Chugai’s approach in a drastically changing business environment

CHUGAI PHARMACEUTICAL CO., LTD.
Chairman of the Board,
President and CEO
Osamu Nagayama

2007.9.13
Today’s Agenda

1. Expectations for Pharmaceuticals
2. Chugai/Roche Strategic Alliance
3. Goal of Chugai
Environment changes around pharma industry

① Increasing medical costs and worsening financial state of health insurance system due to aging society and low birth-rate
   ⇒ Strengthening of cost containment of drugs and stagnation of pharmaceutical market

② “Lull” in discovery faced by new drug R&D
   ⇒ Rapid progress of life sciences
   ⇒ Increasing R&D costs
   ⇒ Decreasing efficiency of development

③ Borderless market for pharmaceuticals
   ⇒ Birth of global mega-pharmas
   ⇒ Increasing competition among companies
Correlation of treatment satisfaction and pharmaceutical contribution (doctor survey)

Source: The Japan Health Sciences Foundation “Report on Key Domestic Technologies”
Diseases and new drugs with significantly increased treatment satisfaction / contribution from pharmaceuticals

In surveys of treatment satisfaction included in the 2000 and 2005 “Report on Key Domestic Technologies” by the Japan Health Sciences Foundation, the rate of treatment satisfaction and the rate of contribution by drugs both increased 5 points between 2000 and 2005 for pharmaceutical products with new active ingredients and efficacy drugs with therapeutic effect in eight disease areas. (Source: OPIR)
### Biopharmaceuticals among the world’s top 100 products

<table>
<thead>
<tr>
<th>Rank</th>
<th>Product</th>
<th>Company</th>
<th>World Sales (Mill$)</th>
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<tr>
<td>4</td>
<td>Epogen/Procrit/Espo</td>
<td>Amgen/J&amp;J/Kirin</td>
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<td>27</td>
<td>Intron A/Revetron</td>
<td>Schering Plough</td>
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<td>35</td>
<td>Neupogen</td>
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<td>Enbrel</td>
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<td>97</td>
<td>Rituxan/Mabthera</td>
<td>Biogen IDEC/Roche</td>
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<td>98</td>
<td>Betaferon</td>
<td>Schering</td>
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<td>Enbrel</td>
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<td>Herceptin</td>
<td>Genentech/Roche/Chugai</td>
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<td>Avastin</td>
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<td>92</td>
<td>Pegasys</td>
<td>Roche/Chugai</td>
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<td>94</td>
<td>Synagis</td>
<td>Medimmune/Abbott</td>
<td>1,165</td>
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**Number / Sales / % of Biopharmaceuticals (top 100 products)**

- **2000**
  - 8 products
  - $10,933 million (8.4%)

- **2006**
  - 20 products
  - $51,444 million (20.7%)

*Japanese market: 9 products

Source: Pharma Future
Expanding share of biopharmaceuticals

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<th>2001-06</th>
<th>2005-10</th>
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<tr>
<td>Total Market</td>
<td>10.5%</td>
<td>4%</td>
</tr>
<tr>
<td>Proteins</td>
<td>14.6%</td>
<td>11%</td>
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<tr>
<td>Antibodies</td>
<td>33.8%</td>
<td>20%</td>
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Sales ($m)

Share of biopharmaceuticals

Rheumatoid Arthritis
Colorectal Cancer
Breast Cancer

Source: DATAMONITOR
1. Expectations for Pharmaceuticals

2. Chugai/Roche Strategic Alliance

3. Goal of Chugai
December, 2001: Signing of Basic Agreement
October, 2002: Completion of merger with Nippon Roche and full-fledged start of the Alliance
Chugai-Roche “Unique” Alliance

- Roche acquired 50.1% of Chugai’s shares
- Chugai and Nippon Roche merged
- Chugai maintained autonomous management

By the Alliance

For Chugai
- Secures foundation for drug discovery technology related to bio-pharmaceuticals
- Acquires more chances to produce innovative products through R&D synergies
- Strengthens total resources, including product/pipeline portfolios
- Gains an option to the global market through Roche’s infrastructure

For Roche
- Acquires local management that understands the Japanese business environment
- Strengthens its presence in Japan - the world’s second largest market
- Increases opportunities to acquire Japan-originated innovative drugs
- Establishes a “Global Management Network” infrastructure (Hub & Spokes)
Establishment of global competitiveness through the Alliance

- Securing diversity & creativity through autonomous management
- Enhancing efficiency & productivity through mutual collaboration
- Competitiveness as the top bio-pharmaceutical group

- Continuous drug creation by leveraging bio-technology
- Satisfying unmet medical needs, with a focus on cancer

- Access to the global market, either independently or in collaboration

Rich pipeline

Chugai

Strengthening of research infrastructure

Roche

Genentech

Exchange of technology, information and knowledge within Roche group
Chugai’s performance since the Alliance

Sales and OP (billion Yen)

OP Ratio (%)

Sales
Operating Profit
OP Ratio

Market value
Stock price

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Areas of focus and products

¥326 billion in 2006 (consolidated net sales)

Cancer
- Furtulon
- Xeloda
- Neutrogin
- Kytril
- Rituxan
- Herceptin
- Avastin*

Renal
- Epogin
- Oxarol
- Renagel

Immunology & Infection
- Tamiflu
- Pegasys
- Copegus*
- Rocephin

Cardio/Cerebro
- Sigmart
- Rythmodan
- Preran

Bone/Joint
- Alfarol
- Rocaltrol
- Suvenyl
- Evista

Others
- Others 9.3%

Others
- Rohypnol
- Amoban
- Ulcerlin
- Euglucon

* Copegus and Avastin were launched in 2007
**Share of Biopharmaceuticals within Chugai**

**December, 2006 (consolidated)**

- **Non-bioproducts 55%**
- **Recombinant proteins 32%**
- **Antibodies 10%**
- **Other Bioproducts 3%**

**Bioproducts 45%**

- **Epogen** (epoetin beta) Renal anemia
- **Neutrogin/Granocyte** (lenograstim), Neutropenia
- **Pegasys** (peglated interferon alfa 2a), Hepatitis C
- **Herceptin** (trastuzumab, anti-HER-2 Mab) Breast cancer
- **Rituxan** (rituximab, anti-CD20 Mab) Non-hodgkin lymphoma
- **Actemra** (tocilizumab, anti-IL-6R Mab) Castleman’s disease
- **Avastin** (bevacizumab, anti-VEGF Mab) Colorectal cancer  
  *Avastin was launched in 2007*

**Biopharmaceuticals in Development**

- **Epogen** (epoetin beta) Chemotherapy-induced anemia (filed)
- **Avastin** (bevacizumab) Adjuvant colorectal cancer (P3), Lung cancer (P2), Breast cancer (P2)
- **Herceptin** (trastuzumab) Adjuvant breast cancer (filed), Gastric cancer (P2)
- **Actemra** (tocilizumab) Rheumatoid arthritis (filed), Multiple myeloma (P2), Crohn’s disease (P1), etc.
- **R744** (cont. erythropoietin receptor activator) Renal anemia (P3), Chemotherapy-induced anemia (P2)
- **Pegasys** (peginterferon alfa-2a agent) Liver cirrhosis (P2/3), Hepatitis B (P2/3)
- **R1273** (pertuzumab) Non-small cell lung cancer (P1)
Chugai shares by product

- Erythropoietin (62%)
- G-CSF (40%)
- Interferon (10.8%)
- Antibodies (43%)

Japan’s biopharmaceutical market in 2006

¥480.9 billion

Chugai (26.4%)

- Erythropoietin (27.6%)
- Growth Hormone (11.6%)
- G-CSF (8.0%)
- Insulin (15.4%)
- Chugai (1.3%)
- Interferon (10.8%)
- Blood Clotting Factors (3.3%)
- Chugai (4.8%)
- Antibodies (11.1%)
- Others (10.8%)

Data: Nikkei Biotech (Dec. 2006)

(Antibodies include TNFR fusion protein)
Development of Actemra and Investments in Production Facilities

**PI/II**

- **Clinical development for Rheumatoid arthritis**
  - *domestic study*
  - *overseas study*

**PII**

**PIII**

- **Investment decision**
  - planning
  - construction
  - validation

- **Expansion of Ukima facilities**
  - *(2,500L × 2)*

- **Utsunomiya I term**
  - *(10,000L × 2)*
  - For clinical trials

- **Launch of Actemra® in Japan (Castleman’s disease)**

- **Utsunomiya II term**
  - *(10,000L × 4)*
  - For commercial use

- **additional**
  - *(10,000L × 2)*

- **Launch of Actemra® in Japan (interim analysis)**

- **extension study (interim analysis)**

- **NDA for RA in Japan (interim analysis)**

**Timeline:**
- 2000
- 2001
- 2002
- 2003
- 2004
- 2005
- 2006
- 2007
No.1 Bio-production based on tri-polar network

Roche Group

Japan

Chugai
Ukima
Utsunomiya

Ukima Antibody Facility
- 2.5KL x 2
Utsunomiya Antibody Facility
- 1st phase (10KL x 2)
- 2nd phase (10KL x 6)

Production Capacity
- Fermentation facility
- Purification facility

Know-how / Talent
- Industrial Process Develop.
- Formulation
- Quality control

Europe

Roche
Basel
Penzberg

Genentech
South SF
Vacaville

North America

Contract
Manufacturing
Organizations
Mammalian cell culture capacity

2006

- 74% (1.9 million L)
- 2%
- 19%
- 5%

2010

- 64% (2.4 million L)
- 8%
- 24%
- 4%

Data: JP Morgan estimates
Today’s Agenda

1. Expectations for Pharmaceuticals
2. Chugai/Roche Strategic Alliance
3. Goal of Chugai
Goal of the mid-term plan “Sunrise 2010”

Double revenue (Rx) and triple operating profit since start of the alliance with Roche

Sales (¥ billion)

2002 2003* 2004 2005 2006 2007 (forecast) 2010

Operating profit

Environment changes after drawing up “Sunrise 2010”
Flat-sum reimbursement and escalation of market competition for Epogin
Return of products to sanofi-aventis
Safety measures for Tamiflu
Low pricing of new bio-products

*FY2003: 9 months

Sales: ¥450 billion
OP: ¥100 billion

2-fold
1.5-fold

Sunrise2010

OP (¥ billion)

0 50 100 150

0 100 200 300 400 500

0 100 200 300 400

0 100 200
Major submissions for approval

- File for approval of NMEs and additional indications every year
- Secure safety and proper market introduction of new drugs

![Diagram showing major submissions for approval with timelines and product names.]
Business environment and Chugai’s countermeasures

**Negative**
- Severe containment of drug costs
  - Reduction of costs in dialysis
    - Flat-sum reimbursement of ESA drugs
    - Low pricing of new ESA drugs
  - Low pricing of new bio-products

**Positive**
- Expectations for innovative drugs
  - Government measures to resolve drug-lag
  - Discussion of new drug pricing system reflecting drug values

- Restructuring of global manufacturers

- Progress of life science and biotechnology

- Increasing interest in drug safety

**Management for transformation and growth**
(organization, system, processes, human resources)

- Offer new drugs based on needs of patients and medical care
  (focus on cancer and bio pharmaceuticals)

- Maximized utilization of synergies of the Roche group
  (resources and knowledge)
Management for transformation and growth

**Improvement of both “Hard” and “Soft” Sides**

**Transformation of hard side**
- Establishment of “Strategic Marketing” function
- Establishment of Oncology Unit
- Specialized MRs in cancer and renal + General MRs
- Strengthening of safety information management system
- Spin-off of production function and restructuring of production sites

**Transformation of soft side**
- Implementation of business process reengineering
  - Improvement of productivity and change of mind-set
- Secure, foster and improve human resources

**Achievement of 2010 goal**
Transformation and challenges in marketing functions

☐ Evidence based Marketing
  ✓ Analysis and action based on market data of products
  ✓ Supply of treatment (drug) information based on evidence

☐ Medical marketing
  ✓ Cooperation and support of clinical research by study groups
  ✓ Lifecycle management (consistent fostering of products from development stage to post-approval)
  ✓ Establishment of drug efficacy, safety and economic efficiency by pharmaco-epidemiology/economics

☐ Stakeholder marketing
  ✓ Support access to the world’s standard treatments (e.g. Karolinska report)
  ✓ Supply of information and activity support to patient groups
  ✓ Support to medical professionals and staff (support increased use of standard guidelines and treatment by specialized teams)
Measures toward transformation and growth

Aim for No.1 position in the Japanese cancer field

- Contribution to treatment and patient health by innovative drugs
  - Herceptin, Xeloda, Avastin, TARCEVA*, etc.
  - Simultaneous development by participation in global studies
  - Active license-in of products from Roche/Genentech

- Comprehensive contribution to cancer treatments
  - Response to changes in medical environment (Basic Law of Countermeasures Against Cancer, improvement of key cancer institutions, fostering of cancer specialists, standardization of treatments, shortening of time-lag of approval from overseas)
  - Supply of information to patients and medical professionals, promotion of standard treatments based on evidence
  - Promotion of proper usage of drugs, timely supply of safety information

- Proactive approach to cutting-edge technologies
  - Investment in technologies related to genome and antibody
  - Establishment of Chugai’s research network
  - Response to increasing demand for antibody drugs
  - Synergy with Roche in research

(PLR: PharmaLogicals Research, FRP: Forerunner Pharma Research) (*overseas product name)
Chugai’s approach based on 3 points of views

~Focus on cancer and biotech~

**New treatments**
Focusing on disease areas where satisfaction of medical treatment is low (refractory diseases such as cancer and rheumatoid arthritis)

**Development of new drugs for unmet medical needs**

**Innovative technologies**
New possibilities in drug discovery by genomic research etc.
Development of biopharmaceuticals

**Improving quality of medical care**
Standardization of medical treatments
Promotion of EBM
Strengthening of drug safety measures
- High-quality MR performance and strengthening of PMS system
- Comprehensive educational activities about diseases

**Proactive approach to new technologies**
Strengthening of medicinal chemistry functions and approaches

2002.10: Merger of chemical functions at Gotemba (Chugai) and Kamakura (Nippon Roche)
  ⇒ Significant expansion of medicinal chemical functions

2002.9: Contract with Roche on cooperative research in low molecular drugs
  ⇒ Mutual access to chemical libraries (one of the world’s largest with over a million compounds)
  ⇒ Mutual utilization of research information such as chemical database
  ⇒ Utilization of Roche’s research tools

2006.9: Start of TP300 (cancer drug) clinical study
2007.1: License-out of research projects to Roche
  ⇒ 2 projects in cancer area
  ⇒ 1 project in diabetes

2003
2004
2005

• Restructuring and consolidation of research organization and functions
• Strengthening of research portfolio management
• Selection and concentration of research projects
• Cooperation with pharmaceutical technology function
Chugai’s Challenges

◆ The environment around the pharmaceutical industry and Chugai is changing drastically and becoming more severe.

◆ There are great expectations for biotech and other cutting-edge technologies to address unmet medical needs.

◆ The strategic alliance between Chugai and Roche started in 2002, aiming to respond to those needs and continuously supply new medicines.

◆ Roche group aims to be the top group in the areas of “cancer” and “biopharmaceuticals” by realizing mutual synergies of group companies.

◆ The group possesses bio-production facilities and know-how — the high hurdles of biopharmaceuticals — in a tripolar network encompassing Japan, US, and Europe.

◆ Chugai has been implementing the “transformation” of organizations, systems, processes, and human resources to achieve its mid-term plan.

◆ Leveraged by “cancer” and “bio/antibody technologies”, Chugai aims to create new value by offering new treatments, utilizing the latest science and technology, and improving the quality of medical care.
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