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SCIENTIA VISION: PRODUCT PINPOINT

THE NEW VACCINES

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PRODUCT NUMBER SV103

1 EXECUTIVE SUMMARY

Vaccines approved in the last five years have not only improved on previous products, but have created entirely new markets addressing patients of all ages. Merck's *RotaTeq* and GlaxoSmithKline's *Rotarix* rotavirus vaccines are intended for infants, Merck's *Gardasil* and GlaxoSmithKline's *Cervarix* (not yet approved in the United States) human papillomavirus (HPV) vaccines are intended for female patients aged 9 to 26, GlaxoSmithKline's *Twinrix* provides protection against both hepatitis A and hepatitis B for patients aged 18 and over, and Merck's *Zostavax* prevents herpes zoster (shingles) in patients aged 60 and over.

Vaccines in new therapeutic areas have created entirely new market segments and expanded the target population for vaccines. Coupled with increased emphasis on immunization worldwide, expensive cancer vaccines on the horizon, and increased immunization in emerging markets, the vaccines market is exploding faster than imagined possible just a few years ago. New blockbuster vaccines have completely changed the face of the market. Leading products and product lines in 2008 totaled US\$10.0 billion (€6.9 billion) and included the following:

- *Pevnar* (Wyeth): 2008 sales of US\$2.7 billion (€1.9 billion);
- *Gardasil* (Merck): 2008 sales of US\$1.4 billion (€959 million), sales estimated at US\$2.3 billion (€1.6 billion) when counting *Gardasil* sales by Merck, Sanofi Pasteur MSD, and CSL;
- *ProQuad/M-M-R II/Varivax* (Merck): 2008 sales of US\$1.3 billion (€867 million);
- *Infanrix/Pediarix* (GlaxoSmithKline): 2008 sales of US\$1.3 billion (€859 million);
- Hepatitis Vaccines (GlaxoSmithKline): 2008 sales of US\$1.2 billion (€838 million);
- Polio/Whooping Cough/Hib Vaccines (Sanofi Pasteur): 2008 sales of US\$1.1 billion (€768 million); and
- Influenza Vaccines (Sanofi Pasteur): 2008 sales of US\$1.1 billion (€736 million).

The worldwide market for vaccines has more than doubled in three years, from US\$11.6 billion (€9.4 billion) in 2005 to US\$25.2 billion (€16.5 billion) in 2008, having grown at a compound annual rate of 31.8% (27.6% for Euros). The market has primarily been driven by the billion-dollar products *Pevnar*; *Gardasil*; Merck's *ProQuad/M-M-R II/Varivax* line; *Infanrx* and *Pediarix*; GlaxoSmithKline's hepatitis

line; Sanofi Pasteur's line of polio/whooping cough/Hib vaccines; and Sanofi Pasteur's line of influenza vaccines.

For the forecast period, SV projects that sales will more than double again to US\$50.7 billion (€34.7 billion) in 2013, reflecting compound annual growth of 21.7% (19.2% for Euros). Growth will be driven by the following:

- Introduction of improved, high-value vaccines, such as those for pneumococcus and meningococcus;
- Continued growth in HPV vaccines as more countries put them on national immunization lists;
- Growth in sales of influenza vaccines for seasonal use and pandemic preparedness;
- Growth in sales of hepatitis vaccines;
- Introduction of improved travel and endemic vaccines;
- Increased immunization rates in developing countries;
- Increased immunization rates in Japan; and
- The introduction of expensive autologous cancer vaccines.

ScientiaVision Product Pinpoint: The New Vaccines breaks the market down by regions, as well as by product categories, with historical, base year, and forecast data for each market segment. Market shares are provided for 2005 through 2008.

1.1 Notes on the Data

The base year for this report is 2008. Historical data cover 2005 through 2007, and forecasts cover 2009 through 2013. All data are presented at the level of product sales by manufacturers. All data are presented in both U.S. dollars and Euros. Global and regional sales and forecasts are presented, with market size and trends for 2005 through 2013 for the U.S., Europe, Japan, China, India, and the rest of the world. Sales for 2005 through 2013, market shares for 2005 through 2008, forecasts, and trends are presented for each of seven vaccine categories: cancer, hepatitis, influenza, meningococcus and pneumococcus, rotavirus, travel and endemic, and other. Corporate financial data reported in currencies other than U.S. dollars or Euros have been converted into both U.S. dollars and Euros. Scientia Veritas

(SV) used average exchange rates for the year in making conversions. For 2005, US\$1 = €0.8045 and €1 = US\$1.2430; for 2006, US\$1 = €0.7970 and €1 = US\$1.2547; for 2007, US\$1 = €0.7308 and €1 = US\$1.3683; and for 2008, US\$1 = €0.6834 and €1 = US\$1.4633. For 2009 and forward, the 2008 exchange rates were used. Corporate financial data was obtained from filings with the U.S. Securities and Exchange Commission (SEC; Washington, DC) that included quarterly reports, and 10K and 20F annual filings; annual reports; and press releases. Market estimates are based on corporate filings and press releases, as well as both primary and secondary research.

1.2 The Market by Region

The worldwide vaccine market is changing dramatically in terms of market shares by region. While the U.S. used to account for over 50% of the market, sales in other regions have increased rapidly. The United States accounted for 38.6% of the worldwide market in 2005, declining to 36.2% in 2008, with SV forecasting that the United States will account for 35.7% of the market in 2013. (See Exhibits 1 through 3.) Europe makes up the second-largest market, accounting for 32.2% of worldwide sales in 2005, 29.9% in 2008, and 28.5% in 2013.

While there is more room for growth in reaching unvaccinated populations in emerging markets, those countries are often purchasing (or having purchased for them) lower-cost, commodity-type vaccines. Extra capacity for growth in developing countries is offset by the introduction of new, higher-priced and combination vaccines in established markets such as the United States and Europe.

Exhibit 1: The Worldwide Market for Vaccines, by Region, in U.S. Dollars, 2005, 2008, and 2013

(In millions of U.S. dollars at the manufacturers' level, except where otherwise noted)

YEAR	UNITED STATES	EUROPE	JAPAN	INDIA	CHINA	REST OF WORLD	TOTAL
2005	\$4,075	\$3,395	\$760	\$275	\$325	\$2,800	\$11,630
2008	\$8,750	\$7,210	\$1,035	\$860	\$425	\$5,870	\$24,150
2013	\$18,130	\$14,435	\$2,180	\$1,630	\$675	\$13,685	\$50,735
COMPOUND ANNUAL GROWTH RATES							
2005-2008	29.0%	28.5%	10.8%	46.2%	9.4%	28.0%	27.6%
2008-2013	15.7%	14.9%	16.1%	13.6%	9.7%	18.4%	16.0%
2005-2013	20.5%	19.8%	14.1%	24.9%	9.6%	21.9%	21.7%

Source: Scientia Veritas, L.L.P.

Exhibit 2: The Worldwide Market for Vaccines, by Region, in Euros, 2005-2013

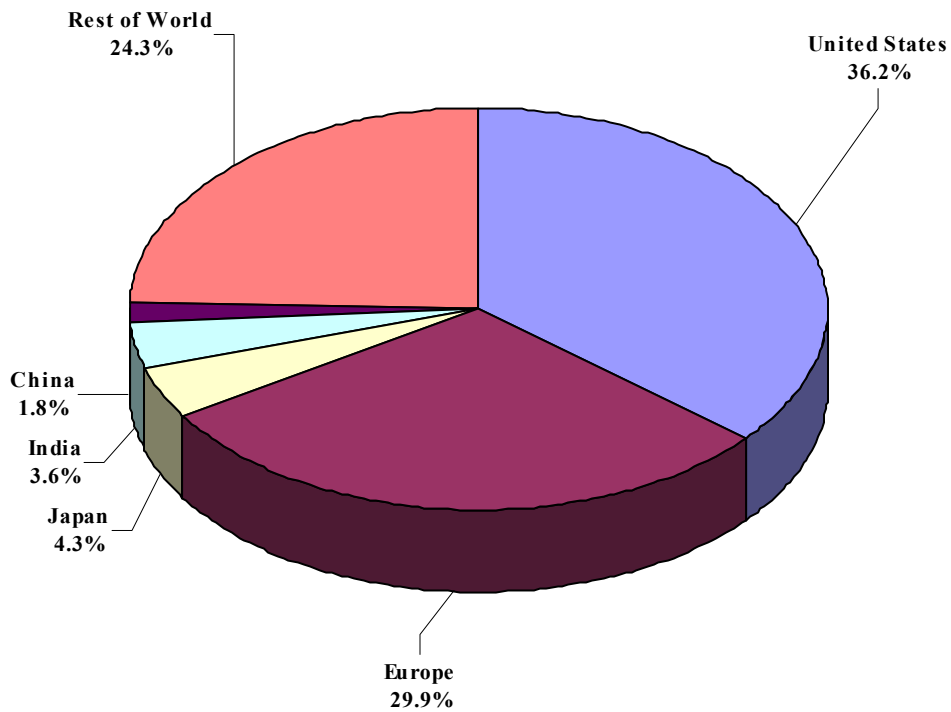
(In millions of Euros at the manufacturers' level, except where otherwise noted)

YEAR	UNITED STATES	EUROPE	JAPAN	INDIA	CHINA	REST OF WORLD	TOTAL
2005	€3,278	€2,731	€611	€221	€261	€2,253	€9,356
2008	€5,980	€4,927	€707	€588	€290	€4,012	€16,504
2013	€12,390	€9,865	€1,490	€1,114	€461	€9,352	€34,672
COMPOUND ANNUAL GROWTH RATES							
2005-2008	22.2%	21.7%	5.0%	38.5%	3.6%	21.2%	20.8%
2008-2013	15.7%	14.9%	16.1%	13.6%	9.7%	18.4%	16.0%
2005-2013	18.1%	17.4%	11.8%	22.4%	7.4%	19.5%	19.2%

Source: Scientia Veritas, L.L.P.

Note: Average exchange rates for 2005 through 2008 were used, with the 2008 rate used for 2009-2013. For 2005, US\$1 = €0.8045; for 2006, US\$1 = €0.7970; for 2007, US\$1 = €0.7308; and for 2008, US\$1 = €0.6834.

**Exhibit 3: The Worldwide Market for Vaccines, by Region, Percent Distribution, 2008
(Pie Chart)**



Source: Scientia Veritas, L.L.P.