# Current Trends in Biosimilars

**EPPIC**
**2010 Annual Conference**

**January 10, 2010**
**Palo Alto, CA**

**Presented by**

KAI

# Katan Associates: Our Business

- Strategic Consulting
- Mergers and Acquisitions
- Business Development and Partnering and Other
- Government and Industry Advisory

# Towards Biologics

## Top 10 Drug Products by Sales in 2014

| Rank | Product | Company | Technology | WW Sales ($m) |
|---|---|---|---|---|
| 1 | Avastin | Roche | Monoclonal antibody | 9,232 |
| 2 | Humira | Abbott & Eisai | Monoclonal antibody | 9,134 |
| 3 | Rituxan | Roche | Monoclonal antibody | 7,815 |
| 4 | Enbrel | Wyeth, Amgen & Takeda | Recombinant product | 6,583 |
| 5 | Lantus | Sanofi-Aventis | Recombinant product | 6,386 |
| 6 | Herceptin | Roche | Monoclonal antibody | 5,796 |
| 7 | Crestor | AstraZeneca | Small molecule chemistry | 5,739 |
| 8 | Spiriva | Boehringer Ingelheim | Small molecule chemistry | 5,552 |
| 9 | Remicade | SGP, J&J & Mitsubishi Tanabe | Monoclonal antibody | 5,220 |
| 10 | Gleevec/Glivec | Novartis | Small molecule chemistry | 5,136 |

By 2014 seven out of the top ten best-selling drugs will be biologic drugs, and, biologics drugs are predicted to account for a 75% of the revenues

# Market Dynamics

# Market Drivers

- Market growth expectations as patents expire for blockbuster biopharmaceutical medicines
- Biosimilars predicted to reduce global healthcare costs
- Technological advances in manufacturing and determining equivalence provides impetus to biosimilars manufacturers
- EMEA legislation for requirements and guidelines for approval of biosimilars sets standard for growth and market development of biosimilars in Europe

# On-Going Hurdles

- Political lobbying by branded companies to protect franchises and intellectual property rights
- Market resistance to substitution of branded products by pharmacists, physicians and patients
- Research/development and commercialization of second generation biopharmaceuticals by innovator companies
- Manufacturing issues related to bioequivalence and substitutability of branded biopharmaceuticals
- The cost and complexity of biosimilar development and manufacturing
- Lack of legislation restricts growth of biosimilars in the United States
- Continued issues concerning the determination of bioequivalence despite advances in analytical techniques

KAI

# EU Position

- Within the European Union guidelines have been prepared and authorize the use of specific therapeutic biopharmaceutical medicines as biosimilars

- In November 2004, the CHMP issued for consultation its Guideline on Similar Biological Medicinal Products (EMEA/CHMP/437/04) and later issued for consultation amongst the Working Parties in June 2005. Following consultation and revisions made to the original document came into effect on the 30th October 2005

- In November 2004, the CHMP issued for consultation its Guideline on Similar Biological Medicinal Products (EMEA/CHMP/437/04) and later issued for consultation amongst the Working Parties in June 2005. Following consultation and revisions made to the original document came into effect on the 30th October 2005

- The EMEA has been involved in preparing a regulatory framework for biosimilars since 1998 (Concept Paper on the Development of a CHMP Guideline on Comparability of Biotechnology-derived Products (CHMP/BWP/1113/98))

# EU Position

- Separate guidelines on comparability of medicinal products containing biotechnology-derived proteins as active substance for both quality as well as clinical and non-clinical issues

- Individual guidelines for similar medicinal products came into effect June/July 2006

- Despite the range and depth of the current European guidelines produced by the EMEA national governments have issued national laws prohibiting the automatic substitution using biosimilars to replace original products in many European countries

KAI

# USA Position

- No approval pathway for biosimilars (follow-on biologics (FOB) in the USA) exists in the USA and is unlikely to exist before 2010

- Complex range of Acts and Bills including The Access to Life-Saving Medicine Act (H.R. 1038), Patient Protection and Innovative Biologic Medicines Act (H.R. 1956), The Biologics Price Competition and Innovation Act of 2007 (S.1695), The Pathway for Biosimilars Act (H.R. 5629) have failed to resolve the legal and regulatory issues

- Considerable dispute exists between lobbyists representing the protagonists and antagonist of biosimilars each representing the interests of originator and generic manufacturers

KAI

# USA Position

- On-going problem concerning the litigious nature of the US pharmaceutical market and predictable frequency that originator companies sue generics manufacturers whilst generic companies regularly contest patents on grounds of invalidity or unenforceability delay consensus on legislation

- Development and/or approval of legislation governing the approval pathway for biosimilars further restrained by the pending Healthcare Reform

# China Position

- It is currently estimated there are over 400 manufacturers in China engaged in the manufacture and development of biopharmaceuticals, including 114 manufacturers of genetically engineered drugs and 28 vaccine manufacturers

- The second amendment brought China's Patent Law into compliance with theTrade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement i.e. to harmonize China's patent system with other WTO member countries.

- A third amendment to the Patent Law is widely expected to be approved by the People's Congress

- The latest draft of the third amendment was released for public comment on March 5, 2008

# India Position

- India's biopharmaceutical industry is projected to grow to about $2.7 billion by the end of 2008 and is predicted to grow to almost $5 billion by the end of 2010 representing a staggering annual growth rate in excess of 30%

- On the 23rd March 2005 the Indian Parliament passed the Patent (Amendment) Bill2005 (Bill No. 32-C of 2005) Retroactive to Jan. 1, 2005 to comply with the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

- Ambitious expansion plans by India's biopharmaceutical major manufactures of biosimilars in the regulated US and European markets

# Conclusions

- Biosimilar market to grow to $20.0 billion by 2012
- The USA is behind Europe and Asia
- Price will drive the market growth **not cost**
- To be a major player in the biosimilars market will require:
  - Money
  - Marketing
  - Biologic manufacturing
  - Clinical trial design
  - Pharmacovilligance

KAI