The Emergence of Biologics - Current Status and Challenge

Submitted by: Japan Bioindustry Association
The Emergence of Biologics
-Current status and Challenge-

Prof. Yoshiaki Tsukamoto
Executive Director
Japan Bioindustry Association

Market of Pharmaceuticals in 2009

Global Market US$ 808.3 billion

- North America (322 billion, 40%)
- Europe (248 billion, 31%)
- Japan (90 billion, 11%)
- Mid/South America (46 billion, 6%)
- Others (103 billion, 13%)

Source: IMS Health Market Prognosis, March 2010
Prediction of Regional Pharmaceutical Market Growth to 2013

Expansion of Merging Market and Slow Down in Developed countries

- **World**
  - Sales: 975-1005B USD
  - Growth Rate: 08-13: 4-7%

- **Europe**
  - Sales: 160-190B USD
  - Growth Rate: 08-13: 1-4%  
  *1 Top 5 in Europe (UK, France, Germany, Italy, Spain)

- **Japan**
  - Sales: 97-107B USD
  - Growth Rate: 08-13: 1-4%

- **USA**
  - Sales: 325-355B USD
  - Growth Rate: 08-13: 2-5%

- **Emerging Market**
  - Sales: 160-190 B USD
  - Growth Rate: 08-13: 13-16%  
  *2 China, Brazil, Russia, India, Mexico, Turkey, Korea

- **Others**
  - Sales: 185-215 B USD
  - Growth Rate: 08-13: 5-8%

*Origin: IMS Health, 09 2009*

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Expansion of Bio-pharmaceutical Market

Mainly Monoclonal Antibody Market

(Million USD)

- **Monoclonal Antibody**
- **Recombinant Protein**

(CAGR: Recombinant Protein 4%, Antibody 11%)

(Source: Evaluate Pharma)
Number of Biologics in World Top 100 Pharmaceuticals

2000

9 products
$11,470 MM (8.8%)

2009

25 products
$81,976 MM (27.6%)

Source: Pharma Future

Bio-pharmaceutical market in Japan

Sales (billion USD)

(* including TNF receptor fusion [Enbrel])

Source: Nikkei Biotech
Number of Bio-Venture in Japan, Europe, USA (2008)

- Japan: 569 (16) Listed Companies
- USA: 1754 (371) Listed Companies
- Europe: 1836 (178) Listed Companies

Legend:
- Japanese ventures are limited under 20 Years
- Beyond borders (Ernst&Young)

Origin of Developed product of Top 10 Pharmaceutical Companies in Japan, USA, Europe

- Japan: 400 Products
- USA: 868 Products
- Europe: 908 Products

Legend:
- Introduced from BioVenture
- Marged BioVenture Origin
- Introduced from Pharma
- Own Original

Origin:
- "Alliance & Performance in Pharmaceutical Companies": Analysis of Major Pharma in Japan, Europe
- Hitotsubashi Univ. Research Working Paper
Number of Pharmaceutical Candidates under developing by Japanese Bio-ventures

![Graph showing the number of candidates under development by Japanese Bio-ventures from 1995 to 2008.](source)

Recent Pharma-Biotech Alliances in Japan

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<th>Biotech Company</th>
<th>Information</th>
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<td>Jan, 2008</td>
<td>Eisai</td>
<td>M's Science</td>
<td>$10bil. Alliance</td>
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<td>Feb, 2008</td>
<td>Fuji Film</td>
<td>Toyama Chemical</td>
<td>$100bil. M&amp;A</td>
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<tr>
<td>Feb, 2008</td>
<td>Takeda</td>
<td>Amgen Japan</td>
<td>$90bil. M&amp;A</td>
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<td>Mar, 2008</td>
<td>Takeda</td>
<td>Cell Genesys</td>
<td>$320mil Alliance</td>
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<td>Apr, 2008</td>
<td>Takeda</td>
<td>Millennium</td>
<td>$8.8bil M&amp;A</td>
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<tr>
<td>Jun, 2008</td>
<td>Daiichi-Sankyo</td>
<td>Ranbaxy</td>
<td>$1500bil. M&amp;A</td>
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<td>Sep, 2008</td>
<td>Shionogi</td>
<td>Sciele Pharma</td>
<td>$1.4bil. M&amp;A</td>
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<td>Oct, 2008</td>
<td>Boehringer Ingelheim</td>
<td>Evec</td>
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<td>Jan, 2009</td>
<td>Taiho</td>
<td>aRigen</td>
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<tr>
<td>Feb, 2009</td>
<td>Shionogi</td>
<td>OncoTherapy</td>
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<tr>
<td>Feb, 2009</td>
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<td>Perseus Proteomics</td>
<td>$1.4bil. M&amp;A</td>
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<td>Sep, 2009</td>
<td>Astellas</td>
<td>REGiMMUNE</td>
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<tr>
<td>Jan, 2010</td>
<td>Asahikasei Pharma</td>
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Recent innovative technology on Biologics in Japan

1. ACTEMRA: Chugai Parma Co.,
   - Humanized Anti-Human IL-6 Receptor Monoclonal Antibody
   - Application: Rheumatoid arthritis, Castleman Disease,
   - Technological Collaboration with Osaka Univ.

2. Potelligent: Kyowa-Kirin Co.
   - Host cell Mutation for Antibody modification
   - Enhance ADCC activity to 100-1000 times,
   - Licensed out to 16 Pharma (GSK, Genentech, Takeda etc.,)

3. Fully Humanized Antibody Production: EVEC Co.,
   - Human lymphocyte Propagation with EB virus for monoclonal antibody
   - Licensed out to Boehringer Ingelheim GmbH.

Challenges in Biologics

1. Utilizing potential of Academia and Bio-venture
   - International Open Innovation in APEC is important.

2. Risk of Investment
   - Total Investment for Biologics is higher than for small molecules.

3. Regulation
   - International Harmonization of reasonable regulation is needed.

4. Clinical research
   - International cooperation in APEC is essential to optimize a plan for clinical research as personal medicine.
For the Prosperity of World Society & Economy

APEC Economies should take Pro-Innovation Action to enhance Biologics & Life Science

APEC International Open Innovation Initiative
Invitation to BioJapan2010

- 29th Sep. - 1st October 2010 at Yokohama.
- The event consists of seminar, exhibition and business matching
- Main themes are Medicine, Medical devices, Functional food, Biomass-plastic and Bio-fuel.
- Many Bio-related big companies, Bio-Ventures, TLOs and Bio-Clusters will attend from 30 countries.

http://expo.nikkeibp.co.jp/biojapan/
See you in Yokohama

Thank you!