix/Pandemrix*™ - adjuvanted split virus pre/pandemic vaccines
  - ❖ Quebec, Canada
    - *FluLaval*® - seasonal TIV
    - Q-PAN adjuvanted split virus pre/pandemic vaccines – anticipated manufacturing



3

## GSK's Pandemic Influenza Vaccine

### Antigen

- ❖ Monovalent antigen
- ❖ Manufactured in Germany and will be started in Canada

### AS03 Adjuvant System

- ❖ Adjuvant is vialled separately
- ❖ Manufactured in Belgium
  
- ❖ Antigen and adjuvant are mixed prior to injection



4

## GSK Seasonal Influenza Vaccines for 2009-2010

- ❖ *Fluarix* is manufactured in Dresden, Germany
  - Indicated for 18 years and older
  - Available in prefilled syringes
  - *Fluarix* will be thimerosal free for the 2009-2010 influenza season
  
- ❖ *FluLaval* is manufactured in Quebec, Canada
  - Indicated for 18 years and older
  - Available in a multidose vial
  - FluLaval contains thimerosal as a preservative (Each 0.5mL dose contains 25mcg of mercury)



5

## Seasonal Influenza Production Update for the 2009-2010 season

- ❖ GSK estimates that up to 20 million doses total (*Fluarix* and *FluLaval*) will be supplied to the US
  
- ❖ These are early estimates provided for planning purposes and not a commitment to dates and amounts of vaccine



6

## Seasonal Flu Delivery Schedule

- ❖ GSK estimates that 1 million doses will be supplied (ready for shipment and CBER release) by the end of July
- ❖ GSK estimates that 80% of the doses it expects to supply this season, will be supplied (ready for shipment and CBER release) by the end of August
- ❖ These are early estimates provided for planning purposes and are not a commitment to dates and amounts of vaccine



7

## Relenza® Update

### Resistance Profile:

- ❖ According to CDC surveillance data as of Spring 2009, no resistance has been observed with any of the influenza types or subtypes tested, including both the seasonal and novel H1N1 strains.

### Manufacturing and Production Update:

- ❖ Since the novel H1N1 outbreak, GSK has reactivated all of its *Relenza* production lines in Zebulon (North Carolina), Evreux (France), and Boronia (Australia)
- ❖ GSK has the global capacity to produce between 50-60 million treatment courses per year for seasonal and pandemic influenza
  - The U.S. site has the capacity to produce approximately 1.6 million courses per month
  - To further increase global capacity, GSK is exploring alternative delivery methods for zanamivir with regulators



8

## GSK's Commitment to the Influenza Market

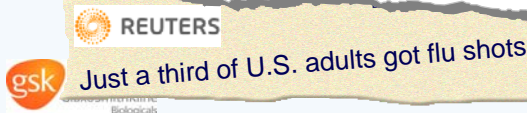
- ❖ Long term vaccine market commitment
- ❖ Continue innovation to improve vaccine effectiveness and product processes
  - Development of technologies such as adjuvant systems to boost the immune response of vaccines and expand capacity
  - Improve and accelerate the manufacturing process
- ❖ Contribute to a comprehensive influenza preparedness effort
- ❖ Committed to looking at avenues to improve influenza vaccination rates



9

## Public Health Partnerships:

- ❖ I HEART Flu Shots – Mended Hearts
- ❖ Flu Vaccination Challenge – Joint Commission Resources
- ❖ Rapid Influenza Survey – RAND Corporation



10