

# Sanofi Pasteur *JE-VAX<sup>®</sup> Supply Update*

February 25, 2008





# Background

- In September of 2003, BIKEN notified sanofi pasteur that it would no longer produce JE-VAX®, Japanese Encephalitis Vaccine
- October 2003, sanofi pasteur notified the military and CDC
- Subsequent discussions resulted in the formation of a stockpile for the military and for the private market, based on historical demand.
- Product was manufactured prior to BIKEN plant closure and has an expiry of Q1 2010.



# JE-VAX<sup>®</sup> Market Demand Review

- Historic Annual Demand (Military & Civilian)
  - ▶ Approximately 100 - 115k doses / year
    - Private/Public sector = ~30k doses / year
    - Military sector = ~75k doses / year
- US Military Stockpile = 410k doses
  - ▶ 135k doses – January 2006
  - ▶ 275k doses – January 2007

## Historic sales of JE-VAX<sup>®</sup> 2000-2006

Year	2000	2001	2002	2003	2004	2005	2006
Doses	100,716	105,444	103,155	86,742	101,385	111,663	203,127*

\*2006 Increase due to shipment for Military Stockpile



# 2007 Review

- In 2007, sanofi pasteur distributed 314,070 doses of JE-VAX®
  - ▶ 39,030 delivered to Civilian market
  - ▶ 275,040 delivered to Military market
    - 【 In 2005, the Military received 28,128 doses
    - 【 In 2006, the Military received 142,140 doses
    - 【 The 2006 and 2007 doses were distributed as part of the Military purchase towards their stockpile



# Current Status 2008

- Doses available for Civilian use as of January 2008:
  - ▶ 23,031 doses as of January 1<sup>st</sup>
    - 【 1,980 doses sold as of January 21<sup>st</sup>
    - 【 21,051 doses in available inventory
      - 2,298 doses reserved for future Pediatric use
        - » Rationale: To support 1 year of pediatric market demand in anticipation of next generation product achieving initial license status of  $\geq 18$  years of age
      - 18,753 doses available for sale



# Supply Restrictions and Reality

- 3 units (9 doses) every 30 days
  - ▶ These restrictions are anticipated to be in place until JE-VAX<sup>®</sup> completely stocks out
  - ▶ Exceptions above this are evaluated on a case by case basis
  - ▶ JE-VAX<sup>®</sup> is a non-returnable product
- Based on 2007 sales and current inventory, sanofi pasteur is expected to stock out of JE-VAX<sup>®</sup> in June 2008



# Potential for Additional Doses

- Discussions are in place to potentially buy back a total of 45,000-50,000 doses from the US Military
  - ▶ Tiered approach with initial purchase of 20,000-25,000 doses
    - ┌ Tiered approach provides risk sharing based on license of next generation product
  - ▶ 45,000 - 50,000 doses would provide an additional 8-12 months of supply based on historical demand and would help with anticipated increased demand for the 2008 Olympics
- Could support transition until next generation product is available for sale in the US