Business Results for FY2007

May 14, 2008

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astellas
Leading Light for Life

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Summary of FY2007

1. Sales and profits increased

- ✓Growth of global products (Prograf, Vesicare)
- ✓Contribution of new products in Japanese market (Celecox, Geninax)
- ✓COG ratio improved, R&D expenses decreased
- ✓Foreign exchange rate (Yen's depreciation against euro)

2. Research and development

- ✓Acquisition of Agensys
- ✓Steady progress of development pipeline

3. Business base strengthened

- ✓Optimization of number of personnel
- ✓Reorganization of European business

4. Capital efficiency

- ✓ROE: FY2006 11.3% => FY2007 16.1%

Financial Results for FY2007 (1)

(billion yen)

	FY2006	FY2007	Changes	Remarks
Net sales	920.6	972.5	+51.9	Impact of foreign exchange fluctuations: +12.8
Cost of goods ratio to sales	284.0 30.9%	279.3 28.7%	-4.7 -2.2ppt	Change in product mix: -1.2ppt Other factors：-1.0ppt
SG&A expenses ratio to sales	278.1 30.2%	282.8 29.1%	+4.7 -1.1ppt	Decrease in Japan Promotional costs increase in the US
R&D expenses ratio to sales	167.9 18.2%	134.4 13.8%	-33.4 -4.4ppt	In-license fees: -47.2 (FY06: in-license from FibroGen 37.5)
Operating profit ratio to sales	190.5 20.7%	275.9 28.4%	+85.3 +7.7ppt	Impact of foreign exchange fluctuations: +11.4

Foreign exchange rate (average)

USD (yen)	117	114	-3
Euro (yen)	150	162	+12

Financial Results for FY2007 (2)

(billion yen)

	FY2006	FY2007	Changes	Remarks
Operating profit	190.5	275.9	+85.3	
Non-operating profit	13.8	24.8	+11.0	Interest income: +2.9 Equity method investment gain:+6.8
Non-operating expenses	6.5	16.5	+10.0	Exchange loss: +11.2
Ordinary profit	197.8	284.1	+86.3	
Extraordinary gain	41.0	13.3	-27.7	FY07) Sale of fixed assets: 11.3 FY06) Sale of subsidiaries' share: 21.2 FY06) Sale of investment securities: 12.3
Extraordinary loss	27.1	28.7	+1.6	FY07) Impairment loss: 9.3 FY07) Early retirement benefit: 12.9 FY06) Integration of business base: 17.6
Net profit	131.2	177.4	+46.1	Tax rate: FY06: 37.1% =>FY07: 33.2%
EPS (yen)	244.07	349.89	+105.82	Number of shares (average) FY06: 537.9mil.=>FY07: 507.1mil.

ROE Improved Toward MTP Target 18%

	FY2005	FY2006	FY2007
ROE	8.8%	11.3%	16.1%
DOE	3.3%	3.7%	5.0%*
Dividend (yen)	70	80	110*
Share buyback	46.1bil. yen (10.98 mil. shares)	219.9bil. yen (44.03 mil. shares)	81.7bil. yen (16.30 mil. shares)
Cancellation of treasury stocks	-	10 mil. shares	45 mil. shares

*Year-end dividend: to be authorized at Annual Shareholders' Meeting

To improve capital efficiency

- Top priority on investment in Rx business for growth
- Cash balance will not be increased from the current level through the business investment and/or shareholder return.

FY2008

- Dividend per share: 120 yen (10 yen increase) (planned)
- Share buyback: 9.1mil. shares or 40bil. yen (maximum) (from May 15 to June 20)
- Cancellation of treasury stocks: 15 million shares*

*Subject to the approval for the reversal of general reserve at Annual Shareholders' Meeting

Forecasts of FY2008

(billion yen)

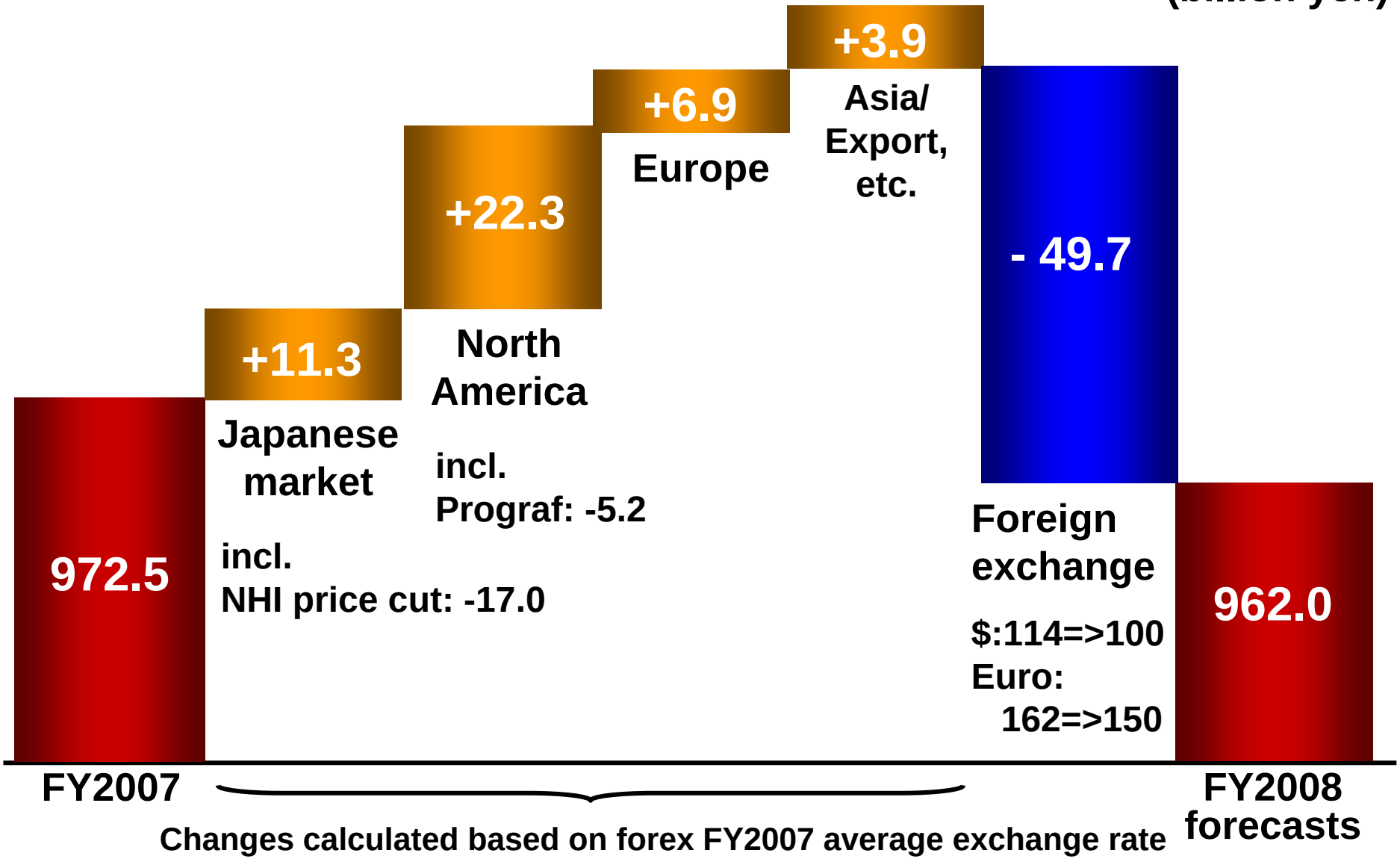
	FY2007 results	FY2008 forecasts	Changes
Net sales	972.5	962.0	-10.5
R&D expenses	134.4	161.0	+26.5
Operating profit	275.9	232.0	-43.9
Ordinary profit	284.1	246.0	-38.1
Net Profit	177.4	159.0	-18.4
Operating profit before amortization of goodwill	277.6	239.7	37.9

Foreign exchange rate (average)

USD (yen)	114	100	-14
Euro (yen)	162	150	-12

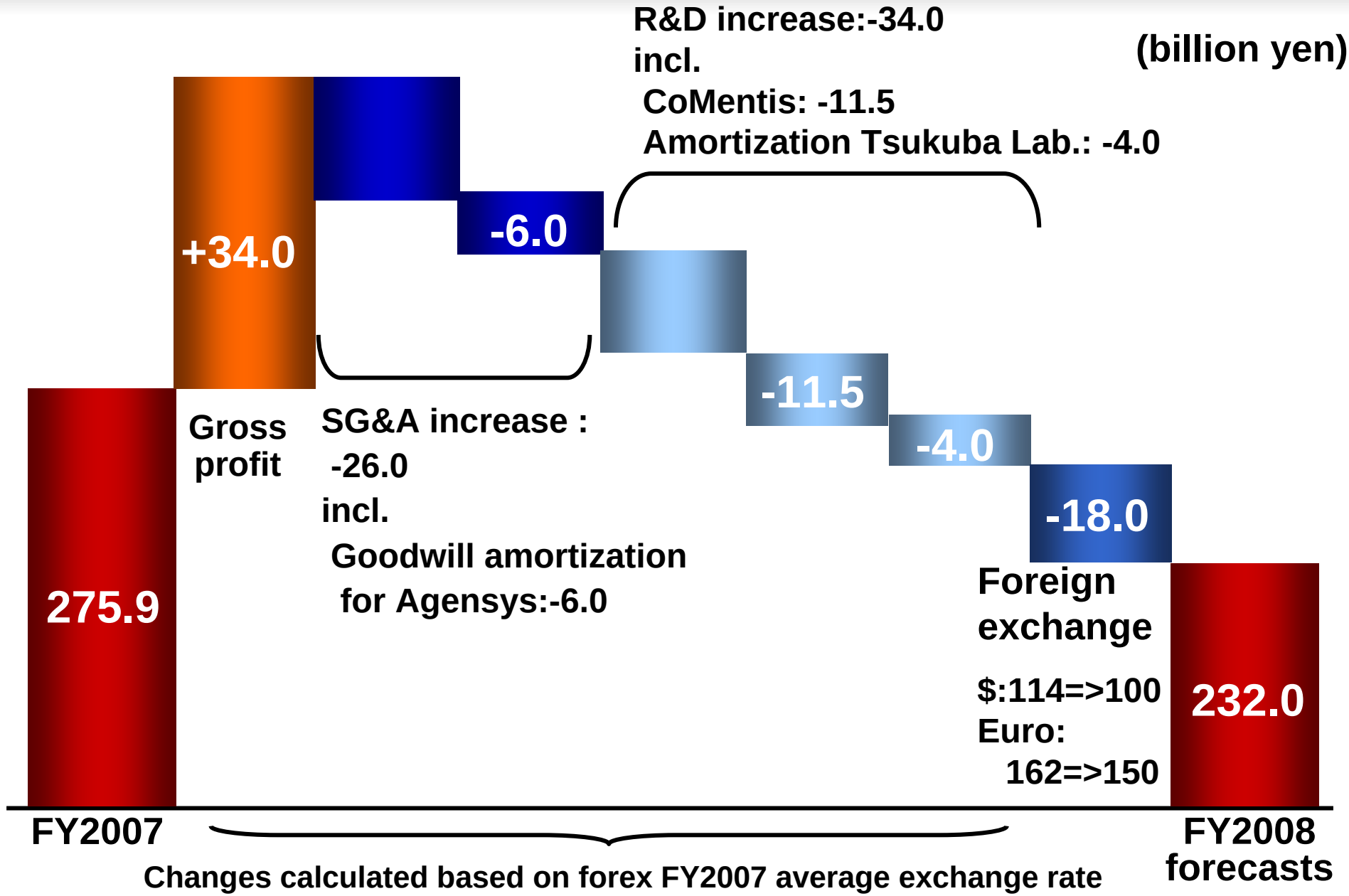
Net Sales Variation Factors: FY07 vs FY08 forecast

(billion yen)



Changes calculated based on forex FY2007 average exchange rate

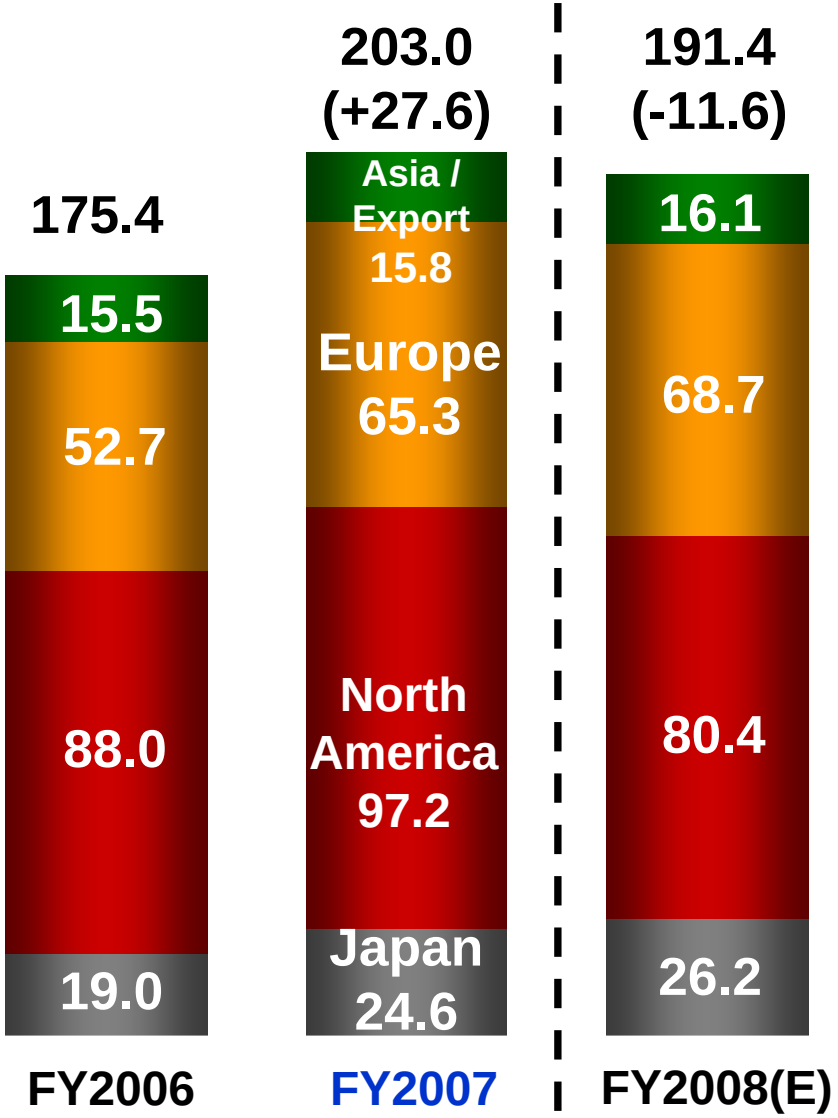
Operating Profit Variation Factors: FY07 vs FY08 forecast



Changes calculated based on forex FY2007 average exchange rate

Global Product: Prograf

Sales (billion yen)



Japan:

- ✓ Contribution of additional indications (RA, lupus nephritis, etc.) in addition to transplant
- ✓ FY08 forecasts: 6.4% increase despite NHI price cut (- 8.5% for oral formulation)

US:

- ✓ CNI market share for newly transplanted patients
  LTx: 93%, KTx: 86%, HTx: 68%
  (source: UNOS as of April 2008)
- ✓ FY08 forecast: Substance patent expired in the US in April /
  5.5% sales decline for N. America sales on US dollar basis
  * US sales in April went well

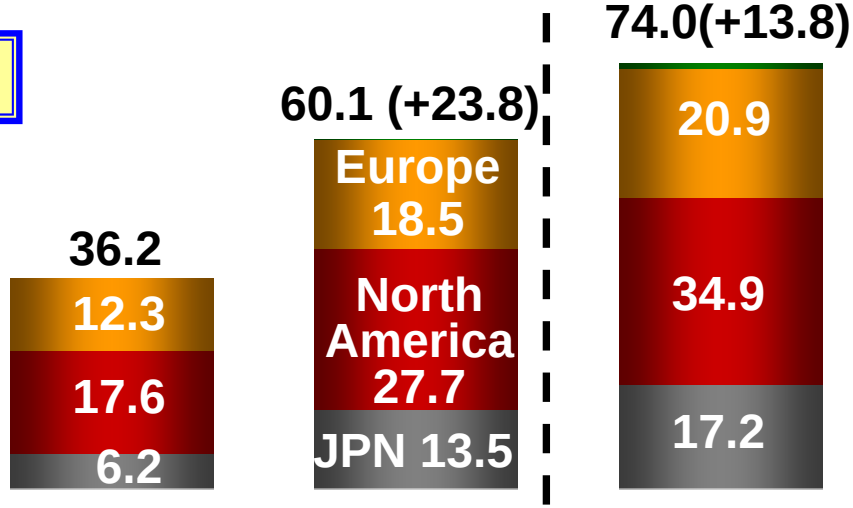
Europe:

- ✓ Advagraf launched in 14 countries
  (as of April 2008)

Global Product: Vesicare / Harnal

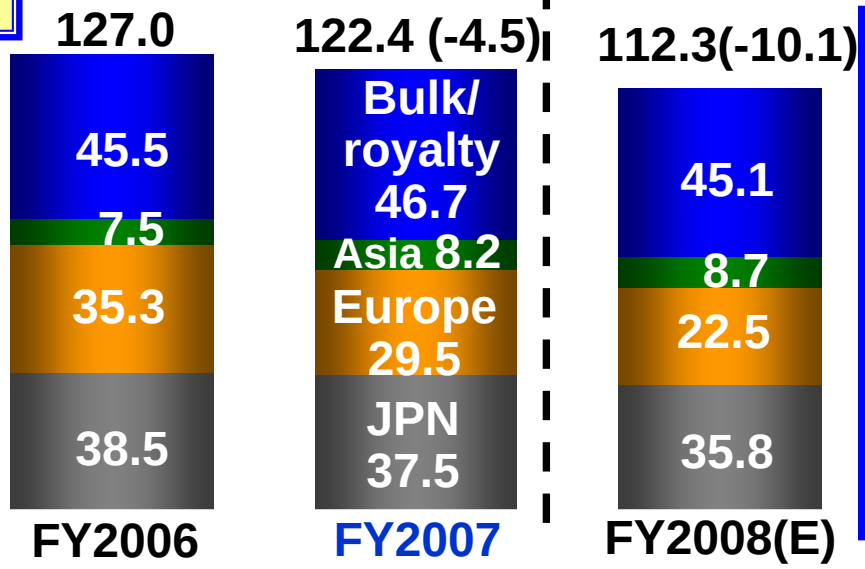
Sales (billion yen)

Vesicare



- JPN: No.1 product in OAB market
  FY07 market share: 35.7%
  (NHI price basis)
- US: Weekly prescription share
  TRx: 14.2%, NRx14.7% (April 25)
- Europe: Market share approx. 27%
- Continued growth expected in FY08

Harnal



- JPN: FY07 sales -2.6%
- Europe: Downward trend, but steady in Spain and non-EU5 market
- Bulk and Royalty:
  Flomax robust sales in the US
  $411M (+13%) (Jan.-Mar. 2008)

Japanese Market: New Products Contribution

(billion yen)

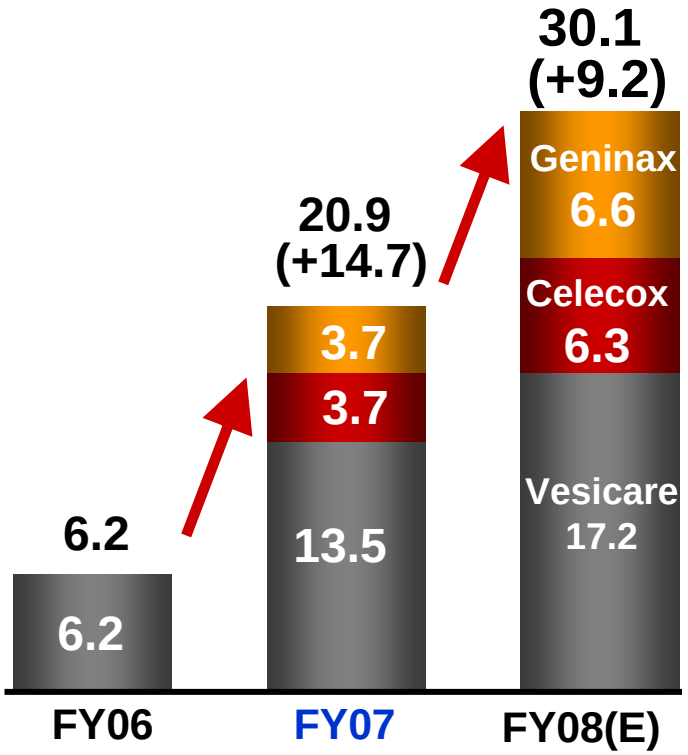
	FY06	FY07	Changes	FY08(E)
Rx sales in Japan	455.2	478.2	+22.9	489.5
Lipitor	94.7	97.7	+2.9	99.2
Micardis	50.3	62.6	+12.2	64.5
Gaster	62.2	60.9	-1.3	56.0
Harnal	38.5	37.5	-1.0	35.8
Prograf	19.0	24.6	+5.5	26.2
Myslee	19.4	21.5	+2.1	23.4
Seroquel	16.8	19.2	+2.3	19.6
Cefzon	14.7	14.5	-0.1	11.6
Vesicare	6.2	13.5	+7.3	17.2
Celecox	-	3.7	+3.7	6.3
Geninax	-	3.7	+3.7	6.6

✓**FY2007:**
Higher growth than market

Astellas:+6.4% > Market +5.5%
(Astellas market share: 7.3%)
(NHI price basis)

✓**New products* expanding**

***Vesicare, Celecox and Geninax**



For Sustainable Growth: Generating New Products

Enhance in-house research capability

- ✓ Acquisition of Agensys (Dec. 2007)
  - Integration process going well
  - Full operation as Astellas' antibody research base

Pursue strategic initiatives

- ✓ Agreement with CoMentis on BACE inhibitor (Apr. 2008)
- ✓ Continue to pursue the opportunities

Make steady progress of development

- ✓ Speeding up the development activities by the appropriate resource allocation on prioritized projects such as YM178, YM150, etc.

Pipeline Update

FK463 (Product Name: Mycamine)

Received approval in Europe in April.

Received approval by the European Commission on April 25, 2008.

- **Indication:**
  - **Treatment of invasive candidiasis ; Adults and Children (including neonates)**
  - **Prophylaxis of Candida infection in patients undergoing allogeneic haematopoietic stem cell transplantation or patients who are expected to have neutropenia for 10 or more days ; Adults and Children (including neonates)**
  - **Treatment of oesophageal candidiasis in patients for whom intravenous therapy is appropriate ; Adults**

- **Mechanism of action: 1,3- beta - D - glucan synthesis inhibitor**

U.S.

March 2008: Withdrawal of the supplemental NDA (New dosage;300mg alternate-day administration) for oesophageal candidiasis.

CVT-3146 (Product Name: Lexiscan)

Received approval in U.S. in April

- **Indication:** Use as a pharmacologic stress agent for radionuclide MPI studies in patients unable to undergo adequate exercise stress
- **Mechanism of action:** $A2_A$ adenosine receptor agonist
- **Formulation:** Injection
- **Character:**
  1. Lexiscan is delivered as a rapid bolus single dose
  2. No need to adjust the dose for body weight

FK506 MR

The instructions by the FDA at the second approvable letter:

- **Liver transplant dated at the end of April, 2008**
  - **ISSUE:**
    Gender difference
  - **RECOMMENDATION:**
    Further analyses of the P3 study and/or additional clinical trials to explore gender difference
- **Kidney transplant dated in the middle of March, 2008**
  - **ISSUES:**
    Pharmacokinetics early post-transplant
    Gender difference seen in liver application
  - **RECOMMENDATION:**
    Submission of P3 data conducted in Europe with additional gender analysis

Our future action plan:

- **Astellas is considering all options in determining the future strategy for FK506 MR**
- **Astellas will continue to discuss these issues with the FDA**

Updated Status of Major projects

■Televancin

Status of cSSSI**: in the U.S.

- Complete Response to the action letter submitted to the FDA on January 21, 2008.

- Expected action date by the FDA: July 21, 2008

**cSSSI; Complicated Skin and Skin Structure Infection

■FK506-MMF(U.S.)

- Response to the action letter with additional data submitted to the FDA in March, 2008.

- 6-months review by the FDA estimated.

Indication: Suppression of organ rejection in kidney transplant

■YM060 (Japan)

- Japanese authority review meeting *(Bukai)* was held in April, 2008, but the description of the labeling was not agreed by the members.

- The review meeting will be held to review labeling again in May.

■ASP0485/Alefacept

- February 2008: Enrollment of Phase II clinical trial in the U.S. started.

YM178 Development Status

Enter the Phase III clinical trial in the U.S. and Europe

■**Summary of study design of Phase III in the U.S.**

- **Study Design:** Randomized, Double-Blind, parallel group, in comparison with placebo
- **Patients:** OAB (overactive bladder)
- **Total enrollment:** 1620
- **Dosage duration:** 12 weeks
- **Primary endpoints:** Number of micturitions/24h
  Number of incontinence episodes/24h
- **Secondary endpoints:** Volume voided per micturition
  Urgency incontinence episodes/24 h
  Number of urgency episodes/24 h

YM178
Results of P-IIa Trial in the U.S. Presented at EAU (1)

YM178 Results of Phase IIa clinical trial presented at European Association of Urology (EAU) on March 26-29, 2008.

■Study design:

- **Patients: OAB**
- **A phase II randomized, Double-Blind, parallel group, proof of concept study**
  YM178 100mg bid (65 pts), 150mg bid (65 pts)
  Placebo (66 pts)
  Tolterodine 4mg once daily (64pts)
- **Primary endpoint: Change in number of micturitions/24h**
- **Dosage duration: 4 weeks**

■Study results:

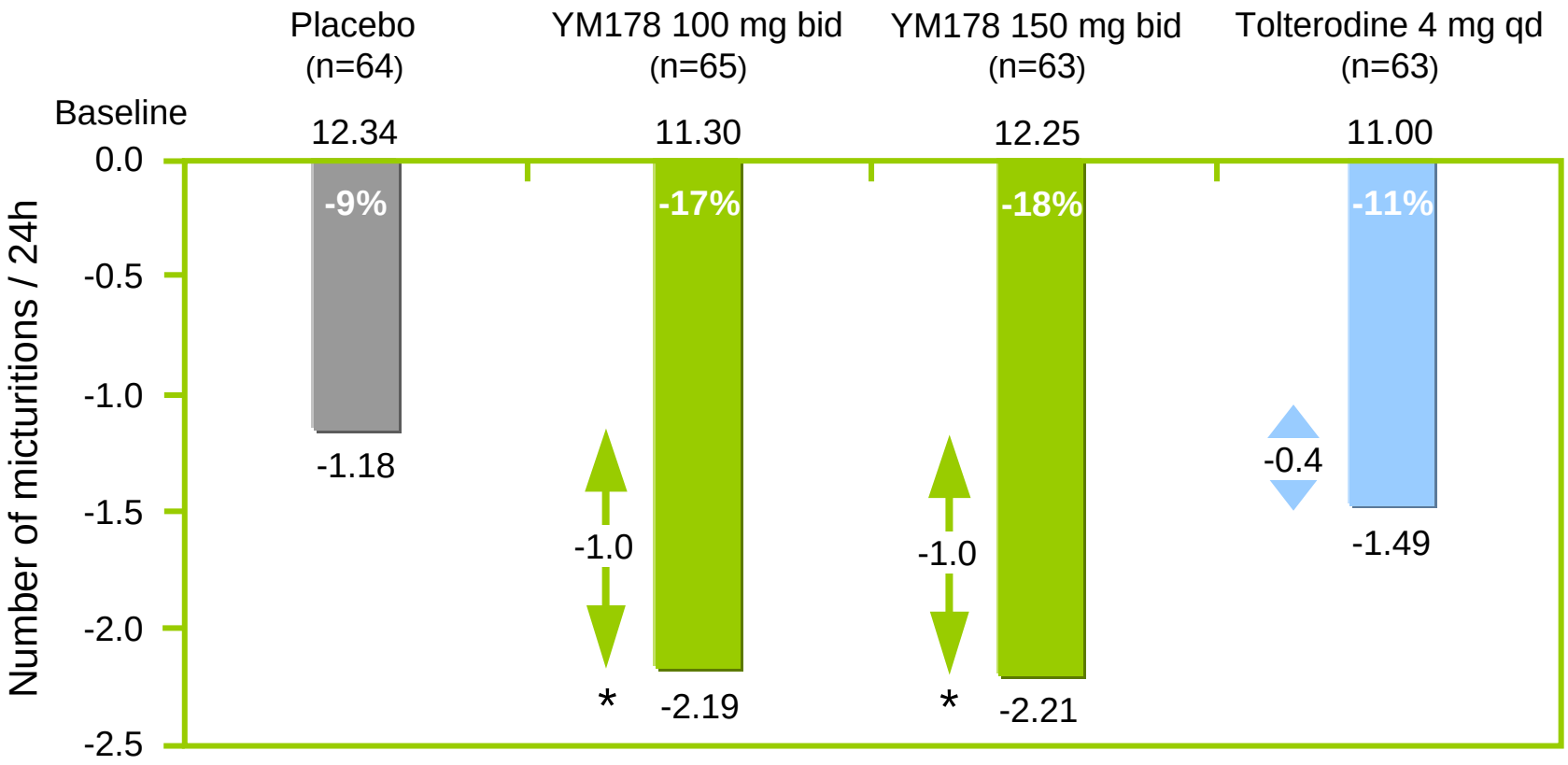
- **The primary efficacy analysis showed a statistically significant reduction of mean micturition frequency following treatment with 100 mg and 150 mg YM178 bid compared to placebo.**
- **Treatment with YM178 was well tolerated at the 100 mg and 150 mg YM178 bid dose.**

■Conclusion:

The Beta 3 receptor agonist YM178, with its novel mode of action, is effective and well tolerated in the treatment of symptoms of OAB in a clinical setting.

YM178
Results of P-IIa Trial in the U.S. Presented at EAU (2)

Figure 3. Micturition frequency/24 hours (mean change from baseline to endpoint [Full Analysis Set])



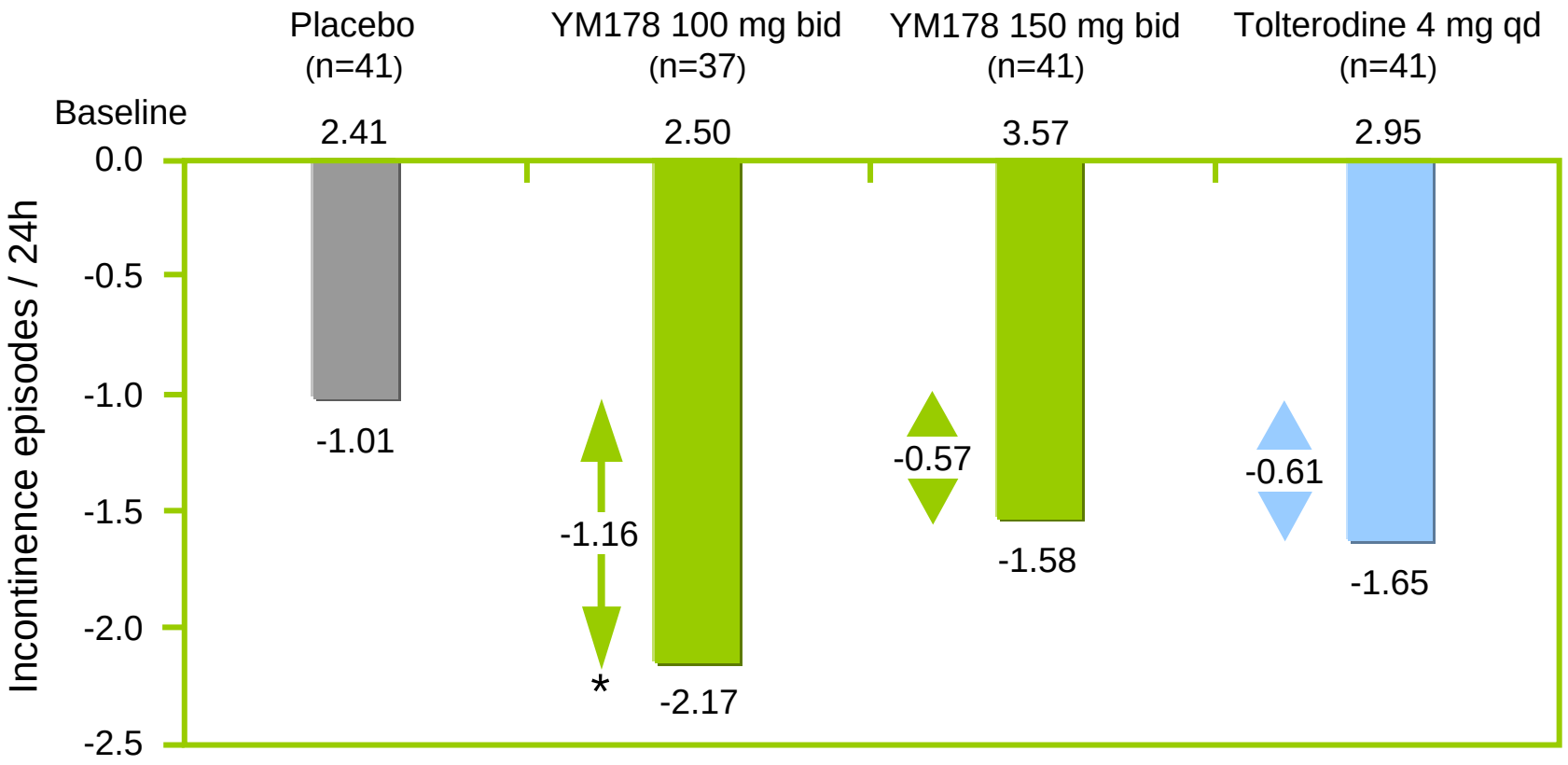
LSM changes from baseline and differences to placebo *p<0.05 vs. placebo

bid=twice daily; qd=once-daily; LSM=least-square mean

Source: European Association of Urology (March,2008)

YM178
Results of P-IIa Trial in the U.S. Presented at EAU (3)

Figure 4B. Incontinence episodes (mean change from baseline to endpoint [Full Analysis Set])



LSM changes from baseline and differences to placebo *p<0.05 vs. placebo

bid=twice daily; qd=once-daily; LSM=least-square mean

Source: European Association of Urology (March,2008)

YM311(FG-2216)/ASP1517(FG-4592)
Update on Clinical Hold

- **Clinical hold of the two compounds was instructed by FDA in May, 2007, following a report of adverse event of fatal hepatic failure occurred to one subject who was in P2 study of YM311. No similar adverse events occurred in any of ASP1517 studies, however, IND for ASP1517 also placed on hold.**
- **Complete Clinical Hold Response (CHR) for CKD was submitted to FDA on February 22, 2008.**
- **FDA responded to CHR on March 24, 2008. After reviewing the CHR, FDA concluded that clinical studies of the two compounds may be resumed.**
- **Key features of CKD clinical studies confirmed with FDA include:**
  - **Implementation of hepatic monitoring plan**
  - **Supplemental DDI studies for YM311**
  - **Implementation of clinical studies for YM311 to ESA hypo-responders**
  - **P2 study will be re-commenced for ASP1517**

HIF-PH Inhibitor Program on Anemia

- **Our first priority is to resume clinical studies of the two compounds as quickly as possible. Current plan* indicates the following timeline for resumption.**

YM311	**2nd Half of FY2008**
ASP1517	**2nd Half of FY2008**

***Transatlantic Clinical Development Plan**

- **In parallel, collaboration efforts with FibroGen will also be put into selection of 3rd generation compounds appropriate for clinical studies.**

YM443 Development Status

■**Mechanism of action:** Acetylcholine Esterase Inhibitor

■**Indication:** Functional Dyspepsia (FD)

■**Status:**

- ●Phase II in the U.S.
  - Conduct a validation study to develop a primary endpoint before Phase III clinical trial
- ●Phase III in Japan
  - March in 2008:Obtained the right of co-development and co-marketing from Zeria Pharmaceutical Co., Ltd.

■**Other:**

The results of Phase IIb clinical trials will be presented at Digestive Disease Week in the U.S held on May 17-22, 2008.

YM443
Results of P-IIb Trial Presented at DDW (1)

Summary of study design:

- Design: Randomised, Double-Blind, placebo-controlled, parallel group study
- Patients: Functional Dyspepsia: FD, Rome II criteria
- Primary outcome measures:

  (1) Adequate overall relief of symptoms in the past 7 days (ORS, Yes/No)

  (2) Overall treatment effect in the past 7 days (OTE, 9 graded)
- Dosage duration: 12 weeks
- Total enrollment: 400 patients

Conclusion:

YM443 300mg tid would be promising agent for FD

*tid : three times a day

Source: Abstract of Digestive Disease Week (May,2008)

YM443
Results of P-IIb Trial Presented at DDW (2)

- **ORS and OTE responder rate of the YM443 at the last week of treatment were numerically greater on but were not statistically significant over placebo.**
- **Results of post-hoc analyses are summarized in table 1.**
  - **Therapeutic gain both in ORS and OTE were highest in the first month. The YM443 at 300 mg tid showed significant difference over placebo.**
  - **Rome III groups (EPS,PDS#) were identified to assess response, and responder rate of the YM443 at 300 mg tid was statistically significant over placebo in EPS and PDS severe subpopulation.**
- **YM443 300mg significantly improved quality of life assessment (Nepean Dyspepsia Index and SF-36).**

Table 1: Responder Rate (%) of YM443 vs. Placebo

Response ≥ 50% wks	Placebo	YM443 300 mg tid	YM443 600 mg tid	YM443 900 mg tid
ORS 1-12 wks	31.3	43.8^	36.9	31.6
ORS 1-4 wks	26.3	55.2**	42.7**	33.7
OTE 1-4 wks	34.3	56.3**	45.6^	34.7
EPS# (ORS)1-4 wks	19.2	52.4**	45.2**	40.0*
PDS# (ORS)1-4 wks	26.3	52.2**	40.7	30.8

*P<0.05, **P≤0.01, ^P≤0.10 #EPS: Epigastric Pain Syndrome, PDS: Postprandial Distress Syndrome

Source: Abstract of Digestive Disease Week (May, 2008)

BACE Inhibitors Licensed from CoMentis

■**Compounds:** BACE (Beta-secretase) inhibitors (including CTS-21166 and drug candidates discovered by the joint research)

■**Targeted indication:** Prevention and treatment of Alzheimer's disease

■**Character:**

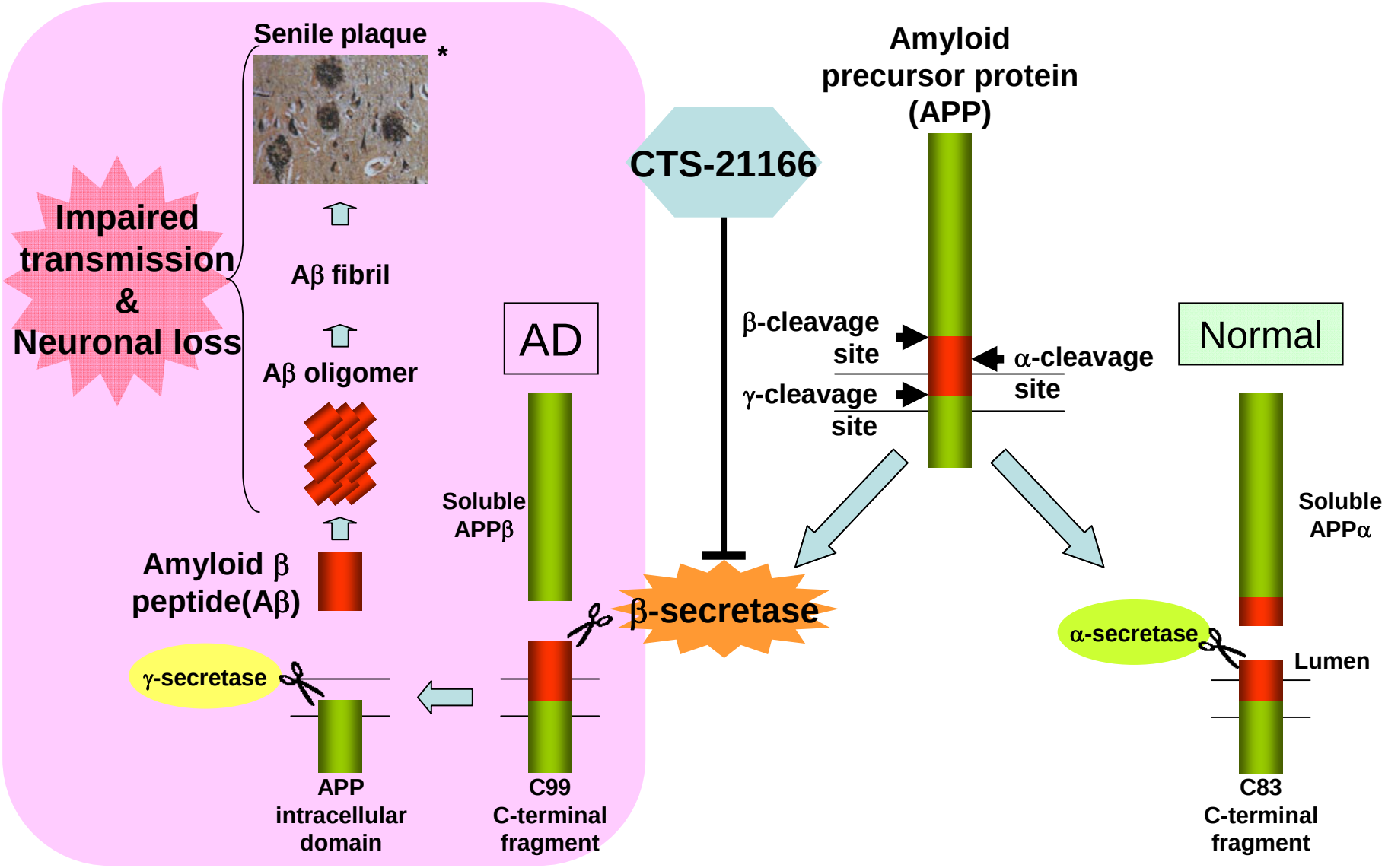
- BACE inhibitor reduces amyloid beta production.
- BACE inhibitor has the potential to slow the progression of Alzheimer's disease and to become the disease modifying therapeutic agent rather than symptomatic therapy.
- CTS-21166 has the high inhibitory activity and selectivity for BACE.

■**Development status:**

CTS-21166

- Intravenous dosage: P-I (CoMentis has conducted.)
- Oral administration: Timing of initiation is under consideration (Co-development)

Mechanism of BACE Inhibitors



*: Color Atlas of Pathology of the Nervous System (Second edition). Asao Hirano, M.D. (published by IGAKU-SHOIN Ltd., Tokyo): p.96