

1st Half of Fiscal 2012 **Financial Results**

November 5, 2012

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SHIONOGI & CO., LTD.

Forward-Looking Statements

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- 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.
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- 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 Half FY2012 Financial Results



Financial Results (Consolidated)

for you! (Units: R von)

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							is: b yen)	
	FY2012	FY2	012	Achieve-	FY2011	Y on Y		
	forecasts	1H forecasts	1H results	ment (%)	1H results	change (%)	change	
Sales	289.0	138.0	137.3	99.5	124.0	10.7	13.3	
Operating income	56.0	24.5	26.1	106.6	18.2	43.1	7.9	
Ordinary income	54.0	23.5	25.1	106.8	18.4	36.2	6.7	
Net income	32.0	14.0	14.9	106.2	8.2	81.2	6.7	

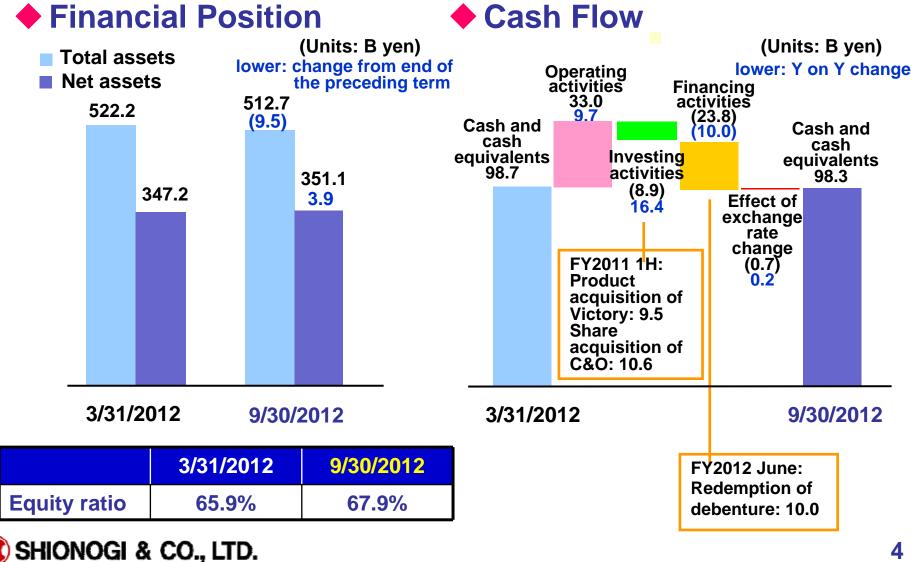
• All income levels from April to September 2012 are higher than the levels achieved in the first half of any prior fiscal year.

* All numerical values are rounded to the nearest unit.
 * The depreciation method for tangible fixed assets has been changed from the declining-balance method predominantly used previously to the straight-line method from FY2012. With this change, operating and ordinary incomes have each increased by 1.4 billion yen in the 1st half of FY2012.

Exchange rate (average)	FY2012 forecasts	FY2012 1H results
USD(\$)	80	79.39
EUR(€)	105	100.49



for you! **Financial Position and Cash Flow (Consolidated)**



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Statements of Income (Consolidated)

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(Units: B ven)

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	FY2	FY2012		FY2011	Y on Y	
	1H forecasts	1H results	Achievement (%)	1H results	change(%)	change
Sales	138.0	137.3	99.5	124.0	10.7	13.3
[Royalty income]	34.5	33.4	96.8	34.3	(2.7)	(0.9)
Cost of sales	29.0 [38.6]	29.3 [38.7]		30.3 [41.8]		
	40.0	40.2	100.5	37.5	7.2	2.7
Gross profit	98.0	97.1	99.1	86.5	12.3	10.6
	53.3	51.7		55.0		
SG&A expenses	73.5	71.0	96.6	68.2	4.1	2.8
Selling & general expenses	47.0	46.0	97.9	42.5	8.2	3.5
R&D expenses	26.5	25.0	94.3	25.7	(2.8)	(0.7)
Operating	17.8	19.0		14.7		
income	24.5	26.1	106.6	18.2	43.1	7.9

* Small numbers in red are percent of sales, and numbers in red provided in parentheses are percent of sales excluding royalty income.



Breakdown of Sales (Consolidated)

(Units: B ven)

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	FY2	012	Achievement	FY2011	Υo	n Y
	1H forecasts	1H results	(%)	1H results	change (%)	change
Prescription drugs	79.5	79.7	100.3	78.7	1.2	1.0
Total of 3 key products	28.7	28.0	97.5	24.3	15.2	3.7
Total of 8 strategic products	40.4	39.8	98.4	34.3	15.9	5.5
Overseas subsidiaries/export	* 14.6	* 14.8	101.4	2.0	607.8	12.8
Shionogi Inc.	7.0	7.5	106.7	(2.4)	-	9.9
C&O	2.9	2.9	100.8	-	-	2.9
Doripenem	1.8	1.4	77.1	1.9	(25.2)	(0.5)
Contract manufacturing	4.7	4.5	94.8	3.7	17.3	0.8
OTC and quasi-drugs	2.7	2.8	103.6	2.7	3.6	0.1
Diagnostics	1.0	1.1	110.2	1.3	(18.6)	(0.2)
Royalty income	34.5	33.4	96.8	34.3	(2.7)	(0.9)
Crestor	32.7	30.7	93.9	32.3	(5.0)	(1.6)
Others	1.0	1.0	105.0	0.9	10.5	0.1
Total	138.0	137.3	99.5	124.0	10.7	13.3

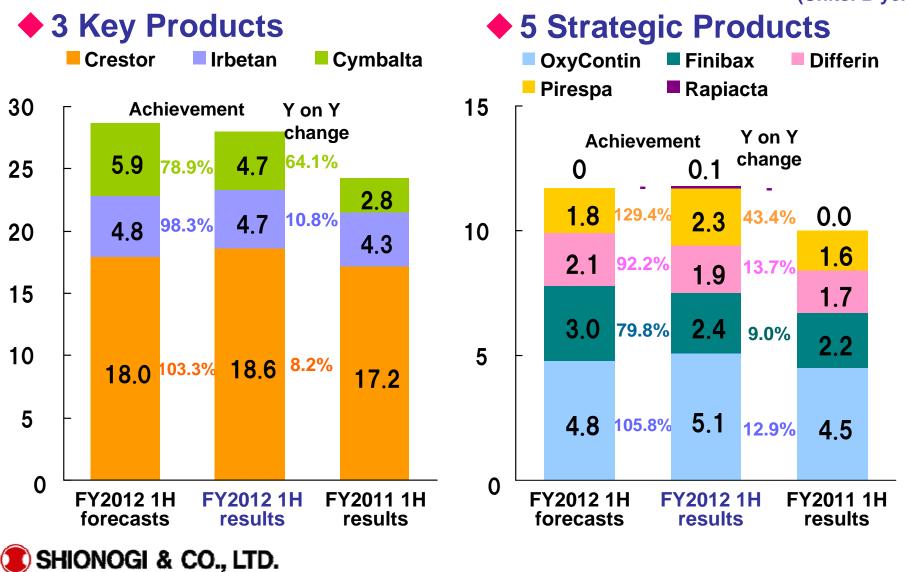
Eight strategic products: Crestor, Irbetan, Cymbalta (3 key products), and OxyContin, Finibax, Differin, Pirespa, Rapiacta

*Taiwan Shionogi has changed its accounting period since Jan. 2012, and 1H results include 9 months from Jan. to Sep. C&O has been consolidated since Oct. 2011, and 1H results include 6 months from Jan. to Jun. 6



Domestic: Sales of 8 Strategic Products

(Units: B yen)



Financial Results of Shionogi Inc.

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		Achievement		
	Full year forecasts	1H forecasts	1H results	(%)
Sales	194 15.5	87 7.0	94 7.5	107.9
Cost of sales	21 1.6	10 0.8	16 1.2	153.2
SG&A expenses	211 16.9	107 8.5	106 8.4	99.2
Operating income	(38) (3.0)	(30) (2.4)	(27) (2.2)	-

* Y on Y changes (%) are calculated in US\$ and are different from those calculated in Japanese yen.

Financial Results of C&O

(Units: B yen) **FY2012** Achievement **Full year** (%) **1H forecasts 1H results** forecasts Sales 5.6 2.9 2.9 100.8 **Operating income** 0.3 0.3 0.5 96.4

* C&O: C&O Pharmaceutical Technology (Holdings) Limited * C&O has been consolidated since Oct. 2011, and 1H results in FY2012 include 6 months from 8 Jan.-Jun. results in 2012.



Review of 1st Half FY2012

Japanese Domestic Sales

- Sales increase in eight strategic products of 16% Y on Y
- Eight strategic products reached 50% of total net sales

Cost Control

- Cost of sales level consistent with plan
- Continued focus on cost containment via budgetary control and prioritization
- Overseas Business Operations
 - Shionogi Inc. (US): Stable business operations and increased sales ⇒ Targets met for four consecutive quarters
 - C&O (China): Continued stable business operation
- R&D
 - Each pipeline compound, including dolutegravir, showed steady progress toward its milestone targets for FY2012
- Crestor Royalty
 - Global sales of Crestor by AstraZeneca in the 1st half of 2012 were down 3% Y on Y





FY2012 Financial Forecasts





Revision of FY2012 Financial Forecasts (Consolidated)

	FY2012							FY2011	
	Full	Year foreca	asts	1H	2H forecasts				Y on Y change
	original	revised	change	results	original	revised	change	results	(%)
Sales	289.0	283.0	(6.0)	137.3	151.0	145.7	(5.3)	267.3	5.9
Operating income	56.0	56.0	-	26.1	31.5	29.9	(1.6)	47.0	19.1
Ordinary income	54.0	54.0	-	25.1	30.5	28.9	(1.6)	46.1	17.2
Net income	32.0	32.0	-	14.9	18.0	17.1	(0.9)	27.1	18.1



(Units: B yen)

FY2012 Forecasts

Revision of Sales by Segments (Consolidated)

(Units: B yen) **FY2012 FY2011** Y on Y **Full year forecasts 1H** 2H forecasts change (%) original revised change results original revised change results **Prescription drugs** 168.6 168.6 79.7 89.1 88.9 (0.2)164.4 2.6 -37.0 18.6 18.4 35.7 Crestor 37.0 19.0 (0.6)3.6 -10.0 10.0 4.7 5.2 5.3 8.9 12.0 Irbetan 0.1 -4.7 **Cymbalta** 13.8 10.8 (3.0)7.9 (1.8)63.3 6.1 6.6 **Total of 3 key products** 57.8 60.8 28.0 32.1 29.8 (2.3)51.3 12.7 (3.0)0.5 5.1 5.1 **OxyContin** 9.7 10.2 4.9 0.2 8.9 15.1 Finibax 6.1 5.1 (1.0)2.4 3.1 2.7 (0.4)4.7 8.5 Differin (0.5)1.9 2.4 (0.3)3.7 9.5 4.5 4.0 2.1 2.1 **Pirespa** 3.9 4.9 1.0 2.3 2.6 0.5 3.4 45.4 Rapiacta 2.5 2.5 0.1 2.5 2.4 (0.1)1.4 83.6 -44.7 **Total of 8 strategic products** 87.5 84.5 (3.0)39.8 47.1 (2.4)73.2 15.4 **Overseas subsidiaries/export** 29.7 28.3 (1.4)14.8 15.1 13.5 (1.6)17.0 66.6 Shionogi Inc. 165.0 15.5 15.5 7.5 8.5 (0.5)5.8 8.0 -2.7 **C&O** 5.6 2.9 2.7 5.6 1.9 190.1 Doripenem 3.4 1.8 (1.6)1.4 1.6 (1.2)4.2 (57.5)0.4 **Contract manufacturing** 10.1 7.6 (2.5)4.5 5.4 3.1 (2.3)7.6 (0.0)**OTC and quasi-drugs** 5.1 5.1 2.8 2.4 2.3 (0.1)5.0 1.5 -**Diagnostics** 2.4 2.4 1.1 1.3 (11.4)1.4 (0.1)2.7 -**Royalty income** 71.2 35.7 69.1 (2.1)33.4 36.7 (1.0)68.7 (0.6)Crestor 63.0 30.7 35.3 32.3 64.7 68.0 (5.0)(3.0)(2.7)**Others** 1.9 1.0 0.9 1.9 0.9 1.9 (1.0)--**Total** 289.0 283.0 (6.0)137.3 151.0 145.7 (5.3)5.9 267.3

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Details of Revised Sales (Consolidated)

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(Units: B yen)

	Change f	rom original f	orecasts	
Breakdown of sale	1H results	2H revised forecasts	Full year forecasts	
Prescription drugs		0.2	(0.2)	-
To be achieved the original plan	Crestor, Irbetan, Rapiacta	0.6	(0.6)	-
	OxyContin	0.3	0.2	0.5
Upward revision based on 1H results	Pirespa	0.5	0.5	1.0
	Flumarin	0.2	0.2	0.4
	Cymbalta	(1.2)	(1.8)	(3.0)
Downward revision based on 1H results	Finibax	(0.6)	(0.4)	(1.0)
	Differin	(0.2)	(0.3)	(0.5)
Downward revision based on market situation	Vancomycin, Imunace	(0.6)	(0.3)	(0.9)
Upward revision based on 1H trend	Others	1.7	1.8	3.5
Overseas subsidiaries/export		0.2	(1.6)	(1.4)
Focus on improvement of earnings	Shionogi Inc.	0.5	(0.5)	-
Downward revision based on global market situation	Doripenem	(0.4)	(1.2)	(1.6)
Contract manufacturing (Cymbalta)		(0.2)	(2.3)	(2.5)
Royalty income			(1.0)	(2.1)
Crestor			(3.0)	(5.0)
Other royalty, up-front payment, etc.			2.0	2.9
OTC and quasi-drugs/Diagnostics			(0.2)	-
Total		(0.7)	(5.3)	(6.0)



To be more influenced by external factors 13

Revision of Statements of Income (Consolidated)

(Units: B yen)

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	FY2012							FY2011	Y on Y
	Full	year forecas	sts	1H	21	2H forecasts			Change
	Original	Revised	Change	results	Original	Revised	Change	results	(%)
Sales	289.0	283.0	(6.0)	137.3	151.0	145.7	(5.3)	267.3	5.9
[Royalty income]	71.2	69.1	(2.1)	33.4	36.7	35.7	(1.0)	68.7	0.6
Cost of sales	28.5 [37.8] 82.4	28.3 [37.4] 80.0	(2.4)	29.3 [38.7] 40.2	28.1 [37.1] 42.4	27.3 [36.2] 39.8	(2.6)	29.1 [39.1] 77.8	2.9
Gross profit	206.6	203.0	(3.6)	97.1	108.6	105.9	(2.7)	189.5	7.1
SG&A expenses	52.1 150.6	51.9 147.0	(3.6)	51.7 71.0	51.1 77.1	52.2 76.0	(1.1)	53.3 142.5	3.1
Selling & general expenses	94.0	94.0	-	46.0	47.0	48.0	1.0	88.9	5.7
R&D expenses	56.6	53.0	(3.6)	25.0	30.1	28.0	(2.1)	53.6	(1.1)
Operating income	19.4 56.0	19.8 56.0	-	19.0 26.1	^{20.9} 31.5	20.5 29.9	(1.6)	17.6 47.0	19.1

* Small numbers in red are percent of sales, and numbers in red provided in percent of sales excluding royalty income



New Agreement for HIV Integrase Inhibitors with ViiV Healthcare Ltd.

New Alliance Scheme for DTG (announced on Oct. 29)

- JV's rights to the integrase inhibitor franchise products are transferred to ViiV Healthcare Ltd. (VHC), and Shionogi becomes a 10% shareholder in VHC with Board representation*
- Shionogi Limited receives dividends from VHC in the UK
- Shionogi receives royalty on net sales of integrase inhibitor portfolio, averaging in high teens
- Financial Impact for FY2012
 - Difference between book value of equity interest in JV and value of equity share in VHC will be allocated as extraordinary income
 - Income and losses may be allocated on the reevaluation of other assets such as goodwill
 - JV development costs will not be incurred after the new agreement
- Financial Impact after FY2013
 - Royalty income and a proportional share of dividends from VHC
 - Development costs and amortization of goodwill and other intangible assets may be reduced

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Dividend Forecast

	Dividends per Share					
	Half-year	Year-end	Annual			
	Yen	Yen (Forecast)	Yen (Forecast)			
FY2012	20.00	20.00	40.00			
FY2011	20.00	20.00	40.00			

• FY2012 forecast: 40 yen as planned









Core Global Dev	velopment Products	As of 3/31/2012	Target Milestones for FY2012Current status (Achieved in 1Q and 2Q)
Ospemifene	Post-menopausal vaginal atrophy	US: NDA submission in preparation	US: NDA submission US: NDA submission (Apr.) EU: NDA submission in preparation
S/GSK1349572* (Dolutegravir)	HIV infection	Global: Phase III	Global: NDA submission Global: NDA submission in preparation
S-297995 (Naldemedine)	Alleviation of opioid-induced adverse effect	US/Japan: Phase IIb	US/Japan: Phase IIb LPO, code-break, meeting with each regulatory agency Japan: Phase IIb US: Phase IIb, code-break, meeting with each regulatory agency in preparation
S-555739	Allergic disease	Japan: Phase IIb US: Phase I	Japan: Phase IIb LPO, code-break US: Phase IIa FPI Japan: Phase IIb LPO, code-break US: Phase IIa registration completion
S-888711 (Lusutrombopag)	Thrombocytopenia	Japan: Phase IIa	Japan: Phase IIb initiation Japan: Phase IIb initiation
S-288310	Bladder cancer	Asia: Phase I/II	Japan: Go/No-go decision based on Phase I/II results <i>Japan: ongoing</i>
S-488410	Esophageal cancer	Japan: Phase I/II	Japan: Go/No-go decision based on Phase I/II Japan: ongoing
S-488210	Head and neck squamous cell carcinoma	EU: Phase I/II IND	EU: Phase I/II FPI EU: screening initiation
S-646240	Age-related macular degeneration	Japan: Phase IIa IND	Japan: Phase IIa FPI Japan: Phase IIa FPI

* Out-licensed to ViiV Healthcare Ltd.



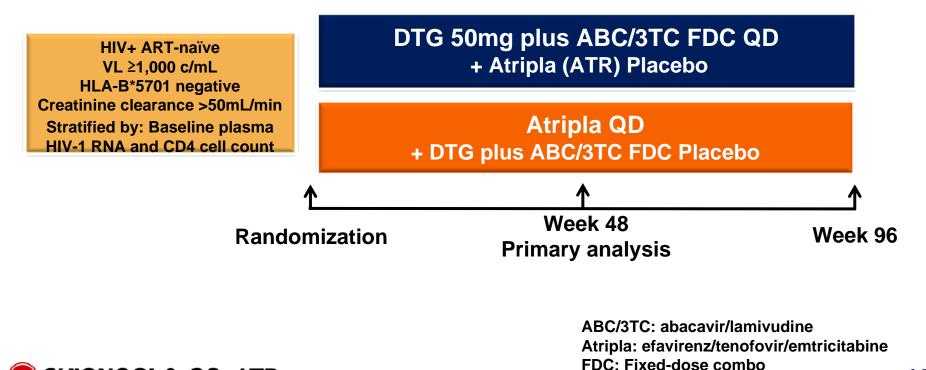
NDA: New drug application, LPO: Last patient out, FPI: First patient in 18 IND: Investigational new drug



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S/GSK1349572 (dolutegravir; DTG): SINGLE Study

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

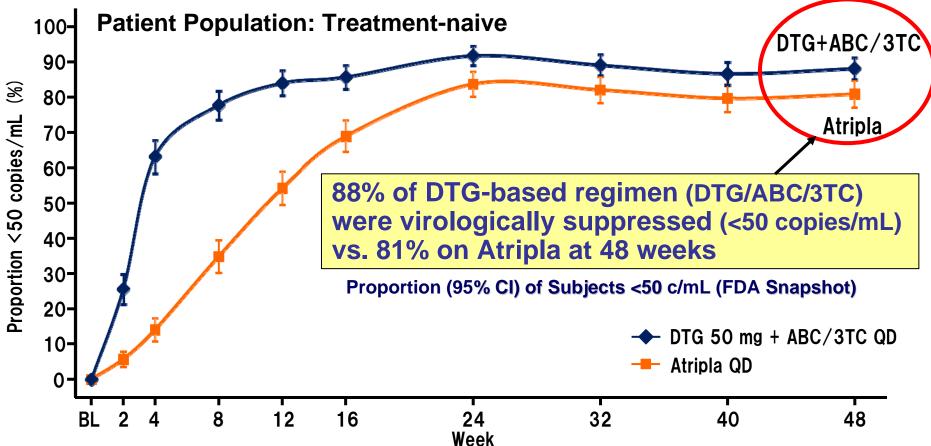






SINGLE

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- DTG 50mg +ABC/3TC QD was statistically superior to Atripla at 48 weeks (Differences in efficacy were primarily driven by a higher rate of discontinuation due to adverse events on the Atripla arm)
- Subjects receiving DTG +ABC/3TC achieved virologic suppression faster than Atripla, median time to HIV-1 RNA <50c/mL of 28 days (DTG +ABC/3TC) vs. 84 days (Atripla), P<0.0001

SINGLE

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S/GSK1349572 (dolutegravir; DTG): SINGLE Study

	DTG 50mg +ABC/3TC QD (n=411) n (%)	Atripla QD (n=419) n (%)
Subjects withdrawn due to adverse events	10 (2)	42 (10)
Most Common Adverse Events		
Dizziness	37 (9)	148 (35)
Abnormal dreams	30 (7)	72 (17)
Insomnia	64 (15)	43 (10)
Diarrhea	72 (17)	75 (18)
Nasopharyngitis	62 (15)	60 (14)
Subjects with Protocol-defined virologic failure	18 (4)	17 (4)
NRTI treatment-emergent major mutations	0	1
NNRTI treatment-emergent major mutations	0	4
INI-r treatment-emergent major substitution	0	0

DTG +ABC/3TC safety and tolerability generally favorable vs. Atripla

No integrase inhibitor (INI) mutations nor NRTI mutations were detected through 48 weeks on DTG +ABC/3TC



S-297995: Product Profile

Mechanism

Orally active peripheral opioid receptor antagonist

Indication

Relief of opioid-induced constipation (OIC)

Development stage

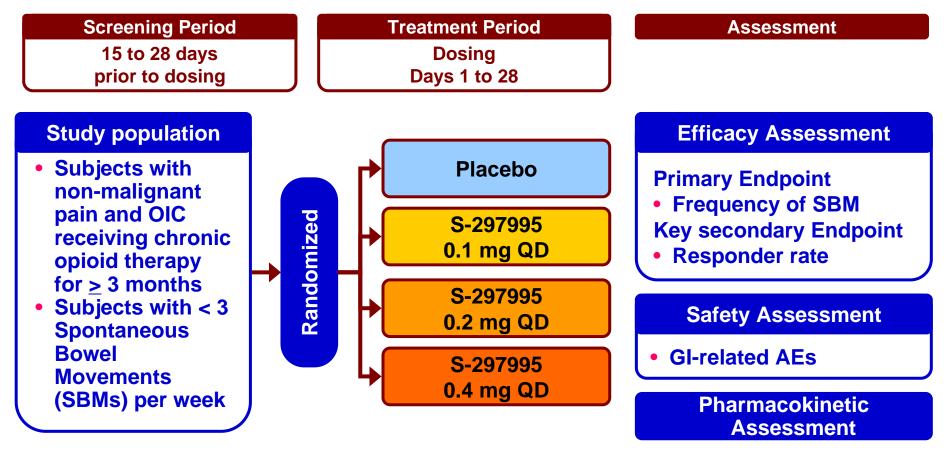
- Under preparation for meetings with regulatory agencies about global Phase III studies
- Phase IIb study in Japan is ongoing





S-297995: US Phase IIb OIC Study

Primary objective is to evaluate the efficacy of oral S-297995 in subjects with non-malignant chronic pain and OIC receiving opioid therapy



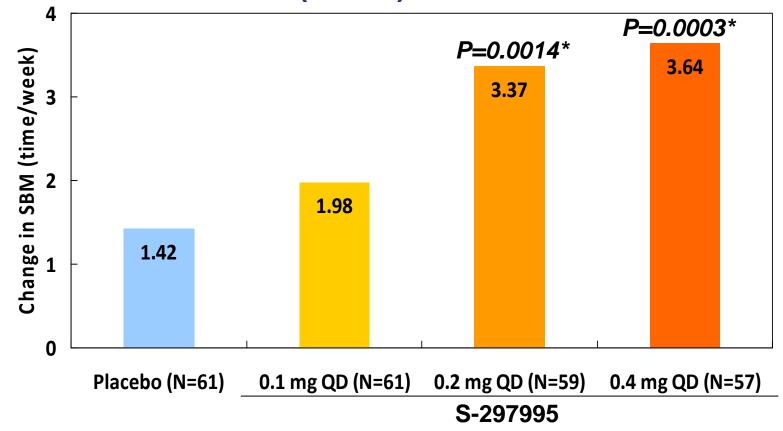


SBM (Spontaneous Bowel Movements): BM except one within 24 hr after administration of general-use laxative agent 23



S-297995: Primary Efficacy Endpoint

Change from baseline in the frequency of spontaneous bowel movements (SBMs)



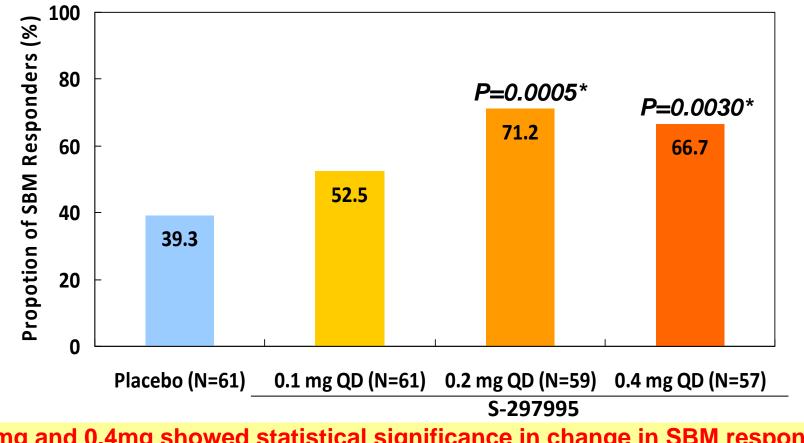
0.2mg and 0.4mg showed statistical significance in change in SBMs as compared to placebo

* Indicates two-sided statistical significance at a 5% level vs. Placebo. The ANCOVA model has the terms for treatment group and baseline value as fixed effects.

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S-297995: Key Secondary Endpoint SBM responder rates for last 2-weeks of treatment period



0.2mg and 0.4mg showed statistical significance in change in SBM responder rate as compared to placebo

* Indicates two-sided statistical significance at a 5% level vs. 25 Placebo. (Chi-square test)



S-297995: Safety Assessment

- The most common adverse events reported were abdominal pain, diarrhea, flatulence, nausea and urinary tract infection (occurred at a rate of at least 5% in any group)
- Gastrointestinal (GI) adverse events were generally mild to moderate, and the majority of GI-related adverse events were resolved within a few days
- No evidence of centrally opioid withdrawal and no change in pain intensity or opioid dosage

S-297995 was generally well tolerated





S-297995: Conclusion

- In the primary endpoint, S-297995 0.2mg and 0.4mg showed statistical significance in change in SBMs as compared to placebo and in the key secondary endpoints such as SBM responder rate
- Once daily S-297995 showed good safety and tolerability



Expect to initiate Phase III global programs in 1H2013



for you! Change of Phases in Japan (since August 2012)

Code No. 【Product name】	Category (Administration)	Indication	Change of Phase
S-877489	DA and NE reuptake inhibitor/Releaser of DA, NE (Oral)	Attention deficit hyperactivity disorder (ADHD)	Phase I ⇒Phase II in preparation
S-877503	Alpha-2A-adrenergic receptor agonist (Oral)	Attention deficit hyperactivity disorder (ADHD)	Phase I ⇒Phase II in preparation
S-120083*	Analgesic agent for inflammatory pain (Oral)	Inflammatory pain	Phase I initiated
Metronidazole 【Flagyl [®] 】	Antibacterial and antiprotozoal agent (Oral)	Infections caused by anaerobic bacteria, Amebiasis, Giardiasis	NDA submission ⇒Approval (Aug. 2012)
Sulfamethoxazole/ Trimethoprim combination 【Baktar [®] 】	Synthetic folate- antagonist/Anti- infectives combination (Oral)	Prophylaxis and treatment of Pneumocystis pneumonia	NDA submission ⇒Approval (Aug. 2012)



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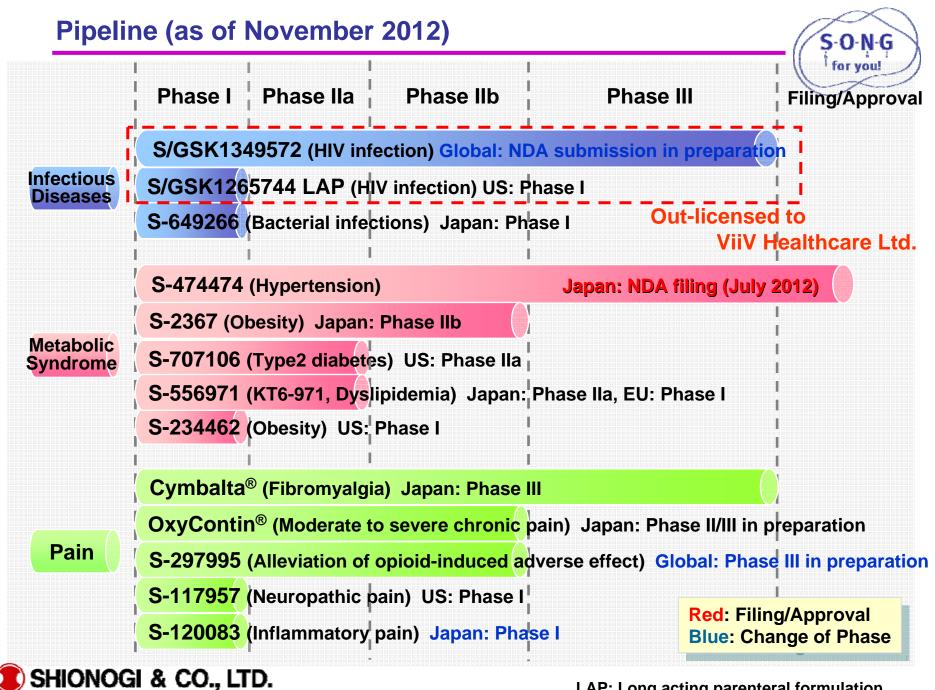
DA: Dopamine, NE: Norepinephrine (noradrenalin) * Global pipeline (co-developed with Purdue Pharma) S-O-N-G



In- and Out-licensing Activities

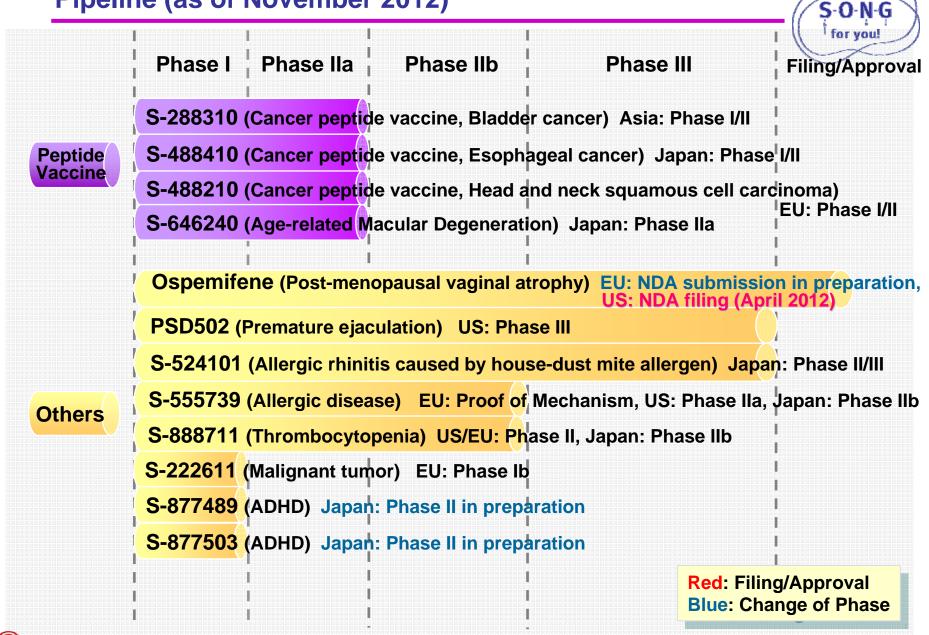
- In-licensing KT6-971, a cholesterol absorption inhibitor
 - Licensed in from Kotobuki Pharmaceutical Co., Ltd.
 - The worldwide rights of development, manufacturing and commercialization
 - Current stage: Japan: Phase IIa completed, EU: Phase I completed
 - ⇒ Providing a novel treatment option to more patients with dyslipidemia, who have poorly-controlled blood cholesterol level or are insufficiently treated with statins
- Out-licensing Anti-Alzheimer's disease drug candidates
 - Licensed out
 ß-secretase inhibitor program to Janssen Pharmaceuticals, Inc.
 - Agreements include research collaboration for back-up compounds
 - After candidate selection for clinical studies, Janssen conducts development and Shionogi receives milestone payments
 - After launch, Janssen promotes, with Shionogi co-promotion right in some territories
 - ⇒ Supply innovative and effective medicines to patients suffering from Alzheimer's disease globally in cooperation with Janssen, which has strong expertise in this therapeutic area





LAP: Long acting parenteral formulation

Pipeline (as of November 2012)





ADHD: Attention deficit hyperactivity disorder



End of File

