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# News Release

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## Sales of Main Products and Updates of R&D Pipeline Stage in First-Quarter FY2002 (April 1 - June 30, 2002)

July 23, 2002, Osaka, Japan---Takeda Chemical Industries, Ltd. ("Takeda") has decided to announce sales of main products and updates of R&D pipeline stage starting from the first quarter of FY2002. Introduction of quarterly financial disclosure is now under study as to its starting timing, contents and format in consideration of the forthcoming revision of relevant laws and regulations.

The results of the first quarter ended June 30, 2002 were as follows:

### Worldwide sales of international strategic products (\*note)

(Billions of Yen)

Product	Launched	1Q 2002	1Q 2001	vs. 1Q 2001	increase/ decrease
<b>Leuprorelin</b>					
Worldwide sales		48.9	43.8	5.1	11.8%
Japan	(92. 9)	13.9	13.0	0.9	6.9%
Americas	(89. 3)	28.0	24.4	3.6	14.8%
Europe	(89. 4)	6.6	6.0	0.5	9.6%
others		0.3	0.3	0.0	20.8%
<b>Lansoprazole</b>					
Worldwide sales		114.5	102.2	12.2	12.0%
Japan	(92.12)	8.9	6.3	2.5	40.7%
Americas	(95. 6)	93.3	86.6	6.7	7.7%
Europe	(91.12)	11.5	8.6	2.9	34.1%
others		0.5	0.5	0.0	0.3%
<b>Candesartan</b>					
Worldwide sales		25.7	21.6	4.0	18.9%
<b>Pioglitazone</b>					
Worldwide sales		37.2	25.6	11.5	44.9%

### (Consolidated basis)

(Billions of Yen)

Product	Launched	1Q 2002	1Q 2001	vs. 1Q 2001	increase/ decrease
Leuprorelin		24.9	24.2	0.7	3.1%
Lansoprazole		35.8	31.2	4.5	14.6%
Candesartan		25.6	20.6	5.0	24.5%
Pioglitazone		37.2	25.4	11.7	46.0%

Takeda is selling four international strategic products around the world, namely, leuprorelin (domestic brand name: *Leuplin*) for the treatment of prostate cancer and endometriosis, lansoprazole (domestic brand name: *Takepron*) for the treatment of peptic ulcers, candesartan cilexetil (domestic brand name: *Blopress*) for the treatment of hypertension, and the antidiabetic drug *Actos*. During the first quarter of this year, these four products posted sales growth over the same quarter of the previous year as shown in the above table, partly due to the weak yen against the US dollar (exchange rate: US\$=¥118 in Jan.-Mar. 2001, US\$=¥133 in Jan.-Mar. 2002).

**\* note:**

“Worldwide sales” represents total sales including the sales of unconsolidated subsidiaries/affiliates outside Japan plus export to the licensees. In case the subsidiaries/affiliates close books in December, the Jan.-Mar. quarter sales are reflected in Takeda’s first quarter of Apr.-Jun.

**Ethical drugs: Domestic sales <Top 10 ranking>**

(Billions of Yen)						
Product	Launched	Category	1 Q 2002	1 Q 2001	vs. 1Q 2001	increase/ decrease
1 <b>Blopress</b>	(99. 6)	All-receptor antagonist	<b>16.8</b>	13.3	3.4	26.0%
2 <b>Leuplin</b>	(92. 9)	LH-RH antagonist	<b>13.9</b>	13.0	0.9	6.9%
3 <b>Basen</b>	(94. 9)	-glucosidase inhibitor	<b>13.0</b>	12.1	0.9	7.5%
4 <b>Takepron</b>	(92.12)	Proton pump inhibitor	<b>8.9</b>	6.3	2.5	40.7%
5 <b>Pansporin</b>	(81. 2)	Antibiotics	<b>4.5</b>	5.3	0.8	15.5%
6 <b>Seltouch</b>	(93. 9)	Topical NSAID	<b>3.4</b>	3.4	0.0	0.1%
7 <b>Isovorin</b>	(99.10)	Cytostatics	<b>3.2</b>	2.2	0.9	42.5%
8 <b>Solita</b>	(62. 2)	Electrolyte solutions	<b>3.2</b>	3.4	0.1	4.9%
9 <b>Calslot</b>	(90. 9)	Calcium channel blocker	<b>3.2</b>	3.6	0.3	10.7%
10 <b>Actos</b>	(99.12)	Insulin sensitizer	<b>2.4</b>	1.9	0.5	27.3%

In the domestic market, the four international strategic products (*Blopress*, *Leuplin*, *Takepron* and *Actos*) and *Basen*, an improving agent for postprandial hyperglycemia, showed increase of sales over the first quarter of the previous year. Meanwhile, the NHI price cut effective this April had a negative impact in other existing products, e.g., antibiotics.

The sales of *Benet*, the treatment for osteoporosis launched in May this year was 1.2 billion yen. For *Actos*, the additional indications for concomitant use with -glucosidase inhibitor was approved on June 17, and a new formulation “*Takepron OD*”, fast disintegrating tablet was launched on June 25, 2002.

Takeda will continue conducting promotional activities, providing high-quality information supported by highly trustworthy scientific data, under the solid strategies for growth of the main products.

Sales of major items - Consumer Healthcare<Top 5 ranking>

(Billions of Yen)

Product	1 Q 2002	1 Q 2001	vs. 1Q 2001	increase/ decrease
1 Alinamin tablets	4.7	5.2	0.4	9.5%
2 Alinamin health tonic	4.6	5.6	1.0	18.2%
3 Biofermin	1.5	1.5	0.0	3.4%
4 Hicee	1.4	1.0	0.3	33.0%
5 Benza	1.0	1.1	0.0	6.8%

In the Consumer Healthcare business, health tonic *Alinamin 7 Gold*, a quasi drug, was launched in April as an additional formulation with fortified ingredients of Alinamin 7. Another new product, *Hicee White 2*, the treatment for skin freckle with twice a day administration, was launched in May. The sales of major items except Hicee decreased over the first quarter of the previous year. Takeda will aim to achieve sales increase even under the current difficult market environment through various measures such as penetration of these new products.

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## Pipeline stage updates

### Overview of project status (additional indications / new formulations)

Development code (generic name)	Drug Class	Brand name (country/region)	Indications or formulation	Country/ region	Stage of development
AG-1749  (lansoprazole)	Proton pump inhibitor	Takepron (Jpn)  Prevacid (U.S.)  Ogast, Zoton  Lansox, etc. (EU)	Fast disintegrating tablets  Gastritis  Injectable formulation	U.S.  Jpn  U.S.  Jpn	Filed (Oct 01)  P-II  P-III  P-
TAP-144-SR  (leuprorelin acetate)	LH-RH agonist	Leuplin (Jpn)  Lupron Depot (U.S.)  Enantone etc. (EU)	3-Month depot/prostate cancer  3-Month depot/premenopausal breast cancer	Jpn  Jpn	Filed (Mar 01)*  P-II
TCV-116  (candesartan cilexetil)	Angiotensin II receptor antagonist	Blopress (Jpn)  Blopress, Amias, Kenzen, etc. (EU)	Chronic heart failure    Diabetic nephropathy  Fixed combination with diuretic  Outcome study, DIRECT (Diabetic RETinopathy Candesartan Trial)	U.S.  Jpn  EU  Jpn  Jpn  EU	P-III  Filed (Dec 01)  P-III  P-II  P-II  P-III
AD-4833  (pioglitazone hydrochloride)	Insulin resistance-decreasing drug	Actos (U.S., Jpn, EU)	Outcome study, PROACTIVE (PROspective pioglitAzone Clinical Trial In macroVascular Events)	EU	P-III
AO-128  (voglibose)	-glucosidase inhibitor	Basen (Jpn)	Impaired glucose tolerance (IGT)	Jpn	P-III
TAK-453-SR  (morphine hydrochloride)	Morphine hydrochloride sustained release capsules		Cancerous pain	Jpn	P-III

\* approved in Jul 02

#### Under the informed consent:

**P - ( Phase )**

Conducted with a limited number of healthy volunteers to determine safety and pharmacokinetic profile.

**P - ( Phase )**

Conducted with a limited number of patient volunteers to look for effective and safe dosage and administration route.

**P- ( Phase )**

Conducted with many patient volunteers to confirm the efficacy and safety in comparison with the existing drugs.

## Overview of project status (new compounds)

Development code (generic name)	Drug Class	Indications or formulation	Country/ region	Stage of development
TAK-147  (zanapexil)	Acetylcholinesterase inhibitor	Dementia of Alzheimer's type	Jpn	P-
TAK-637*  (Not decided yet)	NK1 receptor antagonist	Urinary incontinence	U.S.  Jpn  EU	P-II  P-I  P-II
		Depression	U.S.	P-II
		Irritative bowel syndrome (IBS)	U.S.	P-II
TAK-375  (Not decided yet)	Melatonin receptor agonist	Primary insomnia	U.S.  EU  Jpn	P-II  P-II  P-II
		Circadian rhythm sleep disorder (CRSD)	U.S.	P-II
TAK-427  (Not decided yet)	Eosinophilic infiltration inhibitor	Atopic dermatitis, allergic rhinitis	Jpn  EU	P-II  P-II
TAK-677  (Not decided yet)	3-adrenaline receptor agonist	Diabetes mellitus  Obesity	U.S.  U.S.	P-II  P-II
TAK-013  (Not decided yet)	LH-RH antagonist	Endometriosis, uterine fibroid	Jpn  EU	P-I  P-II
MCC-135  (caldaret)	Ca <sup>++</sup> uptake enhancer/ Na <sup>+</sup> /Ca <sup>++</sup> exchange system inhibitor	Chronic heart failure, myocardial infarction	U.S.  EU	P-II  P-II
TAK-559  (Not decided yet)	Insulin resistance-decreasing drug	Diabetes mellitus	U.S.  EU	P-II  P-II
TAK-370  (Mosapride citrate)	Serotonin 5-HT <sub>4</sub> receptor agonist	Gastro-esophageal reflux disease (GERD)	U.S.	P-II
TAK-475  (Not decided yet)	Squalene synthase inhibitor	Hyperlipemia	EU	P-II
TAK-428  (Not decided yet)	Neurotrophic factor production accelerator	Diabetic neuropathy	U.S.  EU	P-II  P-II

\* Clinical trials of TAK-637 are placed on clinical hold.

### Progress in pipeline stage (1Q 2002)

Development code (generic name)	Indications or formulations	Brand name (country/region)	Progress of development stage	
AD-4833 (pioglitazone hydrochloride)	Concomitant use with - glucosidase inhibitor	Actos (Japan)	NDA Filed	Approved(Jun 02)
AG-1749 (lansoprazole)	Fast disintegrating tablets	Takepron (Japan)	Approved	Launched(Jun 02)

### Discontinuance of development (1Q 2002)

Development code (generic name)	Indications	Stage of development	Reason of discontinuation
TAK-778-SR	Bone fracture	P-II	Results of P-II study, conducted in EU and Japan, did not verify the enough efficacy in a treatment for bone fracture.
TAP-144-SR(4M)	Prostate cancer	P-III	In consideration for the marketability in Europe and the priority, discontinuance of the development was decided.

Takeda will enhance the R&D pipeline as the top priority through; acceleration of research activities based on the genomic information, active in-licensing of products and the advanced technology based on alliance activities, and product life-cycle management by adding indications and formulations.

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