# New Mid-term Business Plan

# “IBI 21”

Tatsuro Kosaka
President and CEO
CHUGAI PHARMACEUTICAL CO., LTD.

January 31/ February 1, 2019

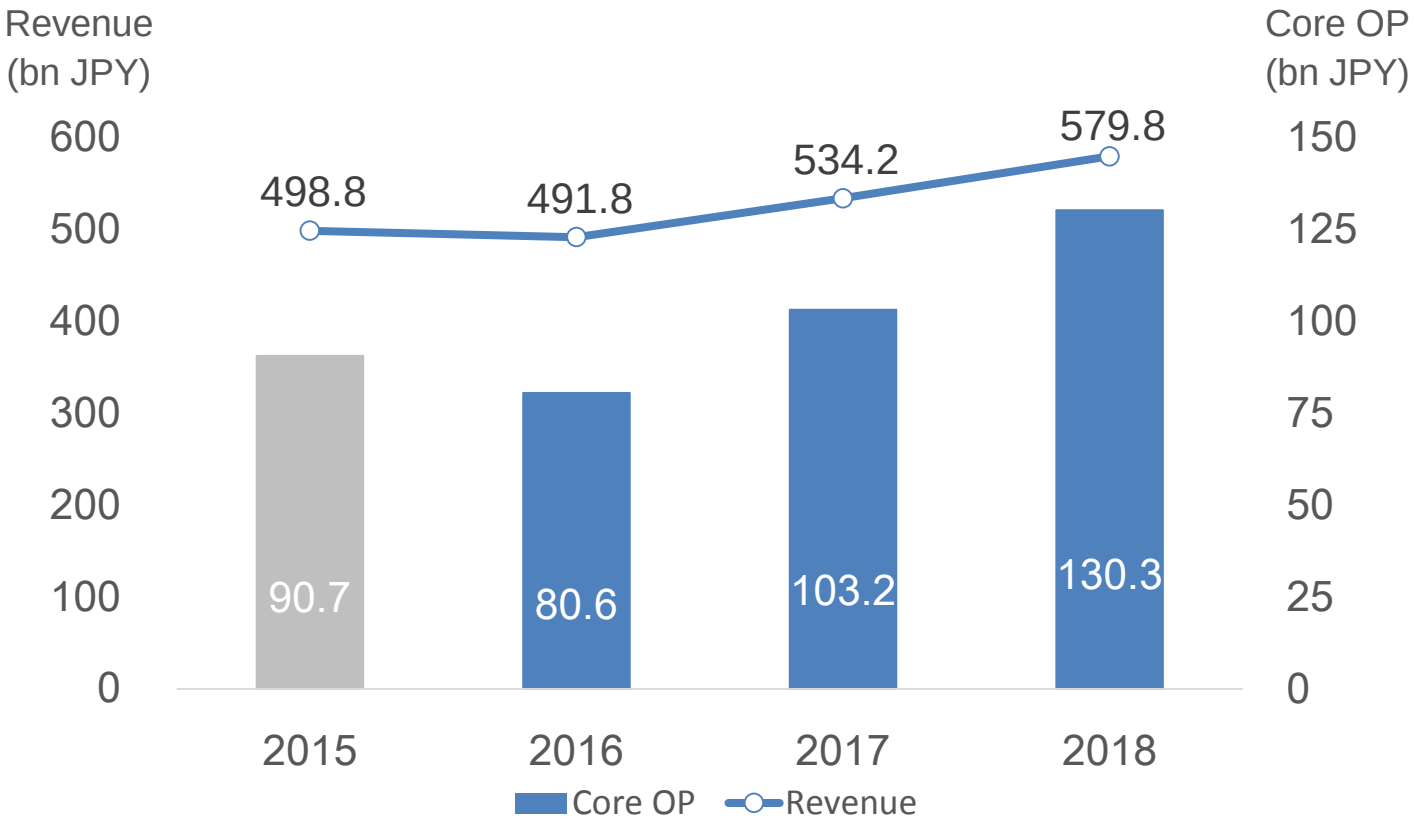
# Forward-Looking Statements

This presentation may include forward-looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. (the “Company”). These statements reflect the Company’s current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company’s businesses.

Note: Amounts shown in this report are rounded to the nearest 0.1 billion yen.
Variance and % are calculated based on the amounts shown.

# Review of 2016 – 2018
# Mid-term Business Plan “IBI 18”

# Business Performance during IBI 18




2015-18 CAGR*

**Revenue +5.1%**

**Core OP +12.8%**

**Core EPS +14.9%**

| | | | | |
|---|---|---|---|---|
| **Core EPS** | 116.4 JPY | 102.5 JPY | 138.7 JPY | 176.4 JPY |

| | | Initial Target | Result | Status |
|---|---|---|---|---|
| **IBI 18 Target** | Core EPS CAGR* (2015-18) | Low single digit** | 17.1%** | ✓ |

*CAGR: Compound Annual Growth Rate (%) ** 3 years, average constant exchange rate for 2015

# Summary of IBI 18

## Achieving record high profit, Chugai is enriching our platforms for further growth

| | | Status |
|---|---|---|
| Financial targets | ● Posted consecutive record revenues and operating profit<br>● Achieved industry-leading market capitalization | ✓ |
| Priority agenda: Acquisition and implementation of global top-class competitiveness | ● Continuously generated new antibody projects and enhanced drug discovery platform for middle molecules<br>● Obtained early approval for Hemlibra<br>● Obtained Tecentriq approval and simultaneously developed drugs for 19 indications<br>● Established system to manage FDA GMP inspections | ✓ |
| Priority agenda: Selection and concentration for accelerated growth | ● Established framework to execute regional strategy through collaboration of 3 Chugai divisions (Marketing & Sales/Medical Affairs/Safety)<br>● Made steady inroads towards accelerated growth based on Hemlibra and Tecentriq | |

# Realization of Becoming a Top Pharmaceutical Company

# Goals of “Top Pharmaceutical Company”

CHUGAI
Roche Roche Group

| Corporate Vision | **Company that focuses on first-in-class/best-in-class products and services, and continuously provides new solutions to patients and medical communities around the world —Innovation all for patients—** |
|---|---|

## Quantitative Targets (in late 2010s)

- ✓ Gain a position among the top 3 major Japanese pharmaceutical companies
- ✓ No. 1 presence in our strategic therapeutic areas in Japan
- ✓ Expanded presence in global market

## Qualitative Targets (in late 2010s)

- ✓ A company that satisfies all its stakeholders and receives their active support and trust
- ✓ A company that works proactively on a global level

# Top Pharma: Quantitative Targets (1)

CHUGAI

Roche Roche Group

## Goal: Rank within the top 3 major Japanese pharmaceutical companies in the following categories

| | |
|---|---|
| Domestic sales share | 5th* |
| Consolidated operating profit margin ✓ | 2nd |
| Consolidated operating profit per employee ✓ | 2nd |
| Domestic sales per MR ✓ | 1st** |

## Goal: No.1 domestic presence in strategic disease areas

| | Market share | Stakeholder satisfaction |
|---|---|---|
| Oncology ✓ | 1st* | 1st*** |

Renal: 2nd*/2nd***, Bone & Joint: 2nd*/2nd***, RA (biologics): 2nd*/1st***

## Goal: No.1 presence in hospital market based on medical care networks linking healthcare providers

| | Market share | Stakeholder satisfaction |
|---|---|---|
| Share of hospital sales (≥100 beds) ✓ | 1st* | 1st*** |

* Copyright© 2019 IQVIA. Source: JPM 2018. Reprinted with permission. The scope of the market is defined by Chugai. (Other companies: 2017, 2018 or years ended March 31, 2018)
** Calculated by Chugai, based on data from Fuji-Keizai Co., Ltd. *** Copyright© 2019 anterio. Source: Rep-i 201808. Reprinted with permission. The scope of the market is defined by Chugai.

# Top Pharma: Quantitative Targets (2)

CHUGAI
Roche Roche Group

## Goal: Expansion of global presence

| | |
|---|---|
| Increase overseas sales ratio | 2008: 10.4%<br>2018: 24.2% |
| Possess 3 major global products | Actemra<br>Alecensa<br>Hemlibra |
| Number of global projects in late-stage development (possess ≥3 projects) | nemolizumab<br>satralizumab<br>SKY59 (expected) |
| Continuous addition of FIC/BIC in-house projects to the portfolio (average 3 projects /year) | During IBI 18<br>8 projects/<br>3 years |

# Top Pharma: Qualitative Targets (1)

## Goal: A company that satisfies all its stakeholders and receives their active support and trust

### 【Patients and Healthcare Professionals】

Play a part in increasing treatment satisfaction and the contribution of drugs in cancer treatments in our capacity as a leading oncology company ✓

### 【Shareholders and Investors】

Realize growth strategies based on innovation
(market capitalization: 31st in Japan overall, 1st in domestic pharmaceutical industry) ✓

※as of Dec. 28, 2018

### 【Roche】

Contribute to growth of Roche Group by out-licensing Actemra, Alecensa, and Hemlibra.
Realize revenue and profit growth by fully leveraging our alliance with Roche. ✓

# Top Pharma: Qualitative Targets (2)

## Goal: A company that works proactively on a global level

**Continuous creation, development, and domestic and overseas launches of products with a competitive advantage in clinical results** ✓

- FDA breakthrough therapy designation for 7 times in 4 products (No. 1 in domestic pharm.)
- Establish world-class manufacturing base (completion of HEM/ALC global inspections)

**Contribution to the Roche Group’s results through product-appropriate fostering and sales** ✓

- Maximize product value through simultaneous global development and filing of Roche products
- No. 1 customer satisfaction in strategic disease areas by establishing a system for providing new solutions

**Leadership in pharmaceutical industry activities** ✓

- Promote personalized healthcare in Japan
- Become an industry leader in biotechnology
- Lead the field of drug safety by establishing a system to provide value-added safety information

**Activities in which all employees have an awareness, sense of responsibility and pride as part of a top pharmaceutical company** ✓

- Raise awareness among employees of Chugai’s goal of becoming a top pharmaceutical company
- Become a world-class company in employees engagement
- Facilitate human resource development that also creates win-win relationships at the individual level through collaboration with Roche

# Realization of Top Pharmaceutical Company

CHUGAI

Roche Roche Group

**Mid-Term Business Plan IBI 18**

- Acquisition and implementation of global top-class competitiveness
- Selection and concentration for accelerated growth

R&D targets / Share and presence targets / Financial targets

Status ✓

**Top Pharmaceutical Company**

- A company that works proactively on a global level
- A company that satisfies all its stakeholders and receives their active support and trust

Major quantitative targets

✓

**Envisioned Future**

**As a most important member of the Roche group, we aim to become a top Japanese pharmaceutical company by providing a continuous flow of innovative new medicines domestically and internationally.**

✓

# Business Environment and Vision for Growth

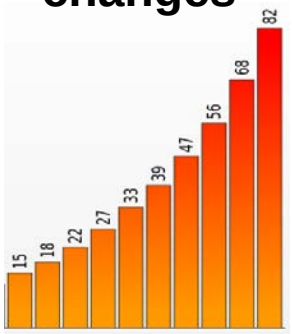
# Drastic Reforms Required for Healthcare Industry while Experiencing Big Changes in the Environment

CHUGAI

Roche Roche Group

## Mega-trends

**Exponential changes**




**Simultaneous global threats**

**Remarkable advances in life sciences and digital technologies**

**Dramatic demographic shifts**

**Threats to sustainability of global environment and social systems**

## Impact on healthcare industry

**Higher benchmarks set for innovation**

- **Falling drug prices due to clampdown on healthcare costs**
- **Stricter evaluation of cost-effectiveness**

**Increased calls to participate in resolving social issues**

# Chugai’s Basic Policy

**Striving for the mutual development of Chugai and Society by solving social issues through the creation of innovative drugs and services**

Chugai growth and development = **Creation of value shared by Chugai and Society**
**Realize advanced and sustainable patient-centric healthcare** = Social growth and development

**Increased corporate value**

**Resolution of social issues**

## Focus on innovation

**Creation of innovative drugs and services**

- **Strategic alliance with Roche**
- **Our science and technologies**

**Chugai business model adopted**

**Key issues selected by Chugai (materiality)**

- Sustainable Healthcare
- Human Rights
- Supply chain management
- Human Resources
- Social Contribution
- Global Environment
- Governance
- Ethics and Compliance

# Renewal of Core Values & Envisioned Future

CHUGAI

Roche Roche Group

## Mission Statement
## ~Innovation all for the patients~

**No change:**
**Maintain as starting point**

### Mission

**Dedicate ourselves to adding value by creating and delivering innovative products and services for the medical community and human health around the world**

**Change:**
**Succinctly describe the most important value assessment criteria**

### Core Values

| | |
|---|---|
| **1. Patient Centric** | Make each patient’s wellbeing our highest priority |
| **2. Pioneering Spirit** | Pursue innovation by improving ourselves and thinking differently |
| **3. Integrity** | Maintain the highest standards in all we do to create shared value with society |

**Change:**
**Redefine the aspect of evolving with society as a higher objective**

### Envisioned Future

**Become a top innovator for advanced and sustainable patient-centric healthcare, powered by our unique strength in science and technology and the alliance with Roche**

# FY2019-21 New Mid-term Business Plan “IBI 21”

# Name of New Mid-Term Business Plan

**While maintaining the concept of “IBI” which express our attitude to pursue continuous innovation and creation, “21” expresses the new stage in which we will take on new challenges.**

# IBI 21

IBI: INNOVATION BEYOND IMAGINATION

# New Mid-Term Business Plan: 5 Strategies

CHUGAI
Roche Roche Group

## Accelerate corporate and social development through innovation focused on innovative products

### Create global growth drivers and maximize value

**1 Value Creation**

Realize innovative drug discovery
to cure and manage diseases

**2 Value Delivery**

Deliver patient-centric solution
to maximize value of growth drivers

**3 Promote advances in personalized healthcare**

Realize the further advancement of PHC and innovate R&D process
by utilizing digital technology and data

### Strengthen HR and infrastructure that support Chugai’s business

**4 Human capital and structural reform**

Develop high-caliber HR talent that support innovation,
and drastically reform costs, systems and processes

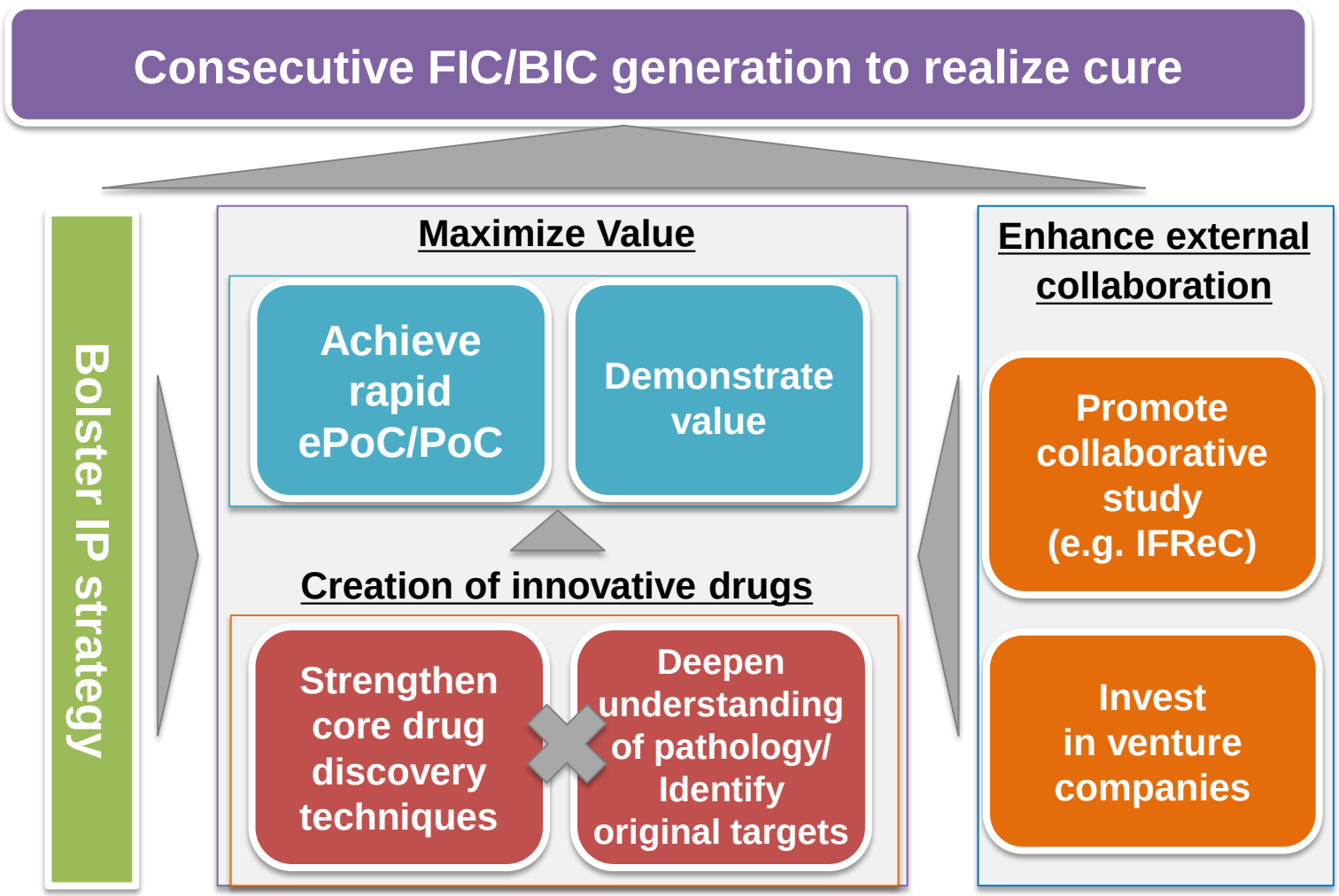
**5 Strengthen sustainable platforms**

Simultaneously realize company growth and sustainable social development

# Strategy 1: Value Creation

CHUGAI
Roche Roche Group

**Realize innovative drug discovery to cure and manage diseases by integrating our core drug discovery techniques and biology, and by achieving rapid PoC**



# Strategy 2: Value Delivery

CHUGAI

Roche Roche Group

## Maximize growth drivers (innovative drugs and services) through patient centric consulting and digital solution

**Maximize value of growth drivers**

**Promote FMI business in Japan**

**Provide solutions through integration between collaboration in variety of specialists and digital technology**

- Deepen 3 Divisions’ collaboration and deliver sophisticated consulting
- Advancement of treatment support/ solution utilizing digital technology

**Additional value to realize personalization and differentiation**

- High quality evidence including RWE
- Real-time safety information

**Innovative drugs/services such as Hemlibra/Tecentriq**

# Strategy 3: Promote Advances in PHC

CHUGAI

Roche Roche Group

## Realize further advancements in PHC and innovate R&D process through ‘PHC2.0’ by utilizing digital technology and data

**Further advance PHC and innovate R&D process**

### Collaboration with Roche

- Utilize Roche Assets (e.g. Flatiron)

### Promote PHC 2.0 to create value

- Advance in cancer genome diagnostics (FMI) (e.g. accelerate developing liquid biopsy etc.)
- Develop high-quality medical DB in collaboration with medical institutes
- Generate insights by establishing data utilization structure and advanced data analysis

### Intelligence

- Collect information incl. science and digital technology
- Confirm feasibility of digital devices

# Strategy 4: Strengthen Human Capital and Conduct Drastic Structural Reform

## Recruit and develop diverse and high-caliber HR talent that support innovation, and conduct drastic structural reforms

**Accelerate innovation by implementing strategies ①–③**

### Strengthen business platforms

#### Recruit and develop HR talent

- Strengthen talent management system
- Diversity & Inclusion
- Reform remuneration system

#### Drastic structural reform

- Structural reform by reviewing costs, systems and processes
- ✖
- Shift resources to facilitate innovation

# Strategy 5: Strengthen Sustainable Platforms

CHUGAI

Roche Roche Group

**With the aim of improving corporate value continuously, specify 6 priority agendas that support our challenge toward innovation, based on expectation/request from the society, economic/environmental/social effects by Chugai, and interest of stakeholders.**

**Corporate value** = **Economic value** + **Social value**

# IBI 21 Quantitative Outlook

**Under the new mid-term business plan, we will make essential investment for future growth, while maintaining the momentum of growth achieved during IBI 18, and realize sustainable profit growth and expansion of corporate value.**

| | |
|---|---|
| **Core EPS CAGR* (2018 – 2021)** | **High single digit**** |

* Compound Annual Growth Rate (%)

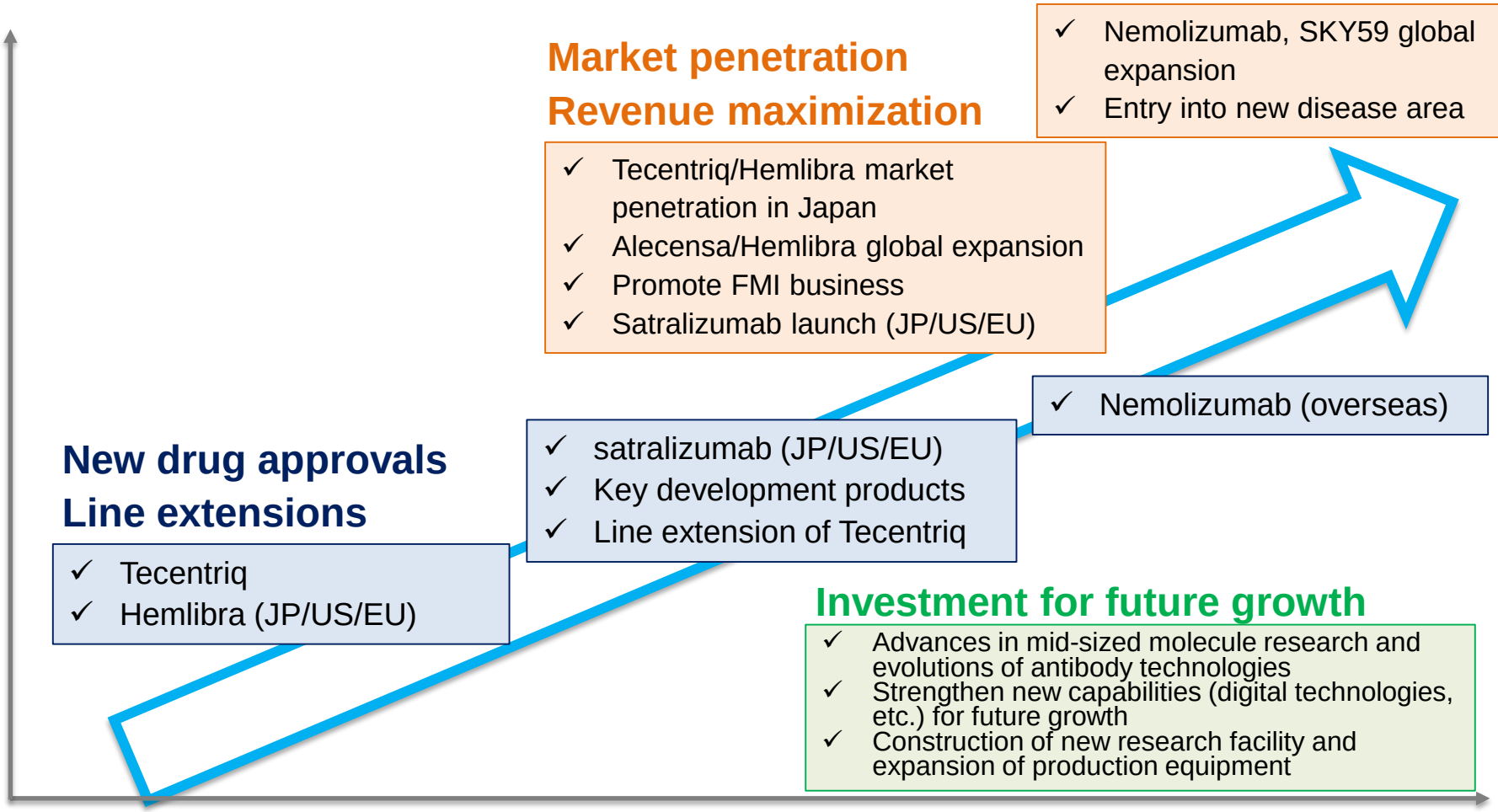
** 3 years, based on constant exchange rate

# Basic Policy of Shareholder Returns

| | |
|---|---|
| **Profit** | To be distributed considering the balance between internal reserves necessary for increasing corporate value, and profit distribution with shareholders |
| **Dividend Policy** | Aim for a dividend payout ratio of 50% on average in comparison with Core EPS to provide a stable dividend to shareholders |
| **FY2019 Dividend** | 96 JPY (forecast) |

# IBI 21 Growth Outlook

**In addition to market penetration of growth drivers in Japan and overseas, the approval and launch of satralizumab will support further growth**



# FY2018 Consolidated Financial Overview (IFRS based)

Toshiaki Itagaki
Executive Vice President and CFO
CHUGAI PHARMACEUTICAL CO., LTD.

January 31/ February 1, 2019

# Full Year Results Summary

■ **Revenues: 579.8 billion yen (+45.6, +8.5% YoY)**

- Domestic sales excl. Tamiflu: despite impact from HIP revision, slight increase due to steady sales growth of mainstay products (+0.8, +0.2%)
- Overseas sales: increase in exports of Actemra and Alecensa to Roche (+33.9, +36.1%)
- Royalties and other operating income: one-time income from transfer of long-term listed products, and from out-licensing of developed products, etc. (+17.0, +48.7%)

■ **Cost of sales / Operating expenses (Core basis)**

- Cost of sales: the ratio to sales improved due to a change in product mix, etc. (-1.1% points, from 50.7% to 49.6%)
- Operating expenses: overall increase mainly due to increase of research and development expenses and general administration expenses, etc. (-9.5, +5.3%)

■ **Profits**

- IFRS results: operating profit 124.3 billion yen (+25.4, +25.7%)
  net income 93.1 billion yen (+19.6, +26.7%)
- Core results: operating profit 130.3 billion yen (+27.1, +26.3%)
  net income 97.3 billion yen (+20.6, +26.9%)
- Core EPS (JPY): 176.42 (+37.74, +27.2%)

# IFRS and Core Results Jan-Dec

| (Billion JPY) | IFRS results 2018 Jan. - Dec. | Non-core items Intangible assets | Non-core items Others | Core results 2018 Jan. - Dec. |
|---|---|---|---|---|
| **Revenues** | **579.8** | | | **579.8** |
| Sales | 527.8 | | | 527.8 |
| Royalties and other operating income | 51.9 | | | 51.9 |
| Cost of sales | -262.8 | +1.0 | | -261.9 |
| **Gross profit** | **316.9** | **+1.0** | | **317.9** |
| **Operating expenses** | **-192.6** | **+5.0** | | **-187.6** |
| Marketing and distribution | -73.7 | | | -73.7 |
| Research and development | -99.2 | +5.0 | | -94.2 |
| General and administration | -19.7 | | | -19.7 |
| **Operating profit** | **124.3** | **+6.0** | | **130.3** |
| Financing costs | -0.1 | | | -0.1 |
| Other financial income (expense) | 0.4 | | | 0.4 |
| Other expense | -3.2 | | | -3.2 |
| **Profit before taxes** | **121.4** | **+6.0** | | **127.5** |
| Income taxes | -28.4 | -1.8 | | -30.2 |
| **Net income** | **93.1** | **+4.2** | | **97.3** |
| Chugai shareholders | 92.5 | +4.2 | | 96.7 |
| Non-controlling interests | 0.6 | | | 0.6 |

(Billions of JPY)

**Non-Core items**

Intangible assets:
- Amortization of intangible assets +1.2
- Impairment +4.8

Others
- none

Core net income attributable to Chugai shareholders 96.7

(Millions of shares)

Weighted average number of shares in issue used to calculate diluted earnings per share 548

(JPY)

Core EPS 176.42

Year on Year (Core)

# Financial Overview Jan-Dec

| (Billions of JPY) | 2017 Jan - Dec | vs. Revenues | 2018 Jan - Dec | vs. Revenues | Growth | |
|---|---|---|---|---|---|---|
| **Revenues** | **534.2** | | **579.8** | | **+45.6** | **+8.5%** |
| Sales | 499.3 | | 527.8 | | +28.5 | +5.7% |
| excl. Tamiflu | 482.4 | | 517.2 | | +34.8 | +7.2% |
| Domestic | 388.4 | | 389.2 | | +0.8 | +0.2% |
| Export to Roche | 76.4 | | 109.9 | | +33.5 | +43.8% |
| Other overseas | 17.7 | | 18.0 | | +0.3 | +1.7% |
| Tamiflu | 16.9 | | 10.7 | | -6.2 | -36.7% |
| Ordinary | 11.9 | | 10.1 | | -1.8 | -15.1% |
| Govt. stockpiles, etc. | 5.0 | | 0.5 | | -4.5 | -90.0% |
| Royalties and other operating income | 34.9 | | 51.9 | | +17.0 | +48.7% |
| Cost of sales | -252.9 | 47.3% | -261.9 | 45.2% | -9.0 | +3.6% |
| **Gross profit** | **281.3** | **52.7%** | **317.9** | **54.8%** | **+36.6** | **+13.0%** |
| Operating expenses | -178.1 | 33.3% | -187.6 | 32.4% | -9.5 | +5.3% |
| **Operating profit** | **103.2** | **19.3%** | **130.3** | **22.5%** | **+27.1** | **+26.3%** |
| Financing costs | -0.1 | | -0.1 | | 0.0 | 0.0% |
| Other financial income (expense) | -0.1 | | 0.4 | | +0.5 | - |
| Other Expenses | -1.7 | | -3.2 | | -1.5 | +88.2% |
| Income taxes | -24.5 | | -30.2 | | -5.7 | +23.3% |
| **Net income** | **76.7** | **14.4%** | **97.3** | **16.8%** | **+20.6** | **+26.9%** |
| EPS (JPY) | 138.68 | | 176.42 | | +37.74 | +27.2% |

Royalties and other operating income +17.0

One-time income from transfer of long-term listed products, and from out-licensing developed products, etc.

Other financial income (expense) +0.5

Exchange gains/losses +0.5

Gains/Losses on derivatives (Gains/Losses on foreign exchange forward contracts) +0.0

Other Expenses -1.5

Settlement for transfer pricing taxation

Cost of sales ratio vs. Sales

| 2017 Jan – Dec | 2018 Jan – Dec |
|---|---|
| 50.7% | 49.6% |

Market average exchange rate (JPY)

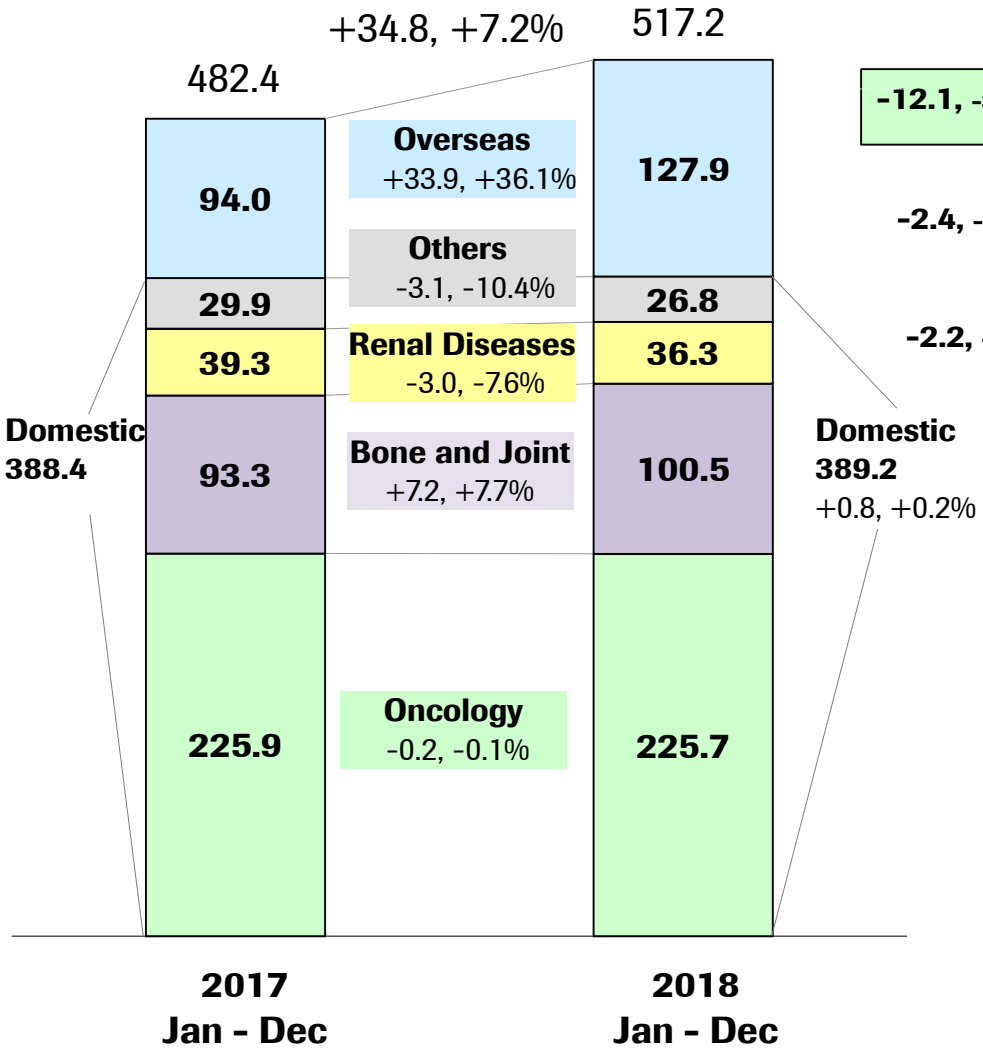
| | 2017 Jan – Dec | 2018 Jan - Dec |
|---|---|---|
| 1 CHF | 113.90 | 112.92 |
| 1 EUR | 126.39 | 130.36 |
| 1 USD | 112.17 | 110.45 |
| 1 SGD | 81.22 | 81.87 |

Year on Year

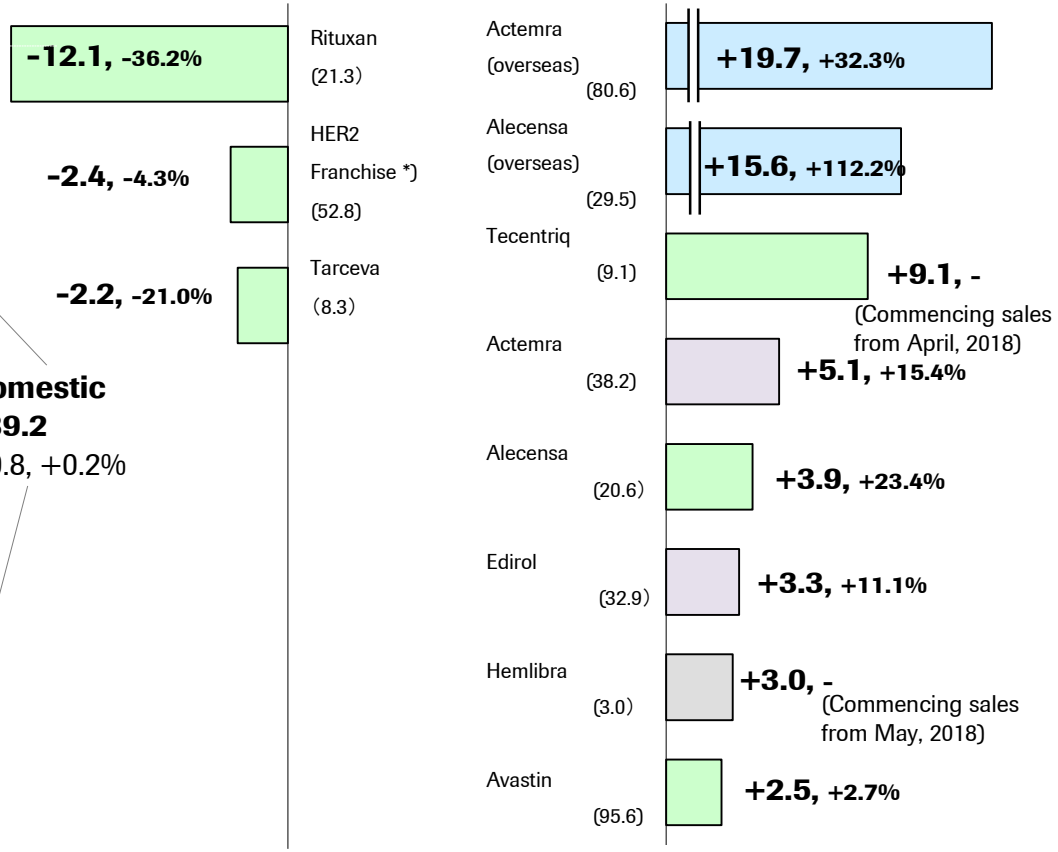
# Sales (excl. Tamiflu) Jan-Dec

## Sales by Disease Area, Year on Year Comparisons

**(Billions of JPY)**




## Sales by Products, Year on Year Changes




*) Details of HER2 franchise

| | | |
|---|---|---|
| Herceptin (28.1) | -5.5, | -16.4% |
| Perjeta (16.1) | +2.5, | +18.4% |
| Kadcyla (8.5) | +0.5, | +6.3% |

( ): Actual sales in FY2018
%: Year-on-year percentage change

# Tamiflu Sales Trends

| (Billions of JPY) | Fiscal Term Sales | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | FY2013 | | FY2014 | | FY2015 | | FY2016 | | FY2017 | | FY2018 | |
| | Jan-Jun | Jul-Dec | Jan-Jun | Jul-Dec | Jan-Jun | Jul-Dec | Jan-Jun | Jul-Dec | Jan-Jun | Jul-Dec | Jan-Jun | Jul-Dec |
| Ordinary | 8.2 | | | | | | | | | | | |
| | | 1.9 | 7.0 | | | | | | | | | |
| | | | | 5.8 | 6.7 | | | | | | | |
| | | | | | | 1.5 | 7.3 | | | | | |
| | | | | | | | | 4.7 | 6.3 | | | |
| | | | | | | | | | | 5.6 | 8.3 | |
| | | | | | | | | | | | | 1.8 |
| | **10.1** | **(-0.1)** | **12.9** | **(+2.8)** | **8.2** | **(-4.7)** | **12.0** | **(+3.8)** | **11.9** | **(-0.1)** | **10.1** | **(-1.8)** |
| Govt. Stockpiles etc. | 0.8 | 0.1 | 0.1 | 0.1 | 0.0 | 0.0 | 0.0 | 1.5 | 1.9 | 3.1 | 0.1 | 0.4 |
| | **0.9** | **(-1.0)** | **0.2** | **(-0.7)** | **0.0** | **(-0.2)** | **1.5** | **(+1.5)** | **5.0** | **(+3.5)** | **0.5** | **(-4.5)** |
| **Total** | **9.0** | **2.0** | **7.1** | **5.9** | **6.7** | **1.5** | **7.3** | **6.2** | **8.2** | **8.7** | **8.4** | **2.2** |
| | **11.0** | **(-1.0)** | **13.0** | **(+2.0)** | **8.2** | **(-4.8)** | **13.5** | **(+5.3)** | **16.9** | **(+3.4)** | **10.7** | **(-6.2)** |

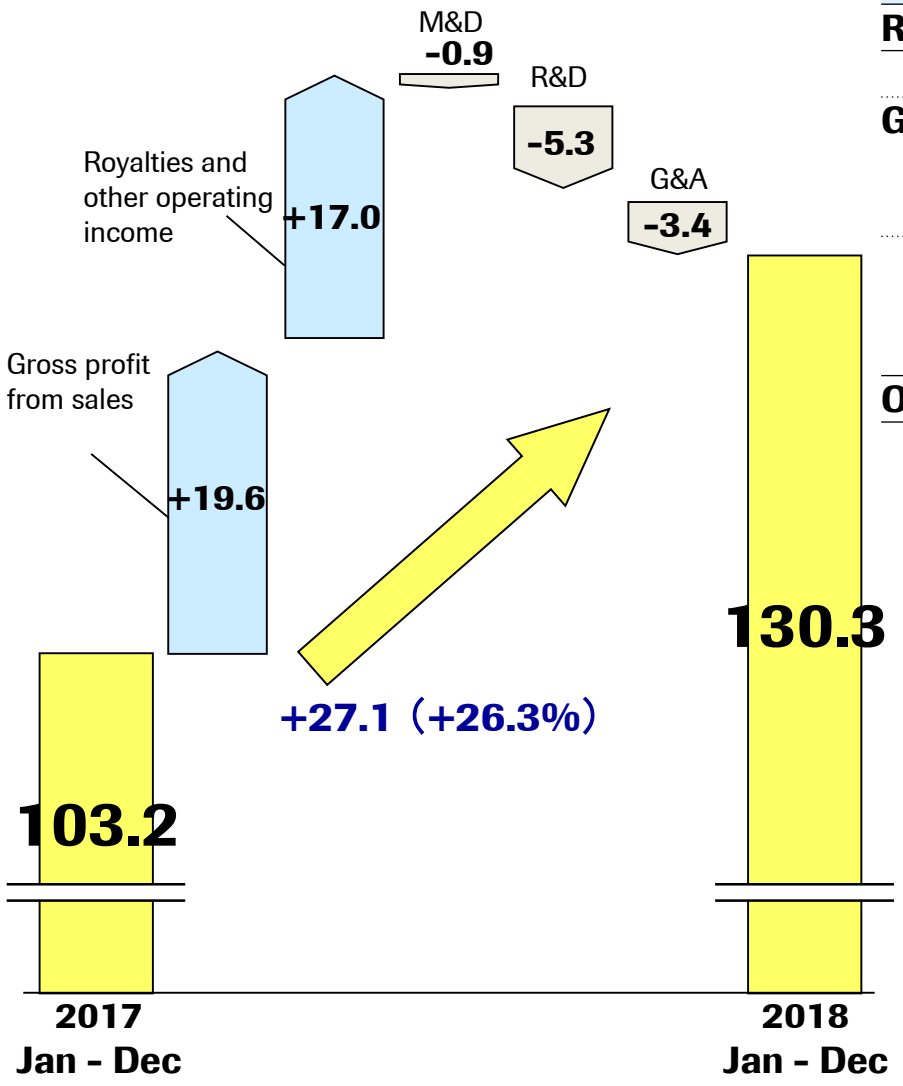
( ) Year on year

| Season (from the second half of FY to the first half of the next FY) | |
|---|---|
| 2012 | **10.6** |
| 2013 | **9.0** |
| 2014 | **12.6** |
| 2015 | **8.7** |
| 2016 | **11.0** |
| 2017 | **14.0** |

Year on Year (Core)

# Operating Profit Jan - Dec

(Billion of JPY)




| (Billions of JPY) | 2017 Jan - Dec | 2018 Jan - Dec | Growth |
|---|---|---|---|
| **Revenues** | **534.2** | **579.8** | **+45.6** |
| Cost of sales | -252.9 | -261.9 | -9.0 |
| **Gross profit** | **281.3** | **317.9** | **+36.6** |
| Sales | 246.4 | 266.0 | +19.6 |
| Royalties, etc. | 34.9 | 51.9 | +17.0 |
| Marketing and distribution | -72.8 | -73.7 | -0.9 |
| Research and development | -88.9 | -94.2 | -5.3 |
| General and administration | -16.3 | -19.7 | -3.4 |
| **Operating profit** | **103.2** | **130.3** | **+27.1** |

Increase in gross profit from sales +19.6
Increase in export to Roche and improvement of cost of sales ratio to sales due to change in product mix, etc.

Increase in royalties and other operating income +17.0

Increase in marketing and distribution expenses -0.9

Increase in research and development expenses -5.3
Progress of projects, etc.

Increase in general and administration expenses, etc. -3.4
Increase in various expenses, including legal expenses and the enterprise tax, etc.

Year on Year (Core)

# Financial Overview Oct - Dec

| (Billions of JPY) | 2017 Oct - Dec | vs. Revenues | 2018 Oct - Dec | vs. Revenues | Growth | |
|---|---|---|---|---|---|---|
| **Revenues** | **146.6** | | **153.3** | | **+6.7** | **+4.6%** |
| Sales | 134.5 | | 139.1 | | +4.6 | +3.4% |
| excl. Tamiflu | 127.7 | | 137.3 | | +9.6 | +7.5% |
| Domestic | 107.5 | | 107.3 | | -0.2 | -0.2% |
| Export to Roche | 15.8 | | 25.8 | | +10.0 | +63.3% |
| Other overseas | 4.5 | | 4.3 | | -0.2 | -4.4% |
| Tamiflu | 6.8 | | 1.8 | | -5.0 | -73.5% |
| Ordinary | 5.6 | | 1.8 | | -3.8 | -67.9% |
| Govt. stockpiles, etc. | 1.2 | | - | | -1.2 | △100.0% |
| Royalties and other operating income | 12.0 | | 14.2 | | +2.2 | +18.3% |
| Cost of sales | -67.3 | 45.9% | -67.6 | 44.1% | -0.3 | +0.4% |
| **Gross profit** | **79.2** | **54.0%** | **85.8** | **56.0%** | **+6.6** | **+8.3%** |
| Operating expenses | -54.7 | 37.3% | -58.7 | 38.3% | -4.0 | +7.3% |
| **Operating profit** | **24.5** | **16.7%** | **27.1** | **17.7%** | **+2.6** | **+10.6%** |
| Financing costs | -0.0 | | -0.0 | | 0.0 | 0.0% |
| Other financial income (expense) | 0.1 | | 0.5 | | +0.4 | +400.0% |
| Other Expenses | -0.6 | | -1.1 | | -0.5 | +83.3% |
| Income taxes | -6.9 | | -3.8 | | +3.1 | -44.9% |
| **Net income** | **17.1** | **11.7%** | **22.7** | **14.8%** | **+5.6** | **+32.7%** |
| EPS (JPY) | 30.88 | | 41.28 | | +10.40 | +33.7% |

Increase in gross profit from sales +4.4

Increase in export to Roche and improvement of cost of sales ratio to sales

Increase in royalties and other operating income +2.2

Increase in milestone income

Increase in operating expenses -4.0

Decrease in marketing and distribution +0.3

Increase in research and development -2..1

Progress of projects, etc.

Increase in general and administration, etc. -2.2

Increase in legal expenses, etc.

Cost of sales ratio vs. Sales

| 2017 Oct – Dec | 2018 Oct – Dec |
|---|---|
| 50.0% | 48.6% |

Market average exchange rate (JPY)

| | 2017 Oct – Dec | 2018 Oct - Dec |
|---|---|---|
| 1 CHF | 114.41 | 113.33 |
| 1 EUR | 132.93 | 128.72 |
| 1 USD | 112.89 | 112.84 |
| 1 SGD | 83.38 | 82.04 |

vs. Forecast (Core)

# Financial Overview Jan - Dec

| (Billions of JPY) | 2018 Jan - Dec Forecast | Actual | +/- | Achievement |
|---|---|---|---|---|
| **Revenues** | **541.5** | **579.8** | **+38.3** | **107.1%** |
| Sales | 498.5 | 527.8 | +29.3 | 105.9% |
| excl. Tamiflu | 492.9 | 517.2 | +24.3 | 104.9% |
| Domestic | 374.8 | 389.2 | +14.4 | 103.8% |
| Export to Roche | 99.6 | 109.9 | +10.3 | 110.3% |
| Other overseas | 18.5 | 18.0 | -0.5 | 97.3% |
| Tamiflu | 5.6 | 10.7 | +5.1 | 191.1% |
| Royalties and other operating income | 43.0 | 51.9 | +8.9 | 120.7% |
| Cost of sales | -252.0 | -261.9 | -9.9 | 103.9% |
| **Gross profit** | **289.5** | **317.9** | **+28.4** | **109.8%** |
| Operating expenses | -181.5 | -187.6 | -6.1 | 103.4% |
| **Operating profit** | **108.0** | **130.3** | **+22.3** | **120.6%** |
| EPS (JPY) | 147.00 | 176.42 | +29.42 | 120.0% |

Increase in gross profit from sales +19.4

Increase in domestic sales and export to Roche, and improvement of cost of sales ratio to sales due to a change in product mix, etc.

Increase in royalties and other operating income +8.9

Increase in one-time income from out-licensing developed products, etc.

Increase in operating expenses -6.1

Increase in legal expenses and expenses for further market penetration of new products and mainstay products

Cost of sales ratio vs. Sales

| 2018 Jan – Dec Forecast | 2018 Jan – Dec Actual |
|---|---|
| 50.6% | 49.6% |

Exchange rate (JPY)

| | 2018 Jan – Dec Assumption | 2018 Jan – Dec Actual * |
|---|---|---|
| 1 CHF | 115.00 | 112.92 |
| 1 EUR | 133.00 | 130.36 |
| 1 USD | 111.00 | 110.45 |
| 1 SGD | 84.00 | 81.87 |

* Market average exchange rate for the period Jan – Dec.

vs. Forecast (Core)



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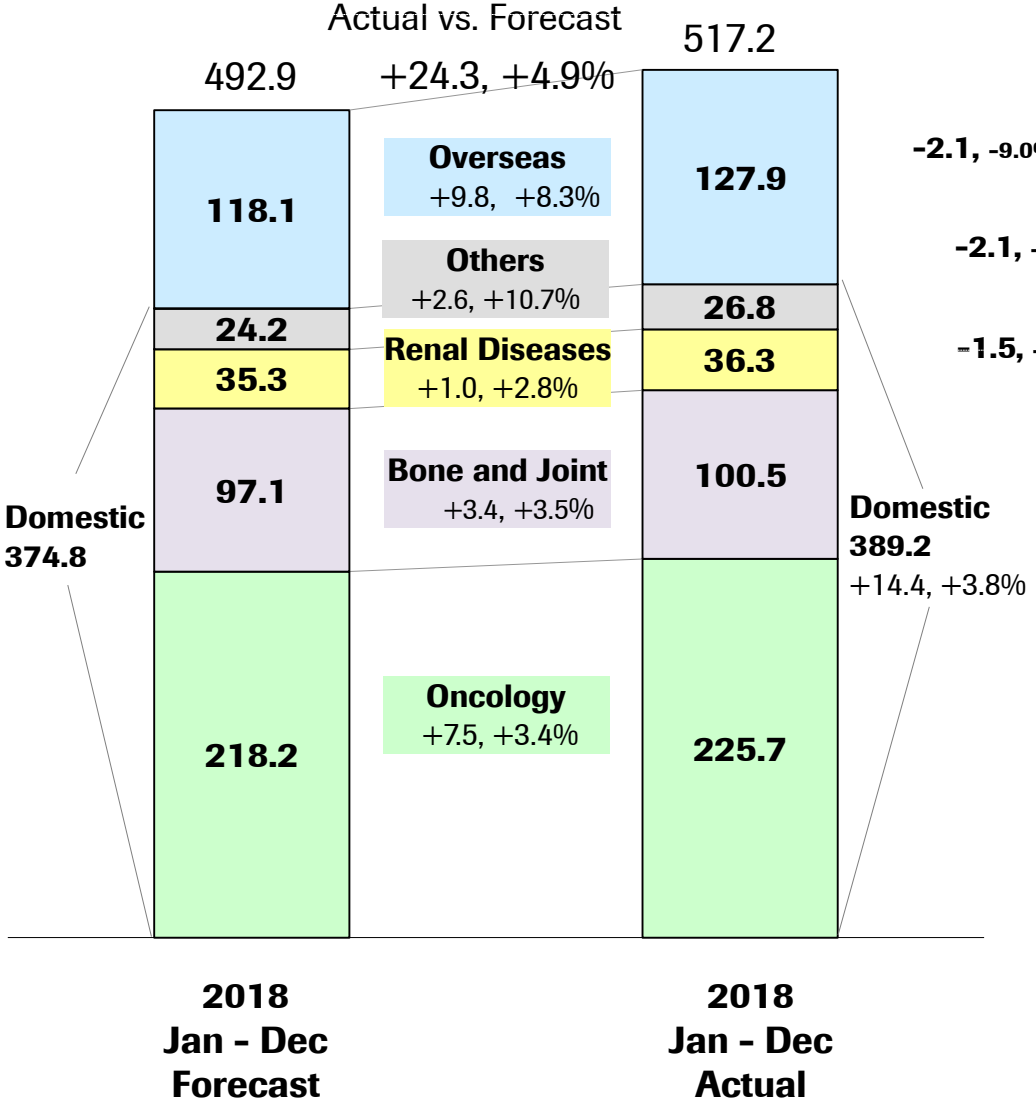
Roche Roche Group

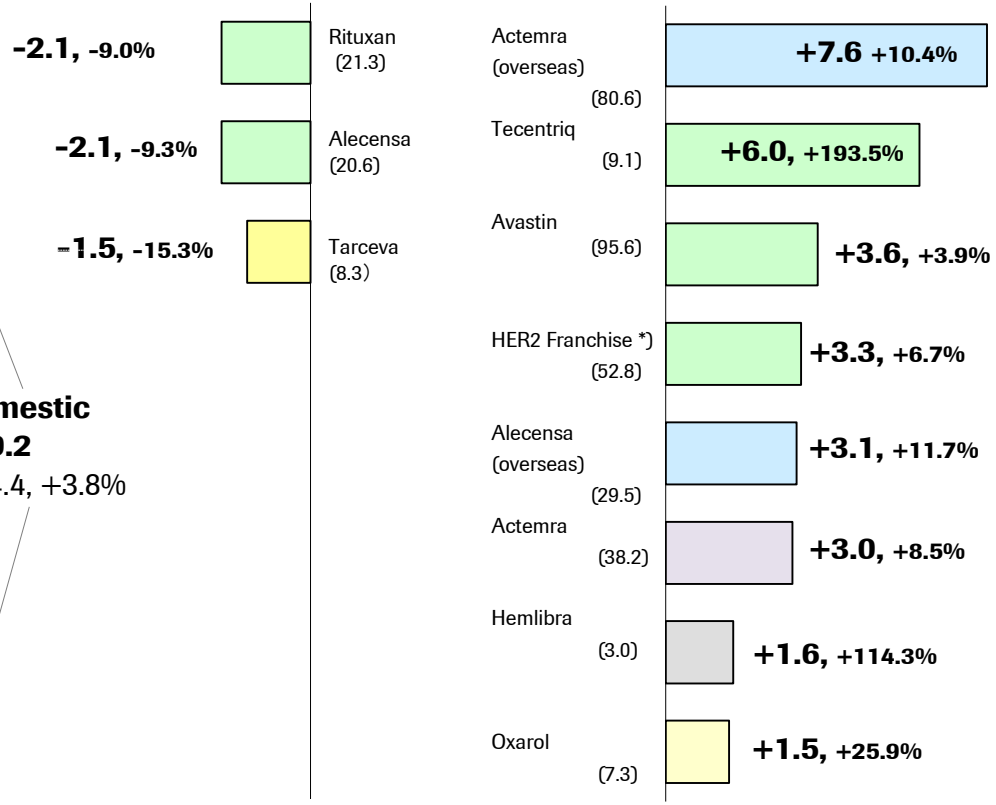
# Sales Progress (excl. Tamiflu) Jan - Dec

(Billions of JPY)

Sales by Disease Area, Actual vs. Forecast




Sales by Products, Actual vs. Forecast




*) Details of HER2 franchise

| | | |
|---|---|---|
| Herceptin (28.1) | +1.5, | +5.6% |
| Perjeta (16.1) | +1.5, | +10.3% |
| Kadcyla (8.5) | +0.2, | +2.4% |

( ): FY2018 Actual
%: Achievement

vs. Forecast (Core)

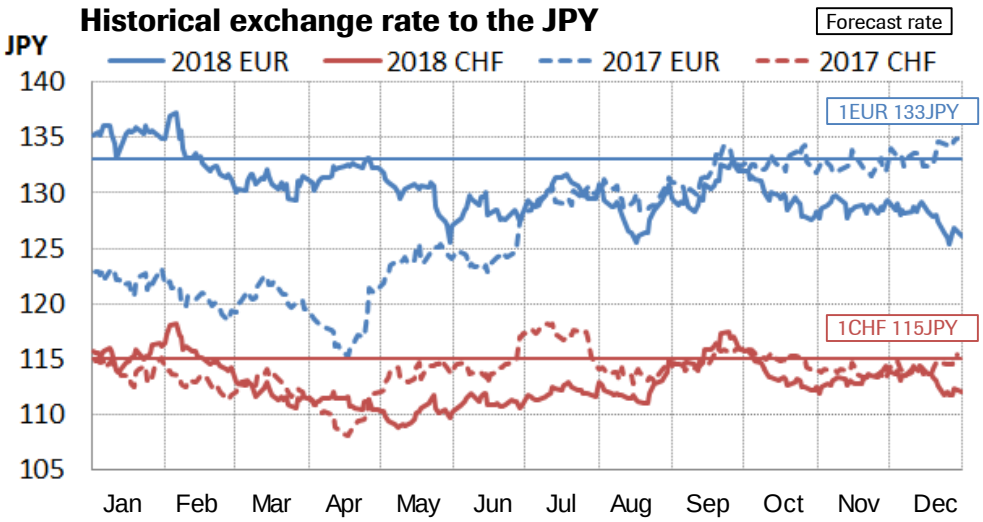
# Impact from Foreign Exchange

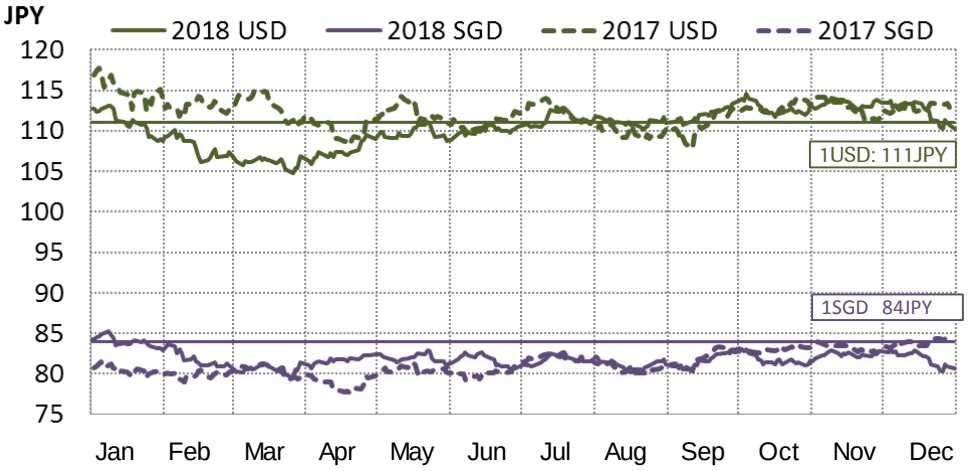
| (Billions of JPY) | FX impact Jan – Dec 2018 (FX impact vs. Assumption) | |
|---|---|---|
| **Revenues** | **-1.2** | |
| | Sales | -0.7 |
| | Royalties and other operating income | -0.5 |
| Cost of sales<br>Operating expenses | Cost of sales | +0.3 |
| | Expenses | +0.6 |
| **Operating profit** | **-0.3** | |

| Actual / Forecast rate* (JPY) | 2017 Jan - Dec Actual | 2018 Jan -Dec Assumption | 2018 Jan - Dec Actual |
|---|---|---|---|
| 1CHF | 113.90 | 115.00 | 112.92 |
| 1EUR | 126.39 | 133.00 | 130.36 |
| 1USD | 112.17 | 111.00 | 110.45 |
| 1SGD | 81.22 | 84.00 | 81.87 |

* Actual: market average exchange rate for the period Jan - Dec

**[Reference]**
**Historical exchange rate to the JPY**



vs. 2017 Year End

# Overview of Financial Position

| (Billions of JPY) | 2017 Dec | 2018 Dec | Change |
|---|---|---|---|
| Trade accounts receivable | 148.5 | 150.8 | + 2.3 |
| Inventories | 169.1 | 159.4 | - 9.7 |
| Trade accounts payable | -38.4 | -35.9 | + 2.5 |
| Other net working capital | -28.4 | -39.1 | - 10.7 |
| **Net working capital** *1 | 250.7 | 235.1 | - 15.6 |
| Property, plant and equipment | 171.6 | 222.4 | + 50.8 |
| Intangible assets | 21.1 | 22.7 | + 1.6 |
| Other long-term assets - net | -3.1 | 25.1 | + 28.2 |
| **Long-term net operating assets** *2 | 189.5 | 270.1 | + 80.6 |
| **Net operating assets** | 440.2 | 505.3 | + 65.1 |
| Debt | -0.3 | -0.2 | + 0.1 |
| Marketable securities | 104.0 | 102.5 | - 1.5 |
| Cash and cash equivalents | 139.1 | 146.9 | + 7.8 |
| **Net cash** | 242.8 | 249.2 | + 6.4 |
| Other non-operating assets - net | 9.9 | 2.1 | - 7.8 |
| **Net non-operating assets** *3 | 252.7 | 251.3 | - 1.4 |
| **Total net assets** | 692.9 | 756.5 | + 63.6 |
| Total assets | 852.5 | 919.5 | + 67.0 |
| Total liabilities | -159.6 | -163.0 | - 3.4 |

*1 Accrued receivable, accrued payable, accrued expenses, etc.

*2 Long-term prepaid expenses, long-term provisions, etc.

*3 Deferred tax assets, corporate income tax payable, etc.

Decrease in net working capital -15.6

- Decrease in inventories -9.7
  - Impact from front-loaded purchases in the previous year and transfer of long-term listed products, etc.
- Decrease in other net working capital -10.7

Increase in long-term net operating assets +80.6

- Increase in Property, plant and equipment +50.8
  - Purchase of a business site in Yokohama for a new laboratory
- Increase in Other long-term assets +28.2
  - Mainly decrease of the deferred income on applying IFRS15 and increase in long-term prepaid expenses for outsourcing of Manufacturing

Increase in net cash +6.4

Decrease in other non-operating assets - net -7.8

Equity ratio attributable to Chugai shareholders +1.0% pts.

- 2018 Dec 82.2%
- 2017 Dec 81.2%

FX rate to the JPY (end of period)

| | 2017 Dec | 2018 Dec |
|---|---|---|
| 1CHF | 115.35 | 112.03 |
| 1EUR | 134.82 | 126.13 |
| 1USD | 112.89 | 110.28 |
| 1SGD | 84.39 | 80.70 |

vs. 2017 Year End

# Net Cash

**Main investment for P.P.E**

**Ustunomiya**: High-mix low-volume production capability for pre-filled syringe form products

**Ukima**: High-mix low-volume production of antibody API for initial commercial products

**Fujieda**: Solid formulation manufacturing facility, etc.

**Main investment for P.P.E**

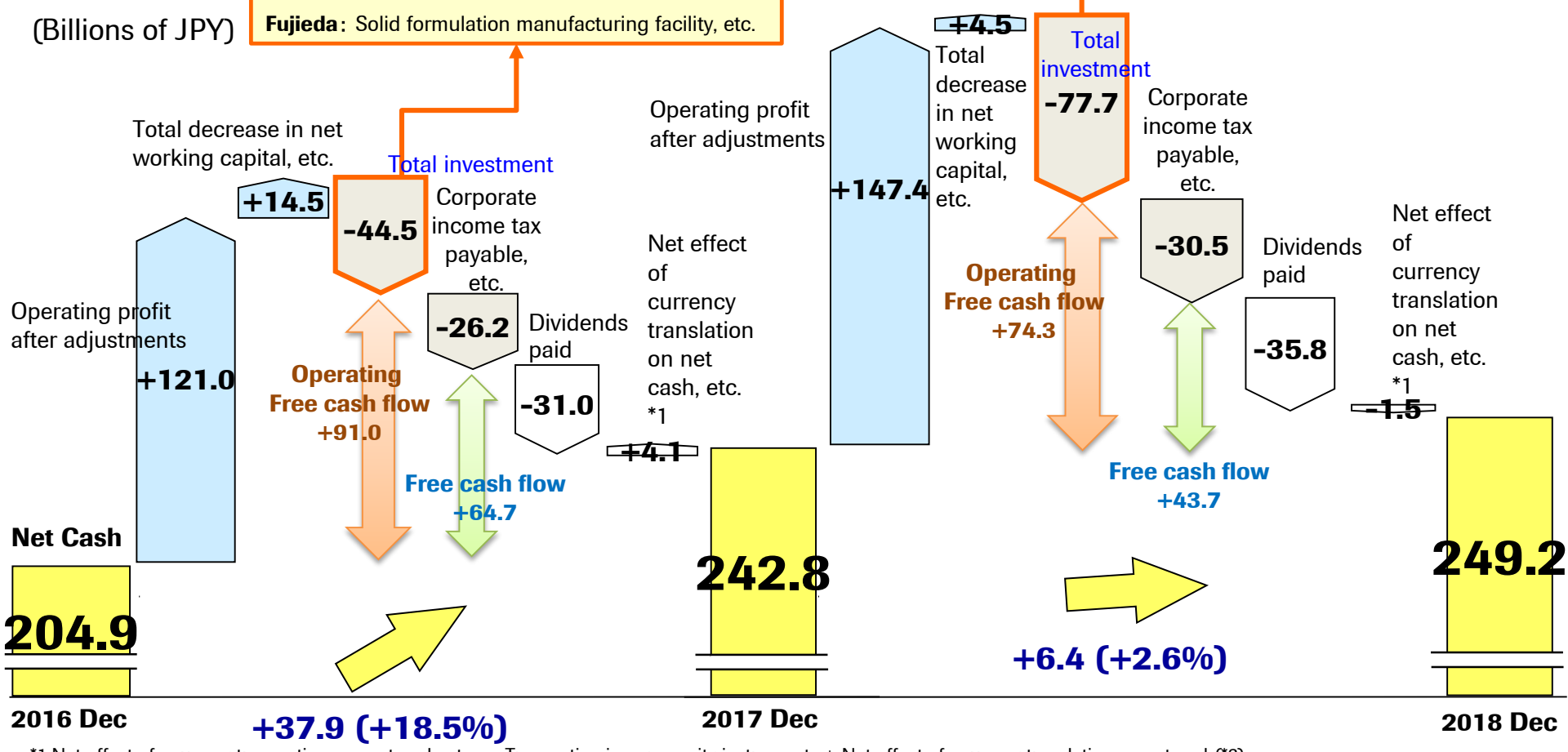
**Yokohama site**: Purchase of business site

**Ustunomiya**: High-mix low-volume production capability for pre-filled syringe form products

**Ukima Plant**: High-mix low-volume production of antibody API for initial commercial products

**Ukima Research Laboratories**: Enhancement of the process development function of small- and middle-molecule active pharmaceutical ingredients

(Billions of JPY)




*1 Net effect of currency transactions on net cash, etc. = Transaction in own equity instruments + Net effect of currency translation on net cash(*2)

*2 A result of using different exchange rate types when consolidating overseas subsidiaries in financial statements, i.e. net cash using end of period exchange rate and free cash flow using average exchange rate. (Chugai defines this term based on International Accounting Standard (IAS) 7 and IAS 21)

# Summary of Earnings Prospects for 2019

- **Revenues: 592.5 billion yen (+12.7 +2.2% YoY)**
- Domestic sales [1]: decrease due to competition with generic drugs and impact of HIP revision (-10.8, -2.7%)
- Overseas sales: increase mainly due to Alecensa and Actemra export to Roche (+11.0, +8.6%)
- Royalty and profit-sharing income. [2]: increase in royalties from Roche for Hemlibra (+29.4, +122.0%)
- Other operating income [2]: decrease in one-time income from transfer of long-term listed products in the previous year, etc. (-16.9, -60.6%)
- **Cost of sales / Operating expenses (Core basis)**
- Cost of sales: the ratio to sales will improve due to change in product mix, etc. (-1.8% points, from 49.6% to 47.8%)
- Operating expenses: overall increase mainly due to the increase of research and development expenses from progress of projects, etc. (-9.4, +5.0%)
- **Profits (Core basis)**

| | | |
|---|---|---|
| Operating profit | 143.0 billion yen | (+12.7, +9.7%) |
| EPS (JPY): | 198.00 | (+21.58, +12.2%) |

1) Domestic sales include Tamiflu sales from FY2019.

2) Details of Royalty and profit-sharing income and Other operating income are shown separately from FY2019.

2019 Forecast (Core)



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Roche Roche Group

# Forecast 2019 Jan - Dec

| (Billions of JPY) | Actual 2018 Jan - Dec | vs. Revenues | Forecast 2019 Jan - Dec | vs. Revenues | Growth | |
|---|---|---|---|---|---|---|
| **Revenues** | **579.8** | | **592.5** | | **+12.7** | **+2.2%** |
| Sales | 527.8 | | 528.0 | | +0.2 | +0.0% |
| Domestic | 399.9 | | 389.1 | | -10.8 | -2.7% |
| Overseas | 127.9 | | 138.9 | | +11.0 | +8.6% |
| Royalties and other operating income | 51.9 | | 64.5 | | +12.6 | +24.3% |
| Royalty and profit-sharing income | 24.1 | | 53.5 | | +29.4 | +122.0% |
| Other operating income | 27.9 | | 11.0 | | -16.9 | -60.6% |
| Cost of Sales | -261.9 | | -252.5 | | +9.4 | -3.6% |
| **Gross Profit** | **317.9** | **54.8%** | **340.0** | **57.4%** | **+22.1** | **+7.0%** |
| Operating Expenses | -187.6 | 32.4% | -197.0 | 33.2% | -9.4 | +5.0% |
| Research and development expenses | -94.2 | | -102.0 | | -7.8 | +8.3% |
| **Operating Profit** | **130.3** | **22.5%** | **143.0** | **24.1%** | **+12.7** | **+9.7%** |
| EPS (JPY) | 176.42 | | 198.00 | | +21.58 | +12.2% |

Increase in gross profit from sales +9.5
- Despite decrease in domestic sales, increase in export to Roche

Increase in royalties and other operating income +12.6
- Increase in royalties from Hemlibra, etc.

Increase in operating expenses -9.4

Increase in research and development -7.8
- Progress of projects, etc.
- Increase in research and development activities

Cost of sales ratio vs. Sales

| 2018 Jan – Dec | 2019 Jan – Dec |
|---|---|
| 49.6% | 47.8% |

Exchange rate (JPY)

| | 2018 Jan – Dec Actual * | 2019 Jan – Dec Assumption |
|---|---|---|
| 1CHF | 112.92 | 114.00 |
| 1EUR | 130.36 | 128.00 |
| 1USD | 110.45 | 111.00 |
| 1SGD | 81.87 | 82.00 |

*Actual: market average exchange rate for the period of Jan – Dec.

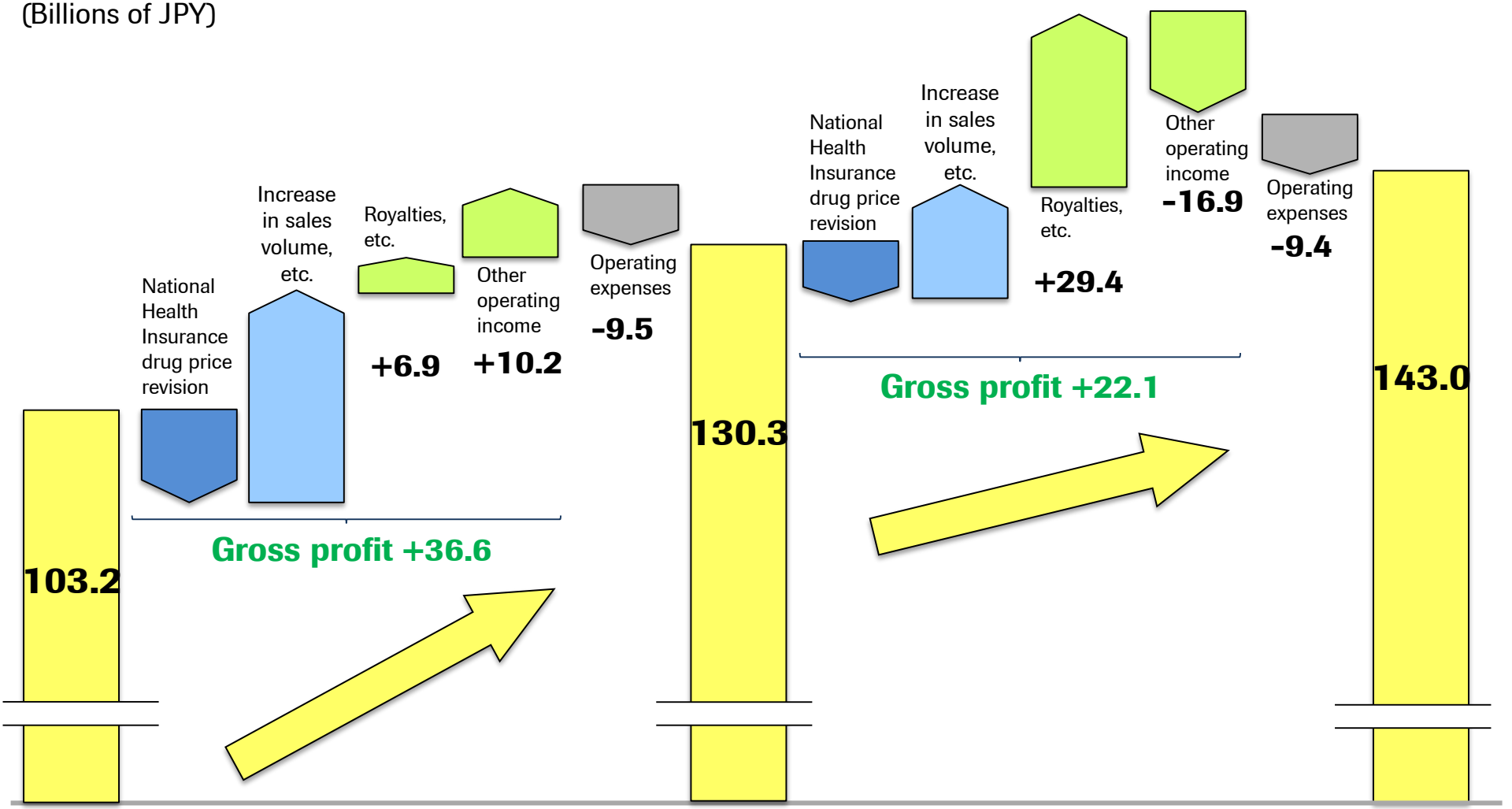
2019 Forecast (Core)



CHUGAI
Roche Roche Group

# Movement of Operating Profit 2017 - 2019

(Billions of JPY)



2019 Forecast (Core)



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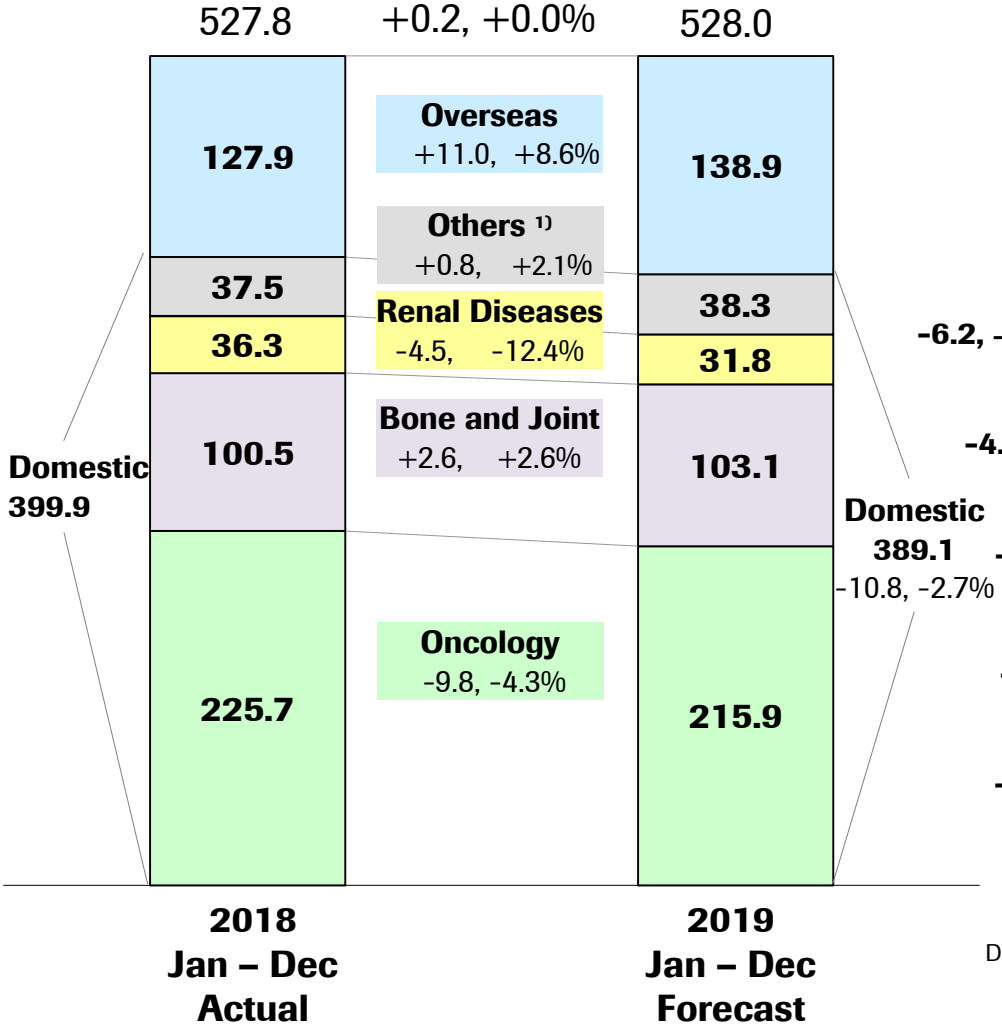
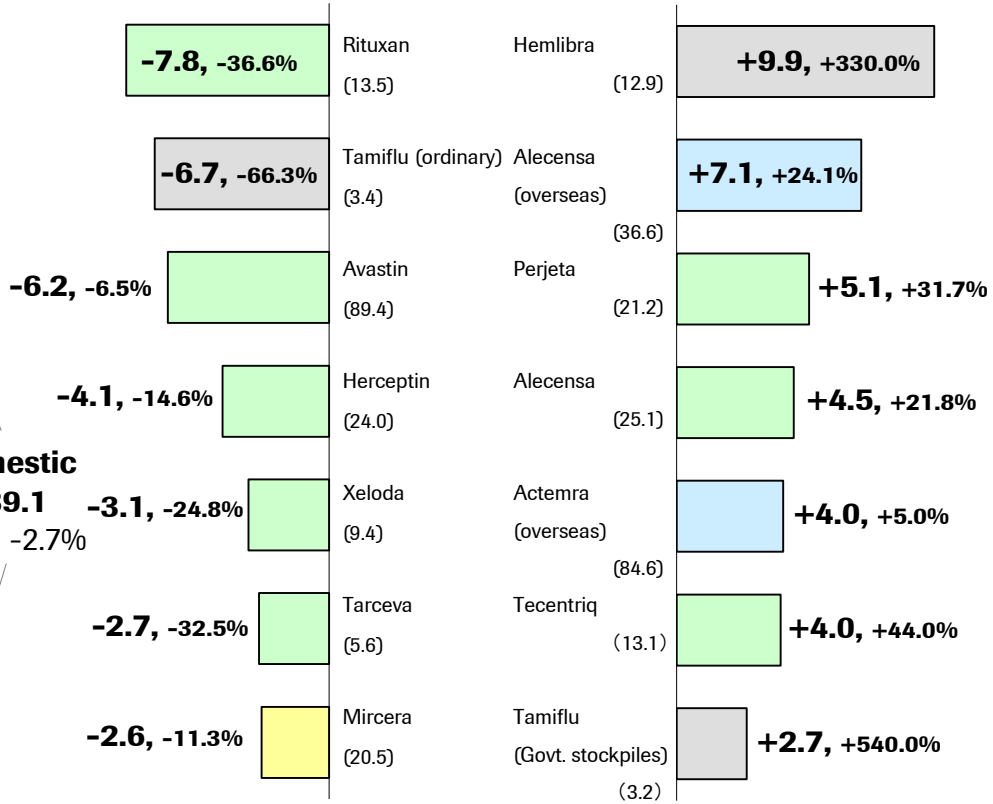
# Sales Forecast vs. 2018 Actual

(Billions of JPY)

## Sales by Disease Area, Year on Year Comparisons




## Sales by Products, Year on Year Changes



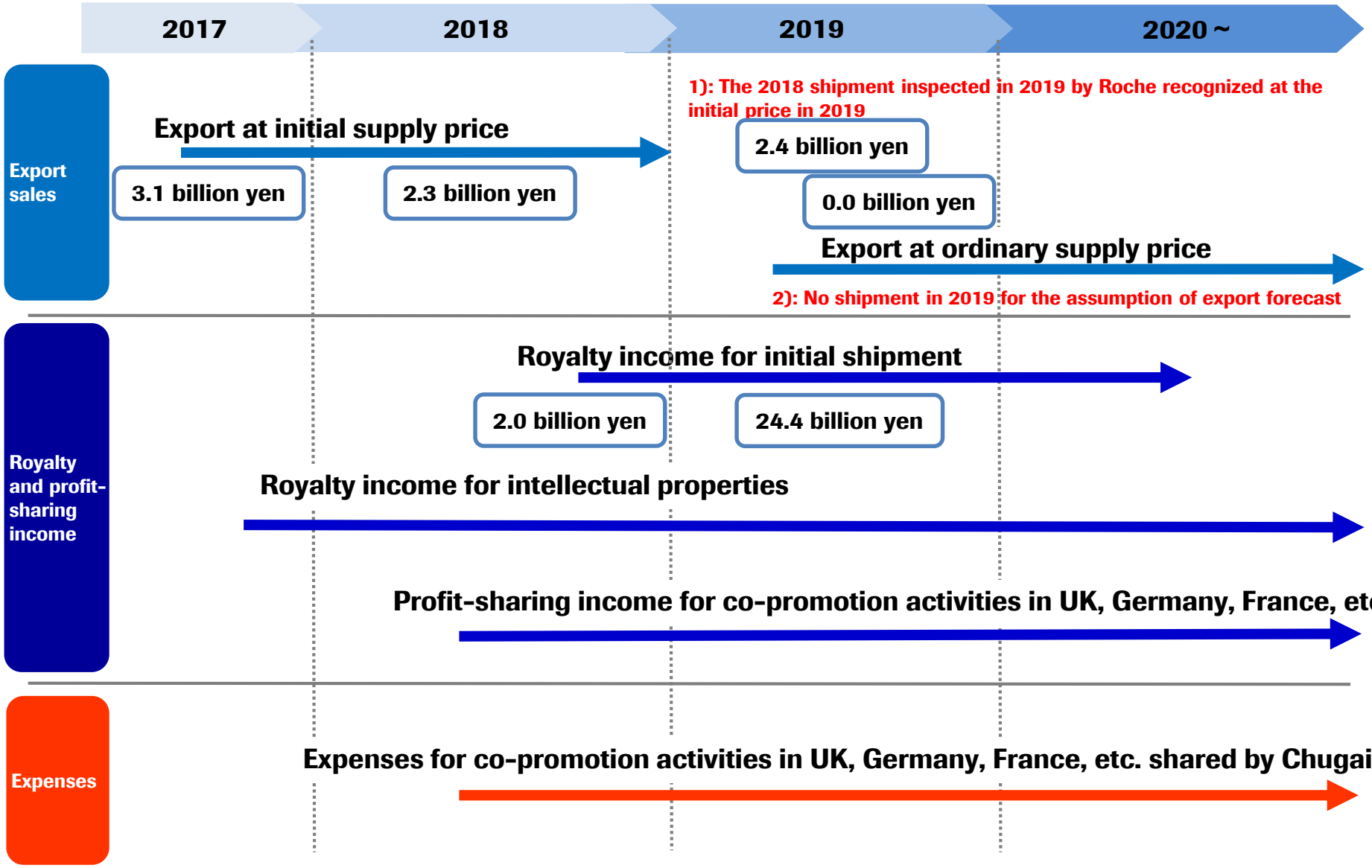

Details of HER2 franchise (54.3) +1.5 +2.8%

| | | |
|---|---|---|
| Herceptin: see the above | | |
| Perjeta: see the above | | |
| Kadcyla (9.1) | +0.6 | +7.1% |

( ): FY2019 forecast
%: Year-on-year percentage change

1) Tamiflu is included in "Others" from FY2019.

# Outline of Hemlibra Sales to Roche



# Current Status / Plan for Major Capital Investments

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Roche Roche Group

**Main Objective**

- Building of state-of-the-art R&D site to create innovative new drug candidates
- Simultaneous development and quick launch of therapeutic antibodies, etc.
- Reduction of manufacturing costs for in-house products
- Enhancement of the process development function of small- and middle- molecule active pharmaceutical ingredients

2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 | 2026

## CPR

**CPR (Singapore):** Accelerate creation of clinical candidates utilizing proprietary antibody technologies

2012-21: 476 million SGD (276 million SGD), incl. capital investments of 61 million SGD (59 million SGD)

2022-26: 282 million SGD, incl. capital investments of 21 million SGD

## Domestic

**Yokohama site:** Purchase of business site

2016-18: 43.4 billion JPY (43.0 billion JPY)

Construction of laboratory

(Details to be officially announced upon final decision)

**Utsunomiya Plant:** Enhancement of high-mix low-volume production capability for pre-filled syringe form products (Installment of tray filler)

2013-18: 6.0 billion JPY (6.0 billion JPY)

**Ukima Plant:** Enhancement of high-mix low-volume production of antibody API for initial commercial products (Expansion of production capability by construction of UK3)

2015-18: 37.2 billion JPY (36.7 billion JPY)

**Ukima Research Laboratories:** Construction of a new synthetic research building for strengthening the process development function of small- and middle-molecule active pharmaceutical ingredients

2018-20: 4.5 billion JPY (1.3 billion JPY)

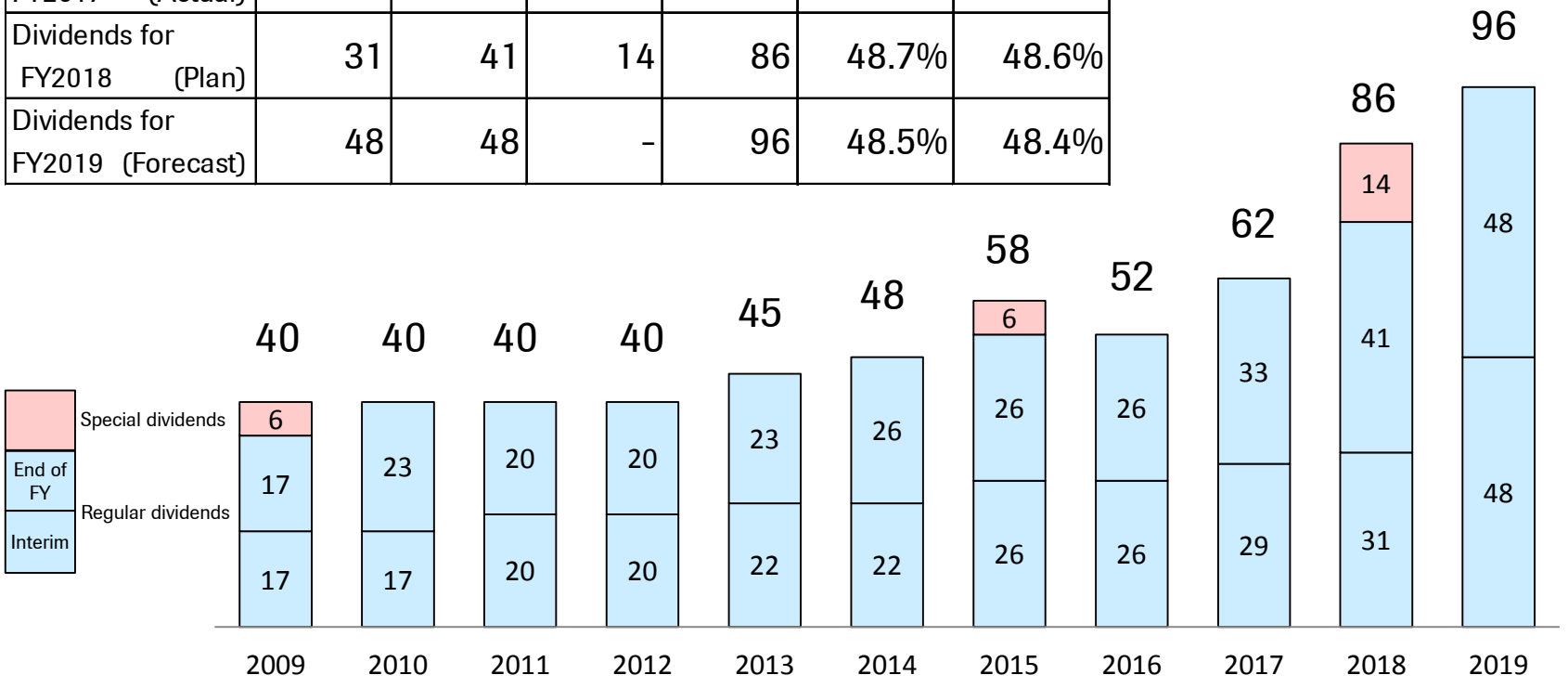
( ): Cumulative amount at the end of Dec., 2018

# Dividend Policy

## Policy

Aiming for a consolidated dividend payout ratio of 50% on average in comparison with Core EPS to provide a stable allocation of profit to all shareholders, taking into account the strategic funding needs and earnings prospects.

| | Annual dividends per share (JPY) | | | | Core payout ratio | |
|---|---|---|---|---|---|---|
| | Interim | End of FY | Special | Total | Single FY | 5-year average |
| Dividends for FY2017 (Actual) | 29 | 33 | - | 62 | 44.7% | 48.4% |
| Dividends for FY2018 (Plan) | 31 | 41 | 14 | 86 | 48.7% | 48.6% |
| Dividends for FY2019 (Forecast) | 48 | 48 | - | 96 | 48.5% | 48.4% |



# Overview of Development Pipeline

CHUGAI PHARMACEUTICAL CO., LTD.
Executive Vice President
Co-Head of Project & Lifecycle Management Unit
Dr. Yasushi Ito

January 31/ February 1, 2019

# New Mid-Term Business Plan: 5 Strategies

CHUGAI
Roche Roche Group

## Accelerate corporate and social development through innovation focused on innovative products

### Create global growth drivers and maximize value

**1 Value Creation**

Realize innovative drug discovery
to cure and manage diseases

**2 Value Delivery**

Deliver patient-centric solution
to maximize value of growth drivers

**3 Promote advances in personalized healthcare**

Realize the further advancement of PHC and innovate R&D process
by utilizing digital technology and data

### Strengthen HR and infrastructure that support Chugai's business

**4 Human capital and structural reform**

Develop high-caliber HR talent that support innovation,
and drastically reform costs, systems and processes

**5 Strengthen sustainable platforms**

Simultaneously realize company growth and sustainable social development

# Target during IBI 21

## Create global growth drivers and maximize Value

| No. of late stage development pipeline* | 28 （including additional indication） |
|---|---|

*Projects under development / launched products which already demonstrated PoC

**Aiming to bring middle molecule projects into the clinical phase, and continuously develop innovative novel antibody engineering technologies**

# Value brought to Roche/Chugai by PHC 2.0

CHUGAI
Roche Roche Group

**Smarter more efficient R&D**


**Deep Scientific Insight**

**Better, earlier Go / No go decision**

**Faster won by efficient trials**

**Improve access & PHC**

**Better patient Tx matching**

**Enhanced physician Tx decision**

**RWD to improve access based on Value**

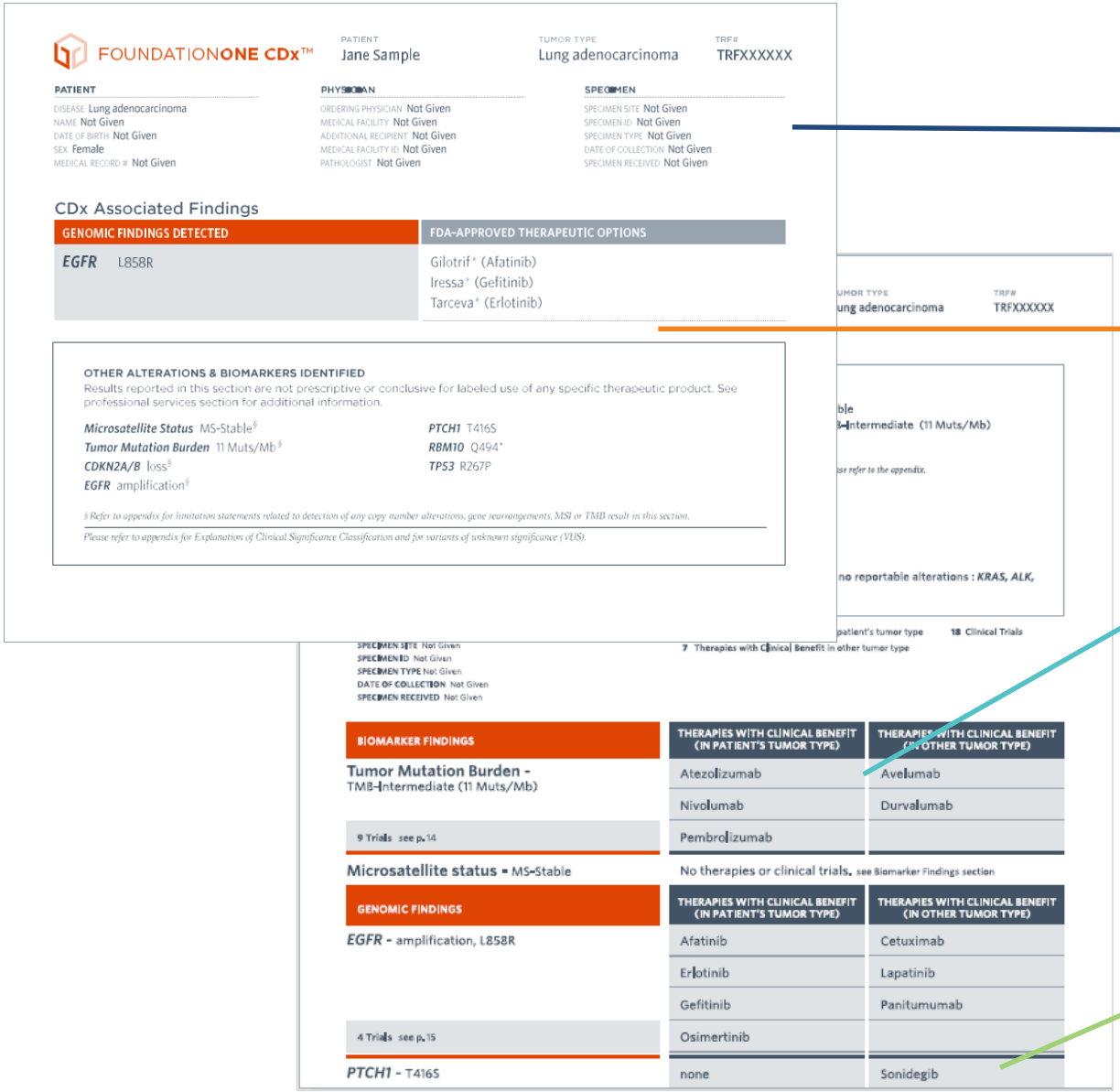
**Clinical Data**

**Genome information**

**Clinical genome information DB which satisfy the requirements of regulatory filing**

Source: Roche slides

# Design of FoundationOne CDx Report



FOUNDATIONONE CDx™

PATIENT Jane Sample | TUMOR TYPE Lung adenocarcinoma | TRF# TRFXXXXXX

**PATIENT**
DISEASE Lung adenocarcinoma
NAME Not Given
DATE OF BIRTH Not Given
SEX Female
MEDICAL RECORD # Not Given

**PHYSICIAN**
ORDERING PHYSICIAN Not Given
MEDICAL FACILITY Not Given
ADDITIONAL RECIPIENT Not Given
MEDICAL FACILITY ID Not Given
PATHOLOGIST Not Given

**SPECIMEN**
SPECIMEN SITE Not Given
SPECIMEN ID Not Given
SPECIMEN TYPE Not Given
DATE OF COLLECTION Not Given
SPECIMEN RECEIVED Not Given

CDx Associated Findings

| GENOMIC FINDINGS DETECTED | FDA-APPROVED THERAPEUTIC OPTIONS |
|---|---|
| *EGFR* L858R | Gilotrif® (Afatinib)<br>Iressa® (Gefitinib)<br>Tarceva® (Erlotinib) |

OTHER ALTERATIONS & BIOMARKERS IDENTIFIED

Results reported in this section are not prescriptive or conclusive for labeled use of any specific therapeutic product. See professional services section for additional information.

*Microsatellite Status* MS-Stable§
*Tumor Mutation Burden* 11 Muts/Mb§
*CDKN2A/B* loss§
*EGFR* amplification§
*PTCH1* T416S
*RBM10* Q494*
*TP53* R267P

§ Refer to appendix for limitation statements related to detection of any copy number alterations, gene rearrangements, MSI or TMB result in this section.

Please refer to appendix for Explanation of Clinical Significance Classification and for variants of unknown significance (VUS).

| BIOMARKER FINDINGS | THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE) | THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE) |
|---|---|---|
| Tumor Mutation Burden - TMB-Intermediate (11 Muts/Mb) | Atezolizumab | Avelumab |
| | Nivolumab | Durvalumab |
| 9 Trials see p.14 | Pembrolizumab | |
| Microsatellite status - MS-Stable | No therapies or clinical trials. see Biomarker Findings section | |

| GENOMIC FINDINGS | THERAPIES WITH CLINICAL BENEFIT (IN PATIENT'S TUMOR TYPE) | THERAPIES WITH CLINICAL BENEFIT (IN OTHER TUMOR TYPE) |
|---|---|---|
| *EGFR* - amplification, L858R | Afatinib | Cetuximab |
| | Erlotinib | Lapatinib |
| | Gefitinib | Panitumumab |
| 4 Trials see p.15 | Osimertinib | |
| *PTCH1* - T416S | none | Sonidegib |

**Background information of Patient, Physician etc.**

**Summary of detected mutations**

**・Approval status of corresponding targeted therapies**
**・Ongoing clinical trials of detected mutations**

**Summary of references on detected mutations and candidates of therapy**

Source : https://assets.ctfassets.net/vhribv12lmne/P1UbtVjOoeAcaOCWoWQkW/613003bbb4a62d6f06ab10b6e8367f92/FoundationOne_CDx_Sample_Report.pdf as of January 28, 2019

# Projects under Development (1) (as of January 31, 2019)

| | Phase I | Phase II | Phase III | | Filed |
|---|---|---|---|---|---|
| Oncology | **CKI27**<br>- solid tumors<br>**GC33 (RG7686) / codrituzumab**<br>- HCC★<br>**ERY974**<br>- solid tumors<br>**RG7421 / cobimetinib**<br>- solid tumors<br>**RG7802 / cibisatamab**<br>- solid tumors<br>**RG7828 / mosunetuzumab**<br>- hematologic tumors | **RG6268 / entrectinib**<br>- NSCLC | **RG3502 / Kadcyla**<br>- breast cancer (adjuvant)<br>**RG435 / Avastin**<br>- RCC<br>- HCC<br>**RG7440 / ipatasertib**<br>- prostate cancer<br>- breast cancer<br>**RG7596 / polatuzumab vedotin**<br>- DLBCL<br>**RG6264**<br>- breast cancer<br>(Fixed-dose combination, subcutaneous injection) | **AF802 (RG7853) / Alecensa**<br>- NSCLC (adjuvant)<br>**RG7446 / Tecentriq**<br>- NSCLC (adjuvant)<br>- urothelial carcinoma<br>- MIUC (adjuvant)<br>- RCC<br>- RCC (adjuvant)<br>- early breast cancer<br>- ovarian cancer<br>- prostate cancer<br>- HCC<br>- HNC (adjuvant) | **RG7446 / Tecentriq**<br>- breast cancer ★<br>- SCLC ★<br>**RG6268 / entrectinib**<br>- solid tumors ★ |
| Bone & Joint | | | **NRD101 / Suvenyl (China)**<br>- knee osteoarthritis /shoulder periarthritis | | **ED-71 / Edirol (China)**<br>- osteoporosis |
| Renal | **EOS789**<br>- hyperphosphatemia | | | | |

In principle, completion of first dose is regarded as the start of clinical studies in each phase.

HCC: hepatocellular carcinoma
NSCLC: non-small cell lung cancer
SCLC: small cell lung cancer
MIUC: muscle invasive urothelial carcinoma
RCC: renal cell carcinoma
DLBCL: diffuse large B-cell lymphoma
HNC: head and neck carcinoma

**Letters in orange: in-house projects**
**★: Projects with advances in stages since October 24, 2018**
**★: Multinational study managed by Chugai**

# Projects under Development (2) (as of January 31, 2019)

| | Phase I | Phase II | Phase III | Filed |
|---|---|---|---|---|
| Autoimmune | **RG7845 / fenebrutinib**<br>- rheumatoid arthritis | | **MRA (RG1569) / Actemra**<br>- systemic sclerosis | |
| Neurology | **RG7935 / prasinezumab**<br>- Parkinson's disease<br>**GYM329 (RG6237)**<br>- neuromuscular disease<br>**RG7906**<br>- psychiatric disorders★ | **RG7916 / risdiplam**<br>- spinal muscular atrophy | **RG1450 / gantenerumab**<br>- Alzheimer's disease<br>**RG7412 / crenezumab**<br>- Alzheimer's disease<br>**SA237 (RG6168) / satralizumab**<br>- NMOSD ★<br>**RG6206**<br>- DMD (PII/III) | |
| Others | **PCO371**<br>- hypoparathyroidism<br>**RG7716 / faricimab**<br>- wAMD<br>**AMY109**<br>- endometriosis | **CIM331 / nemolizumab***<br>- pruritus in dialysis patients<br>**SKY59 (RG6107)**<br>- paroxysmal nocturnal hemoglobinuria (PI/II) | **RG7716 / faricimab**<br>- DME | **ACE910 (RG6013) / Hemlibra (EU)**<br>- hemophilia A (non-inhibitor) |

In principle, completion of first dose is regarded as the start of clinical studies in each phase.
wAMD: wet age-related macular degeneration
DME: diabetic macular edema
DMD: Duchenne muscular dystrophy
NMOSD: neuromyelitis optica spectrum disorder

* Atopic dermatitis is under development by licensees [Galderma (overseas) and Maruho (Japan)]

**Letters in orange: in-house projects**
**★: Projects with advances in stages since October 24, 2018**
**★: Multinational study managed by Chugai**

# Development Status (1)

In-house

## ACE910 / Hemlibra®

Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A without factor VIII inhibitors, administered once weekly, every two weeks, or every four weeks. *

Approved in December 2018 (Japan)
Filed in January 2019 (Taiwan)

Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with hemophilia A with factor VIII inhibitors, administered once weekly.

Approved in December 2018 (Taiwan)

* Additional dosing options of every two weeks or every four weeks in adults and children with hemophilia A with factor VIII inhibitors are also included.

# Development Status (2)

In-licensed

## RG7446 / Tecentriq®

- Previously untreated unresectable advanced or recurrent non-squamous NSCLC (combination with Avastin and chemotherapy)
  - Approved in December 2018
- SCLC (1L)
  - Filed and designated as an Orphan drug in December 2018
- Triple negative breast cancer (1L)
  - Filed in December 2018
- HER2 positive early breast cancer (neoadjuvant) (combination with Herceptin and Perjeta)
  - Started global Phase 3 study (IMpassion050) in January 2019

In-licensed

## RG6268 / entrectiniab

*NTRK* fusion positive solid tumors

Filed and designated as an Orphan drug in December 2018

In-licensed

## RG7906

Psychiatric disorders

Started Phase 1 study in January 2019

# Other Progress

FMI business

## FoundationOne® CDx / Cancer Genomic profile

- Gene mutation analysis program for solid tumors
  (for use in cancer genome profiling)
  Somatic gene mutation analysis program (for use in assessing anticancer drug indications)
  - Approved in December 2018
- Expanded use as companion diagnostic for entrectinib
  - Filed in January 2019

In-house

## SA237 / satralizumab

NMO / NMOSD

Breakthrough Therapy Designation by the U.S. FDA in December 2018

# Results of Clinical Trials / Conference (1)

In-house

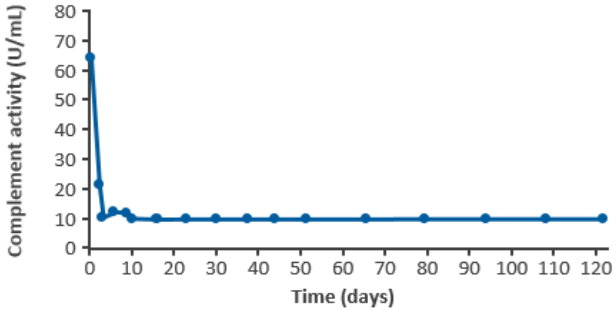
## SKY59 (RG6107)

Paroxysmal Nocturnal Hemoglobinuria (PNH)

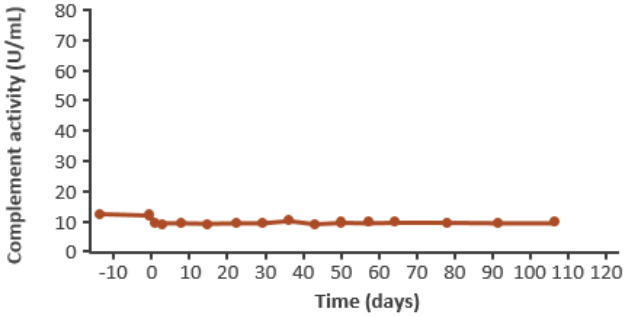
Interim analysis data of Phase 1/2 study in patient subjects presented at the American Society of Hematology (ASH) in December 2018

- Complete complement inhibition was achieved for all PNH patients treated with SKY59 and good control of intravascular hemolysis was shown
- SKY59 was well tolerated and no severe adverse events were observed

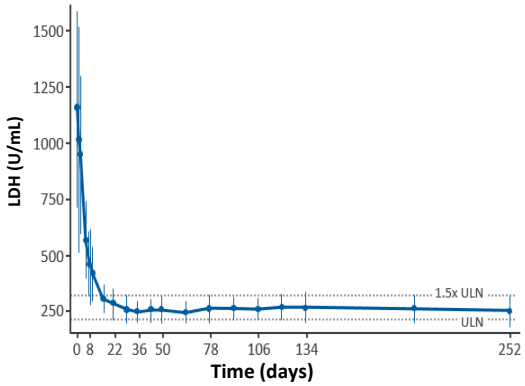
**Mean Terminal Complement Activity (LIA assay)**



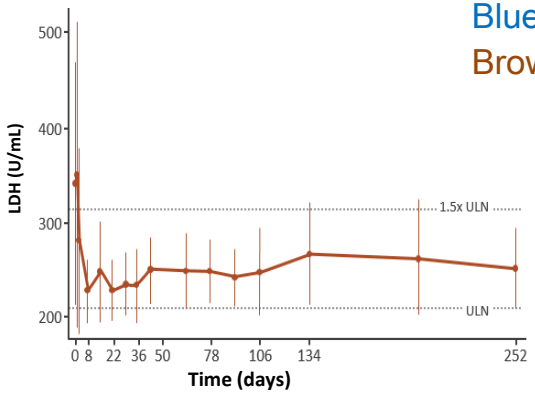

**Mean Terminal Complement Activity (LIA assay)**




**Mean LDH Levels**




**Mean LDH Levels**




Blue : Treatment naïve PNH patients
Brown : ECU pre-treated PNH patients switched to SKY59

LIA : Liposome Immuno Assay
LDH: lactate dehydrogenase
ECU: Eculizumab

Source : ASH (2018) slides

# Results of Clinical Trials / Conference (2)

In-house

## SA237 / satralizumab

### NMOSD

Primary end point was met in SAkuraStar study (Phase 3) in December 2018

- Satralizumab routine administration statistically reduced the risk of relapse as primary endpoint compared to placebo

In-house

## CIM331 / nemolizumab

### Atopic dermatitis

Primary end point was met in Phase 2b study conducted by Galderma in October 2018

- Nemolizumab improved Eczema Area and Severity Index (EASI) scores from baseline compared to placebo

Overview of Development Pipeline

# Projected Submissions (Post PoC NMEs and Products)

as of January 31, 2019

CHUGAI

Roche Group

**NME** **line extension**

**in-house**

**in-licensed**

NSCLC: non-small cell lung cancer
RCC: renal cell carcinoma
SCLC: small cell lung cancer
MIUC: muscle invasive urothelial carcinoma
HCC: hepatocellular carcinoma
HNC: head and neck carcinoma
DLBCL: diffuse large B-cell lymphoma
NMOSD: neuromyelitis optica spectrum disorder
FDC: fixed-dose combination
sc: subcutaneous injection

## Filed

- TECENTRIQ (RG7446) SCLC
- EDIROL (ED-71) Osteoporosis (China)
- TECENTRIQ (RG7446) Breast Cancer
- HEMLIBRA (ACE910/RG6013) Hemophilia A non-inhibitor (EU)
- entrectinib (RG6268) Solid tumors (NTRK+)
- ACTEMRA (MRA) Systemic Sclerosis
- satralizumab (SA237/RG6168) NMOSD
- entrectinib (RG6268) NSCLC (ROS1+)
- SUVENYL (NRD101) Knee Osteoarthritis /Shoulder Periarthritis (China)

## 2020

- TECENTRIQ (RG7446) Ovarian Cancer
- AVASTIN (RG435) RCC
- risdiplam (RG7916) Spinal Muscular Atrophy
- TECENTRIQ (RG7446) RCC
- RG6206 Duchenne Muscular Dystrophy
- TECENTRIQ (RG7446) MIUC (adjuvant)
- ipatasertib (RG7440) Breast Cancer
- TECENTRIQ (RG7446) NSCLC (adjuvant)
- KADCYLA (RG3502) Breast Cancer (adjuvant)

## 2021 and beyond

- ipatasertib (RG7440) Prostate Cancer
- TECENTRIQ (RG7446) HNC (adjuvant)
- nemolizumab* (CIM331) Pruritus in Dialysis Patients
- AVASTIN (RG435) HCC
- faricimab (RG7716) Diabetic Macular Edema
- TECENTRIQ (RG7446) HCC
- crenezumab (RG7412) Alzheimer's Disease
- TECENTRIQ (RG7446) Prostate Cancer
- gantenerumab (RG1450) Alzheimer's Disease
- TECENTRIQ (RG7446) Early Breast Cancer
- ALECENSA (AF802/RG7853) NSCLC (adjuvant)
- TECENTRIQ (RG7446) RCC (adjuvant)
- RG6264 (FDC, sc) Breast cancer
- TECENTRIQ (RG7446) Urothelial Carcinoma
- polatuzumab vedotin (RG7596) DLBCL

2019 2020 2021 and beyond

*Atopic dermatitis is under development by licensees [Galderma (overseas) and Maruho (Japan)]

# Updates on the Development Requests for Unapproved Drugs/Indications

## Review Committee of Development Requests for Unapproved Drugs/Indication

- 1st round requests: all approved (ten indications, including additional dosages and administrations of eight products)
- 2nd round requests: all approved (three indications of three products)
- 3rd round requests: requests were made for three indications of three products, including additional dosages and administrations, and two of them were approved

| Product | Indication | Current Status |
|---|---|---|
| Avastin® | Additional dosage and administration for ovarian cancer | Submitted company opinion and waiting for evaluation by the committee |

- 4th round requests: requests were made for four indications of four products and one of them was approved

| Product | Indication | Current Status |
|---|---|---|
| Xeloda® | Neuroendocrine tumor | Submitted company opinion and waiting for evaluation by the committee |
| Avastin® | Cerebral edema induced by radiation necrosis | Submitted company opinion and waiting for evaluation by the committee |
| Neutrogin® | Combination treatment with chemotherapy including fludarabine for relapsed/refractory AML | Submitted company opinion and waiting for evaluation by the committee |

Letters in orange: projects with advances in status since July 26, 2018

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