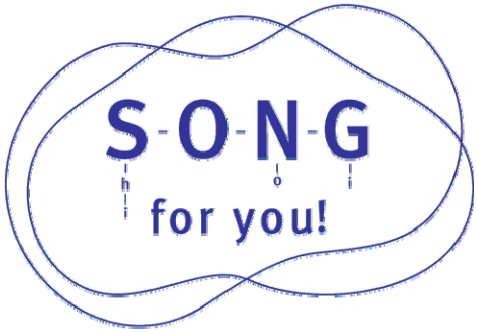


1st Quarter of Fiscal 2012

Conference Call

August 6, 2012

SHIONOGI & CO., LTD.

Forward-Looking Statements

- This presentation contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements.
- Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products.
- The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.
- This material contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kinds.

Overview of
1st Quarter FY2012 Results

Financial Results (Consolidated)

(Units: B yen)

	FY2012 forecasts	FY2012		Progress vs. forecasts (%)	FY2011 Apr-Jun results	Y on Y	
		1H forecasts	Apr-Jun results			Change (%)	Change
Sales	289.0	138.0	67.8	49.1	63.7	6.4	4.1
Operating income	56.0	24.5	12.2	49.8	11.5	6.6	0.7
Ordinary income	54.0	23.5	12.1	51.3	11.7	3.2	0.4
Net income	32.0	14.0	6.9	49.4	3.8	82.8	3.1

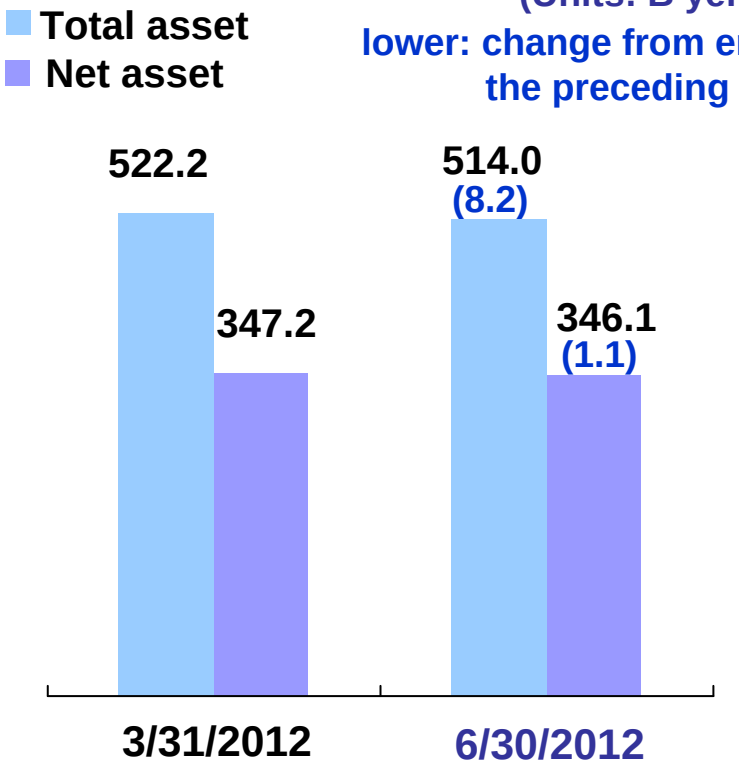
* All numerical values are rounded to the nearest unit.

* The depreciation method of tangible fixed asset has been changed from declining-balance method mainly we used to straight-line method since FY2012. With this change, operating income and ordinary income are increased 0.6 and 0.7 billion yen respectively in the 1st quarter of FY2012.

Financial Position and Cash Flow (Consolidated)

Financial Position

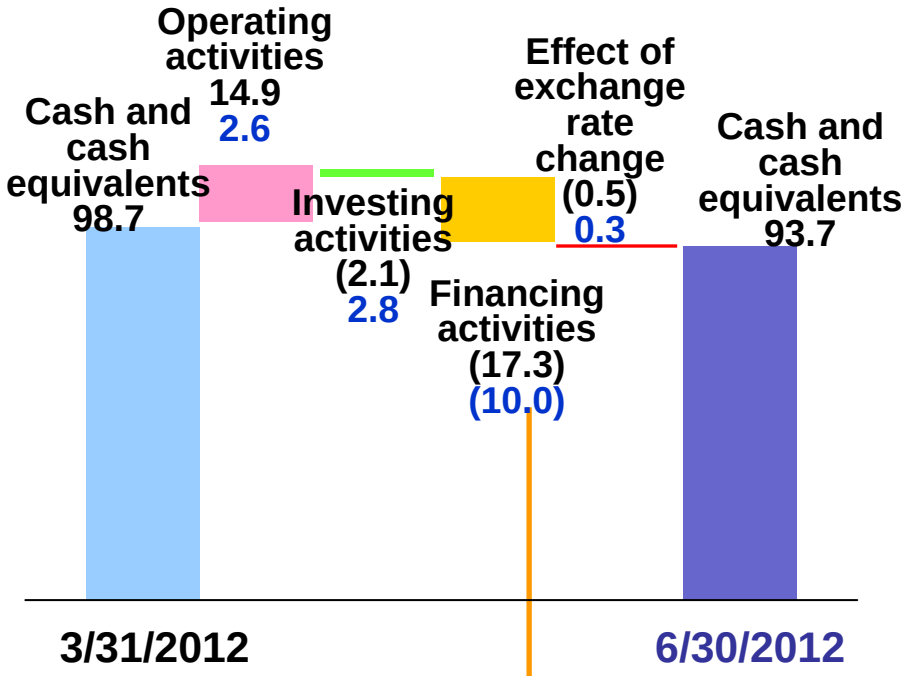
(Units: B yen)
lower: change from end of the preceding term



	3/31/2012	6/30/2012
Equity ratio	65.9%	66.7%

Cash Flow

(Units: B yen)
lower: Y on Y change



Redemption of debenture:
10.0 B yen

Statements of Income (Consolidated)

S-O-N-G for you!

(Units: B yen)

	FY2012		Progress vs. forecasts (%)	FY2011 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			Change (%)	Change
Sales	138.0	67.8	49.1	63.7	6.4	4.1
[Royalty income]	34.5	16.0	46.5	15.9	0.9	0.1
Cost of sales	29.0 (38.6) 40.0	30.3 (39.7) 20.6	51.4	28.3 (37.7) 18.0	14.0	2.6
Gross profit	98.0	47.2	48.2	45.7	3.4	1.5
SG&A expenses	53.3 73.5	51.7 35.0	47.7	53.7 34.2	2.4	0.8
Selling & general expenses	47.0	23.3	49.5	21.2	10.1	2.1
R&D expenses	26.5	11.8	44.4	13.1	(10.0)	(1.3)
Operating income	17.8 24.5	18.0 12.2	49.8	18.0 11.5	6.6	0.7

* Small numbers in red are percentages of sales, and numbers in red provided in parentheses are percentages of royalty excluded sales.

Breakdown of Sales (Consolidated)

(Units: B yen)

	FY2012		Progress vs. forecasts (%)	FY2011 Apr-Jun results	Y on Y	
	1H forecasts	Apr-Jun results			Change (%)	Change
Prescription drugs	79.5	39.7	49.9	39.3	0.8	0.4
Total of 3 key products	28.7	13.1	45.6	11.8	11.0	1.3
Total of 8 strategic products	40.4	18.9	46.7	16.6	13.6	2.3
Overseas subsidiaries/export	14.6	* 7.4	50.5	4.3	71.4	3.1
Shionogi Inc.	7.0	3.5	50.1	2.5	35.4	1.0
C&O	2.9	1.5	51.6	-	-	1.5
Doripenem	1.8	0.6	31.5	0.5	8.4	0.1
Contract manufacturing	4.7	2.3	49.8	1.6	39.7	0.7
OTC and quasi-drugs	2.7	1.3	49.3	1.2	4.9	0.1
Diagnostics	1.0	0.6	57.6	0.7	(20.6)	(0.1)
Royalty income	34.5	16.0	46.5	15.9	0.9	0.1
Crestor	32.7	14.7	44.9	15.2	(3.5)	(0.5)
Others	1.0	0.5	45.7	0.4	(1.3)	0.1
Total	**138.0**	**67.8**	**49.1**	**63.7**	**6.4**	**4.1**

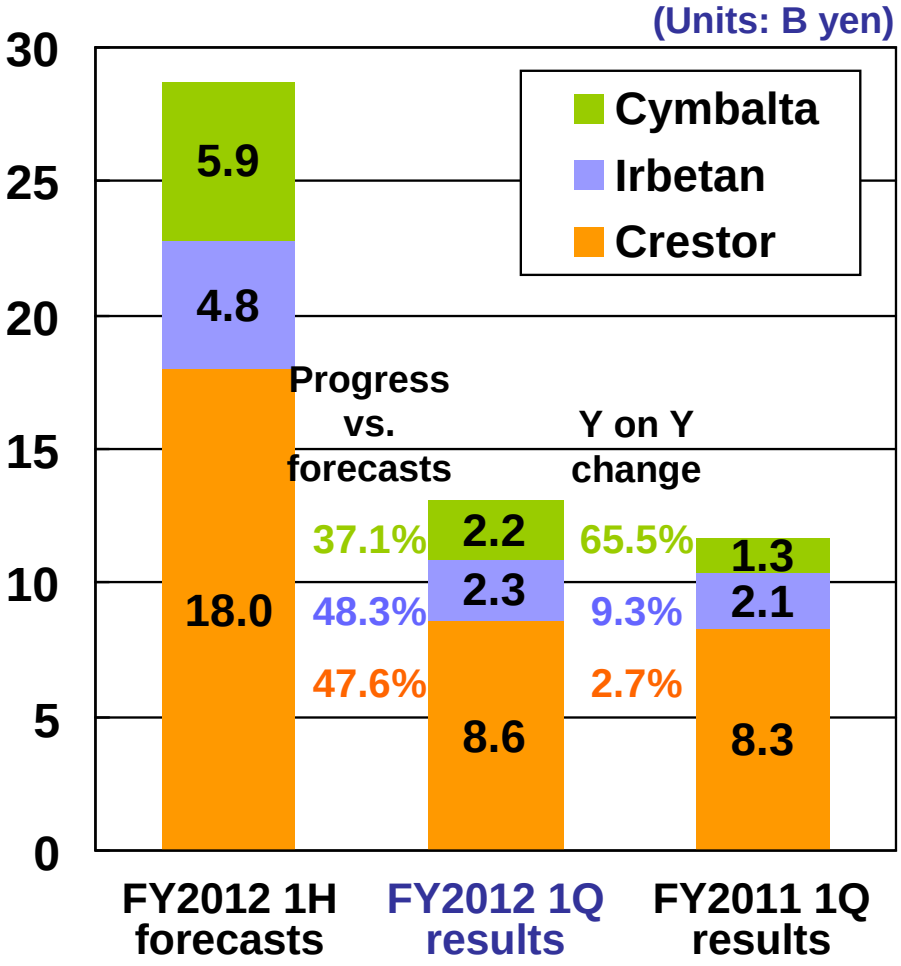
8 strategic products: Crestor, Irbetan, Cymbalta (3 key products), and OxyContin, Finibax, Differin, Pirespa, Rapiacta

* Taiwan Shionogi has changed its accounting period since Jan. 2012, and Apr.-Jun. results include 6 months from Jan. to Jun.

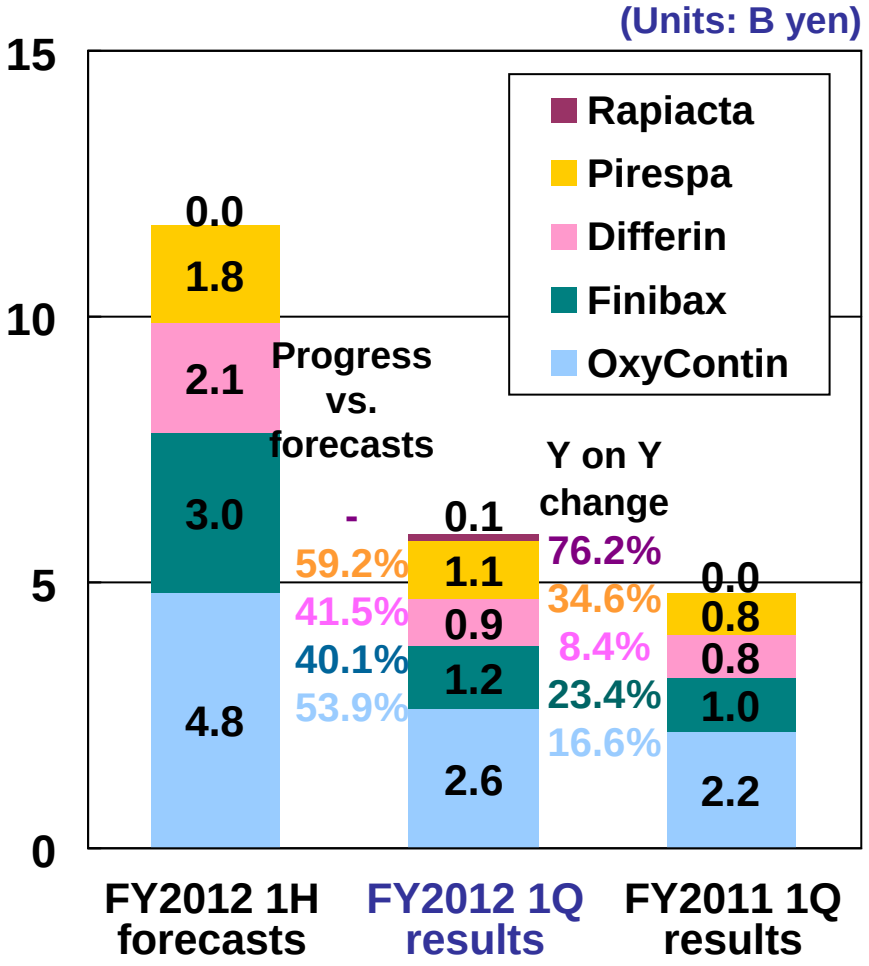
* C&O has been consolidated since Oct. 2011, and Apr.-Jun. results include 3 months from Jan. to Mar.

Domestic: Sales of 8 Strategic Products

◆ 3 Key Products



◆ 5 Strategic Products



Financial Results of Shionogi Inc.

(Units: upper/million dollar, lower/billion yen)

	FY2012			Progress vs. forecasts (%)
	Full year forecasts	1H forecasts	Apr-Jun results	
Sales	194 15.5	87 7.0	44 3.5	50.1
Cost of sales	21 1.6	10 0.8	9 0.8	92.3
SG&A expenses	211 16.9	107 8.5	51 4.1	47.8
Operating income	(38) (3.0)	(30) (2.4)	(17) (1.3)	-

* As Y-on-Y changes (%) are calculated in US$, they are not the same as Y-on-Y changes calculated in Japanese yen.

◆ Results in 1Q FY2012

- Sales: Kapvay kept steady growth, Fortamet AG and Orapred showed smooth progress, and Naprelan stayed flat. Sales reorganization in 2Q will strengthen Naprelan.
- COGS: Increased loss on disposal of stocked non-promoted products
- SG&A: Continued focus on cost containment
- Operating income: On track for the 1st half target (except for high COGS)

Financial Results of C&O

(Units: B yen)

	FY2012			Progress vs. forecasts (%)
	Full year forecasts	1H forecasts	Apr-Jun results	
Sales	5.6	2.9	1.5	51.6
Operating income	0.5	0.3	0.1	48.6

* C&O: C&O Pharmaceutical Technology (Holdings) Limited
* C&O has been consolidated since Oct. 2011, and Apr.-Jun. results in FY2012 include 3 months from Jan.-Mar. results in 2012.

◆ Results from Jan. - Mar. of 2012

- **Sales:** Negative impact from the examination of the clinical use of antibiotics bottomed out. Total sales were as planned;
  - Amolin: changed prescription from competitors
  - Flumarin: increased institutions adopting
- **Operating income:** On track for the 1st half target including costs
  ⇒ Steady progress is going on after April

Discussion with AstraZeneca about Crestor Royalty

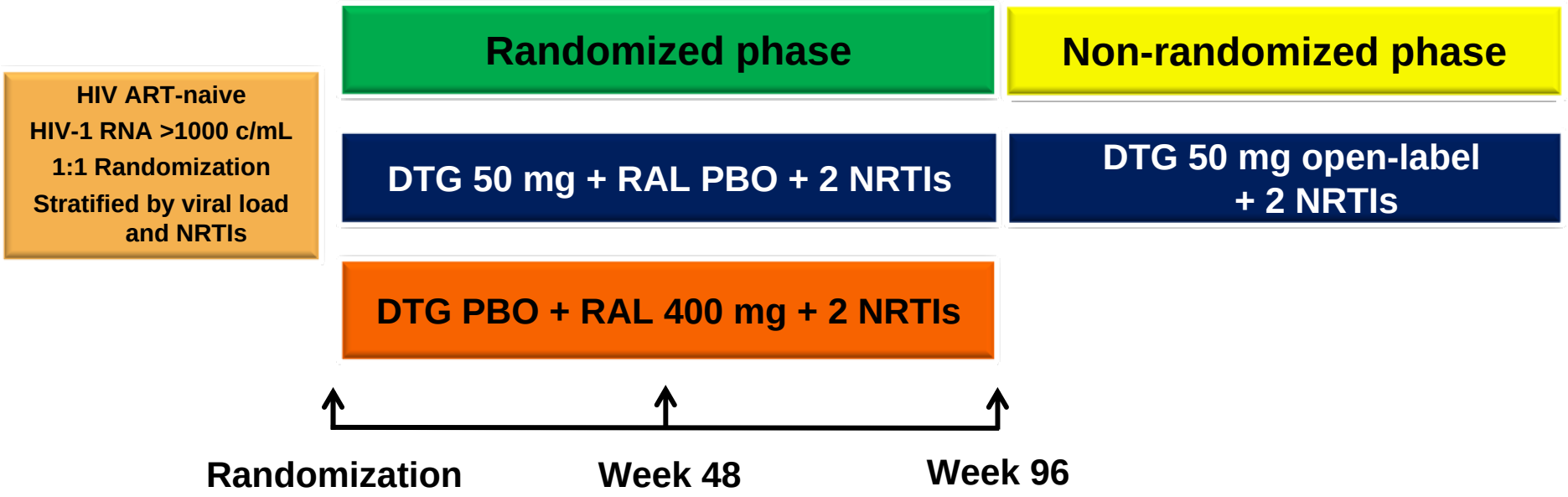
◆ Arbitration proceedings

- Shionogi initiated arbitration proceedings to resolve issues relating to the treatment of certain excise taxes and others in the calculation of royalties on Crestor sales of AstraZeneca in the world
- Initiation date: July 20, 2012

Pipeline

S-349572 (dolutegravir; DTG)*: SPRING-2 Study

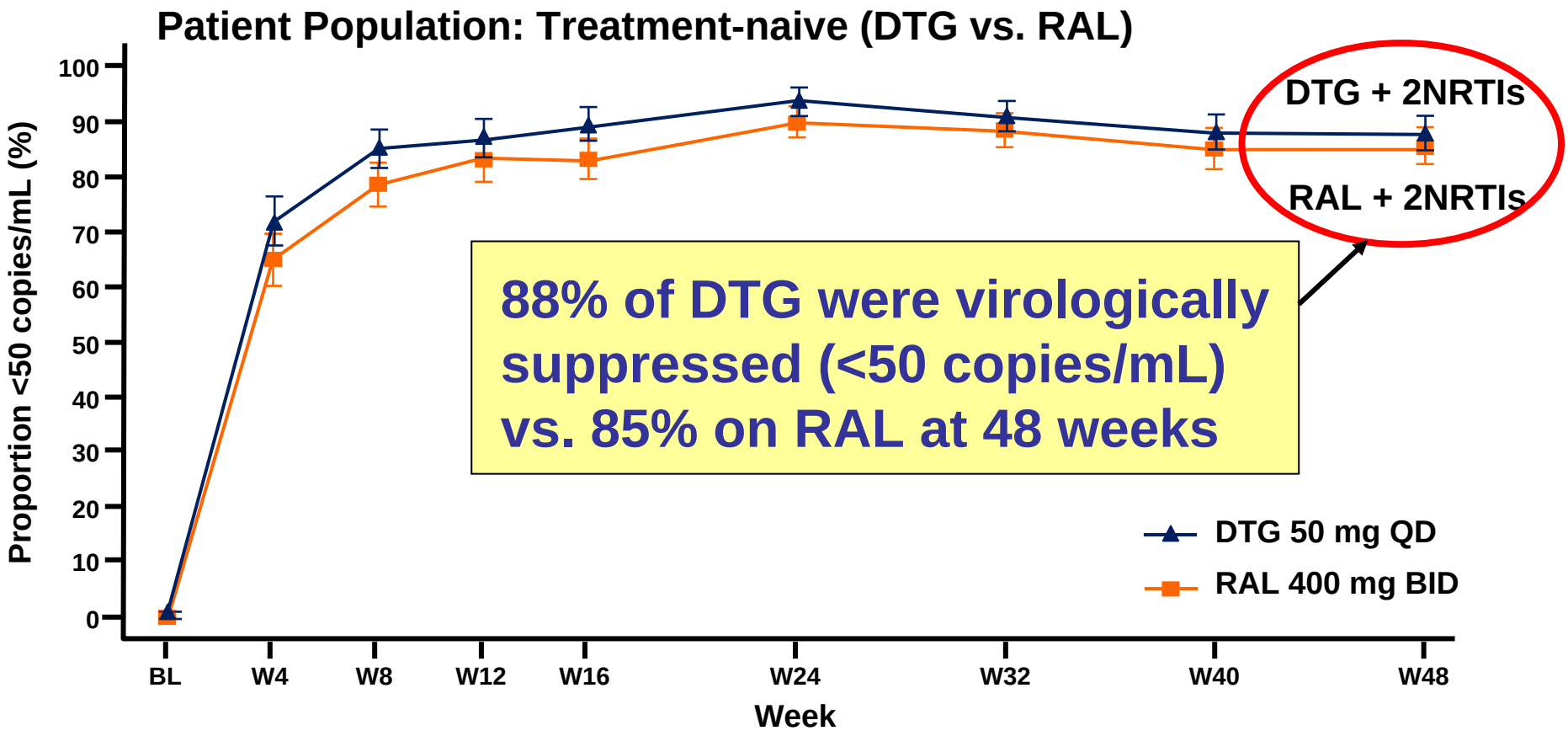
Study No.	Patient Population	Study Design
ING113086 SPRING-2	Treatment-naive	n=822 (non-inferiority design) DTG 50 mg QD vs. RAL 400 mg BID (+ ABC/3TC or TDF/FTC)



* Developed by Shionogi-ViiV Healthcare LLC

RAL: raltegravir PBO: Placebo
2 NRTIs: Combination drug of two nucleoside reverse transcriptase inhibitors
ABC/3TC: abacavir/lamivudine TDF/FTC: tenofovir/emtricitabine

S-349572 (dolutegravir; DTG): SPRING-2 Study



- Once daily DTG 50 mg was non-inferior to twice daily RAL 400 mg
- Good safety profile
- No integrase inhibitor (INI) mutations nor NRTI mutations were detected through 48 weeks on DTG (n=1/18 for INI and 4/19 for NRTI on RAL)

S-349572 (dolutegravir; DTG): SINGLE Study

Study No.	Patient Population	Study Design
ING114467 SINGLE	Treatment-naive	n=833 (non-inferiority design) DTG 50 mg/ABC/3TC QD vs. Atripla QD

◆ Initial data from Phase III SINGLE study

- **Primary endpoint**
  - Ratio of virological suppression (<50 copies/mL) at 48 weeks:
    DTG-based regimen (DTG/ABC/3TC): 88% vs. Atripla: 81%
    ⇒ Show superiority of antiviral activity of DTG
    [Difference and 95% CI; 7.4%, (+2.5% to +12.3%), p=0.003]

    Differences in efficacy were primarily driven by a higher rate of discontinuation due to adverse events on the Atripla arm
- **Secondary endpoint**
  - Ratio of discontinuation due to adverse events:
    DTG-based regimen: 2% vs. Atripla: 10%
  - The most common drug related adverse events:
    DTG-based regimen: GI system organ class; 22% (Atripla; 22%)
    Atripla: Nervous system organ class; 41% (DTG-based; 15%)

Atripla: efavirenz/tenofovir/emtricitabine

Progress of Ospemifene, S-297995 & S-555739

◆ Ospemifene

- FDA accepted the NDA: June 25, 2012
- PDUFA action date: February 26, 2013

◆ S-297995

- US: Completion of registration in Phase IIb study

◆ S-555739

- Japan: Combination therapy with antihistamine in Phase IIb study showed reproducible significant effects compared with antihistamine alone in co-primary endpoints: changes from baseline of three nasal symptoms of allergic rhinitis
- US: Started phase IIa study in the US as part of the global development of S-555739 from the study results in Japan

PDUFA: Prescription Drug User Fee Act
(FDA's action date for judging for new drugs approval)

Change of Phases (since May 2012)

Code No.【Product name】	Category (Administration)	Indication	Area	Change of Phase
S-811717【OxiFast®】	Oxycodone hydrochloride hydrate (Injection)	Moderate to sever pain in patients with cancer pain	Japan	Launched (May 2012)
S-4661【Finibax®】	Carbapenem antibiotic (Injection)	Pediatric infection	Japan	NDA submission ⇒ Approval (May 2012)
S-474474	Angiotensin receptor blocker/diuretic combination (Oral)	Hypertension	Japan	NDA submission in preparation ⇒ NDA submission (July 2012)
S-524101	Sublingual tablet of HDM allergen extracts for immunotherapy	Allergic rhinitis caused by HDM allergen	Japan	Phase II in preparation ⇒ Phase II / III
S-555739	Prostaglandin D2 receptor antagonist (Oral)	Allergic disease	US	Phase IIa in preparation ⇒ Phase IIa
S-888711	Small molecule thrombopoietin mimetic (Oral)	Thrombocytopenia	Japan	Phase IIa ⇒ Phase IIb

HDM: House-dust mite

Change of Phases (since May 2012)

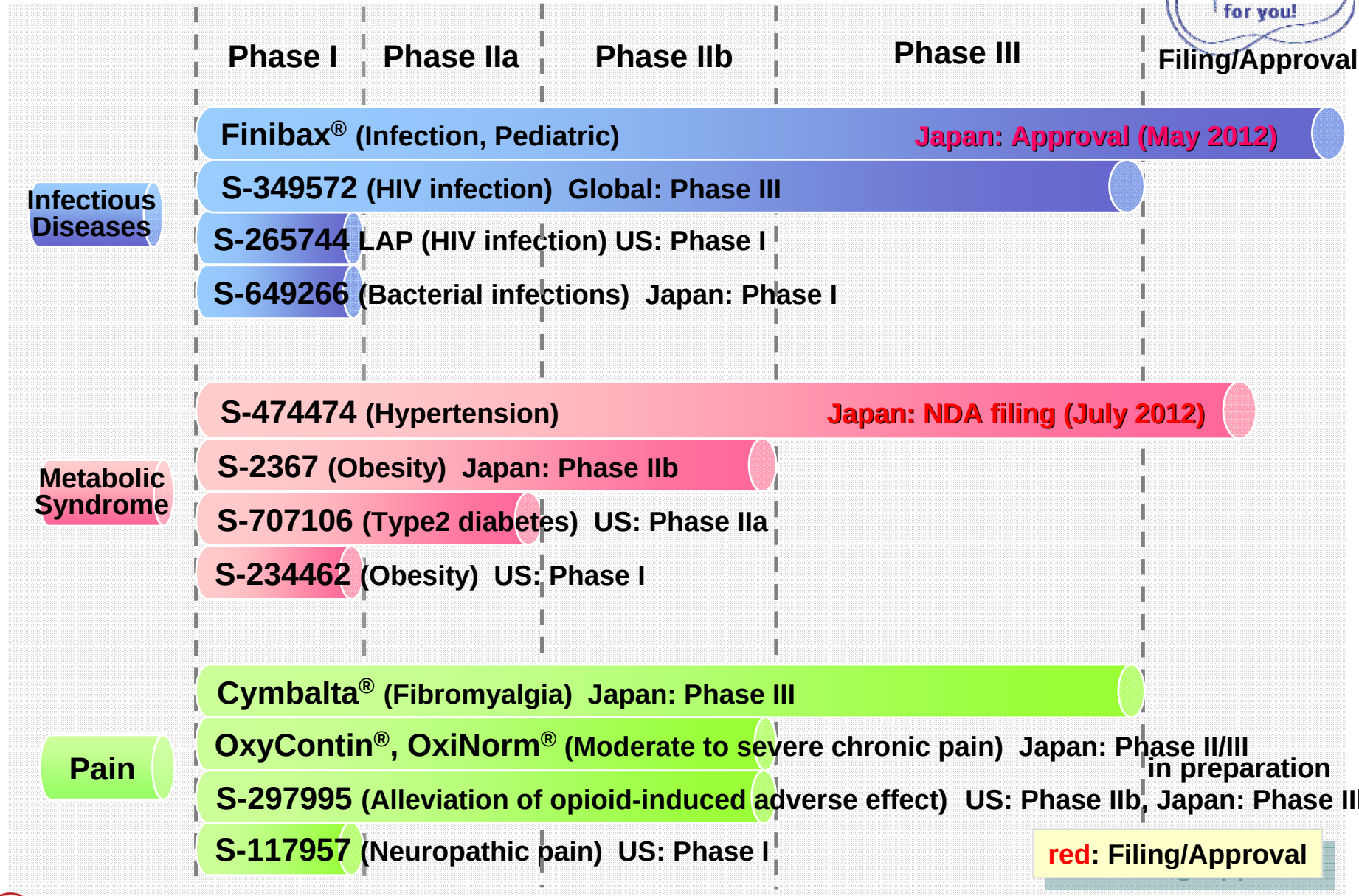
Code No.【Product name】	Category (Administration)	Indication	Area	Change of Phase
Lisinopril hydrate【Longes®】	ACE inhibitor (Oral)	Childhood hypertension	Japan	NDA submission ⇒ Approval (June 2012)
Metreleptin	Human leptin (Genetical Recombination) (Injection)	Lipodystrophy	Japan	NDA submission in preparation ⇒ NDA submission (July 2012)

ACE: Angiotensin-converting enzyme

◆ Metreleptin (NDA Filing)

- In-licensed from US-based Amylin Pharmaceuticals, Inc.
- Department of Medicine and Clinical Science at the Kyoto University Graduate School of Medicine conducted an investigator-initiated trial using metreleptin as a potential leptin-replacement therapy for lipodystrophy patients.
- Leptin is a hormone secreted by fat tissue, which suppresses appetite. It is also reported that leptin improves insulin resistance, glucose metabolism and lipid metabolism.
- Lipodystrophy
  - A rare and life-threatening disorder characterized by a lack of required fat tissue for normal metabolic function throughout the whole body or in certain parts of the body
  - Highly correlated to metabolic abnormalities such as diabetes and severe insulin resistance, hypertriglyceridemia and fatty liver disease. It is known that common treatments for diabetes and hyperlipidemia are not effective for lipodystrophy.

Pipeline (as of August 2012)



LAP: Long acting parenteral formulation

Pipeline (as of August 2012)

	Phase I	Phase IIa	Phase IIb	Phase III	Filing/Approval
Peptide Vaccine	S-288310 (Cancer peptide vaccine, Bladder cancer) Asia: Phase I/II				
	S-488410 (Cancer peptide vaccine, Esophageal cancer) Japan: Phase I/II				
	S-488210 (Cancer peptide vaccine, Head and neck squamous cell carcinoma) EU: Phase I/II				
	S-646240 (Age-related Macular Degeneration) Japan: Phase IIa				
Others	Ospemifene (Post-menopausal vaginal atrophy) US: NDA filing (April 2012)				
	PSD502 (Premature ejaculation) US: Phase III				
	S-524101 (Allergic rhinitis caused by house-dust mite allergen) Japan: Phase II/III				
	S-555739 (Allergic disease) EU: Proof of Mechanism, US: Phase IIa, Japan: Phase IIb				
	S-888711 (Thrombocytopenia) US/EU: Phase II, Japan: Phase IIb				
	S-222611 (Malignant tumor) EU: Phase Ib				
	S-877489 (ADHD) US: Phase I				
	S-877503 (ADHD) Japan: Phase I				

red: Filing/Approval
blue: Change of Phase

ADHD: Attention deficit hyperactivity disorder

End of File