Sanofi Global Pharmaceutical company in Japan

March 17, 2014



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1. Pharmaceutical market overview



Global: 4% annual growth (2008-2012)

Japan: 3.5% annual growth (2004-2012)



- 2.6 times growth between 1997 and 2007:
- Global pharmaceutical market in 2012:
- Japan pharmaceutical market in 2012:

\$255 billion to \$667 billion¹ \$962 billion \$93 billion



(\$ billion)

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2. Introduction to Sanofi

Sanofi

- Global integrated healthcare company engaged in the research, development, manufacturing and marketing of healthcare products.
- 110,000 employees in 100 countries
- \$38.2 billion sales in 2012

Sanofi Japan

All for more than 13M Patients* in Japan



Patient numbers are calculated internally based on several industry data

*Patients mean those who use our products for prevention, cure and healthcare in general



**Patients in lysosome disease and patients using Thyrogen

***The numbers are calculated from the market share of two major products, Frontline and Cardomec

3. Introduction to EFPIA Japan

EFPIA Japan – 24 members Sales and Development of New and Innovative Products

EFPIA Member Companies in Japan Sales (2011)





4. Challenges in pharmaceutical innovation

- Drug development ¹
 - Duration: 9 to 17 years
 - Probability of success:
 - 1/20,000
- Cost for drug development²
 - Average cost: \$1.2 billion
- Unmet medical needs ³
 - Number of diseases: 30,000
 - Treatment available: 1/4

Average cost to develop one new medicine - Including the cost of failure





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5. Past issues and recent improvements Situation in 2006: Strong Pressure on ROI





5. Past issues and recent improvements Current business environment





6. Improvements in the innovation environment

- Premium price in drug innovation: Implemented in 2010 (impermanent)
- Number of drug development projects: 81% Increased (2009 vs. 2012)
- Investment for drug development: 35% increased (2009 vs. 2012)





Some projects were initiated prior to request for the development of unapproved drugs.

Source: EFPIA Japan survey (data from 15 companies)

7. Many Unmet medical needs remain



BPH: Benign prostatic hypertrophy. COPD: Chronic obstructive pulmonary disease. IBS: Irritable bowel syndrome. PAD: Peripheral artery disease. SLE: systemic lupus erythematosus Note: Among the new drugs (drugs with new active ingredients and drugs with new indications) being developed by 20 companies ranked top in terms of domestic drug sales amount in fiscal 2012, which are in the development stage from phase I to approval application as of January 2013, 333 drugs related to 60 diseases surveyed for degree of treatment satisfaction in fiscal 2010 are targeted (prepared based on "Report of Domestic Base Technology Survey Results in Fiscal 2010 – Prospect of Medical Needs in 2020 –" of Japan Health Sciences Foundation and published materials of each company). Source: "Drug Approval/Development Status Related to Unmet Medical Needs", News No. 38 (March 2013) from Public Policy Institute, Office of Pharmaceutical Industry Research 10

8. Public Private Partnerships (PPPs) in healthcare for innovation

- PPPs involve collaboration between industry, academia, biotech companies, regulators, and patients' organizations.
- Links know-how and resources of the pharmaceutical industry with external pools of knowledge.
- Attractive means to leverage resources dispersed across industry, academia, and voluntary health organisations in order to address multiple challenges in an era of constrained resources.





9. The Innovative Medicines Initiative (IMI)

- Europe's largest public-private R&D initiative
- 2 billion euro (JPY2400 *oku*) investment for 10 years
- 40+ public-private consortia, launched in 2009
- 1,000+ jobs created
- Currently involved:
 - 363 EFPIA teams
 - 594 academic and research teams
 - 109 SMEs
 - 9 regulators
 - 18 patient organizations





9. The Innovative Medicines Initiative (IMI) Results to date

Validated models and biomarkers	 Alzheimer's Diabetes Schizophrenia Asthma
Robust tools	 Drug safety prediction, prevention and monitoring
Establishment and regulatory submission of key standards and tools	 Drug development in infectious diseases COPD Diabetes
Improved clinical trial design & process	SchizophreniaAutism
Major R&D programs	Antimicrobial resistance

