



R&D Initiatives at Takeda

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May 8, 2014

Takeda Pharmaceutical Company Limited

Takeda R&D Mission



Takeda will lead the pharmaceutical industry in providing meaningful solutions to patients with unmet medical needs

Looking Back on FY2013

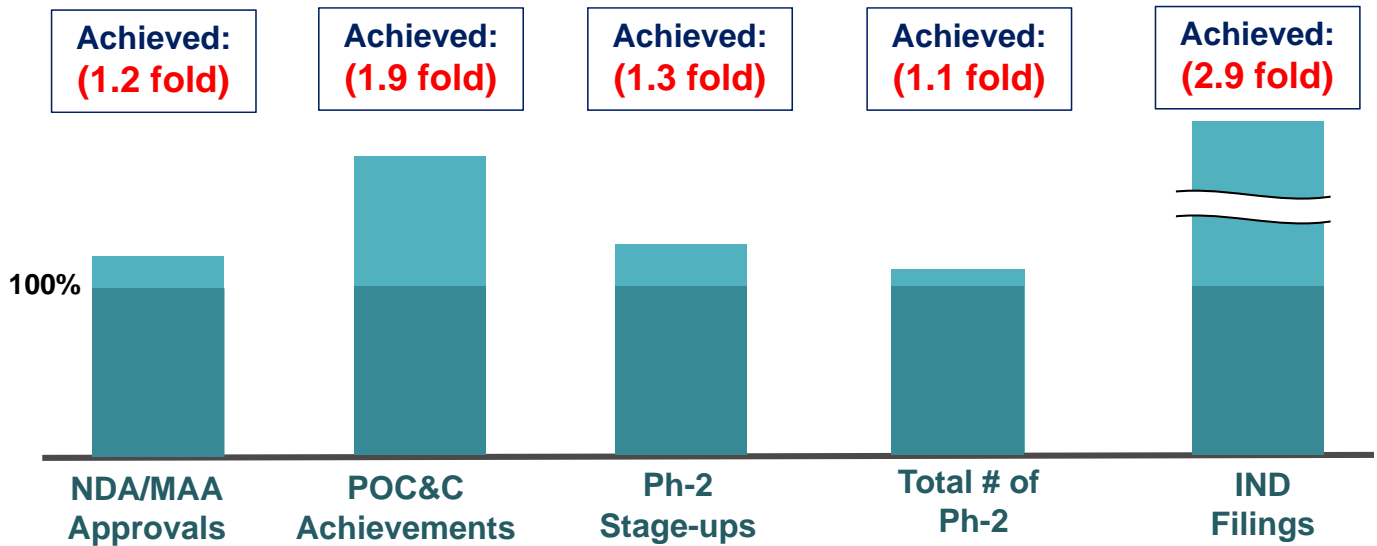
Approvals and Filings in FY2013

				Filing	Approval
BRINTELLIX®	vortioxetine	Major depressive disorder	US		
OBLEAN®	cetilistat	Obesity with both type 2 diabetes mellitus and dyslipidemia	JP		
ADCETRIS®	brentuximab vedotin	Relapsed or refractory Hodgkin lymphoma Relapsed or refractory anaplastic large cell lymphoma	JP		
ZACRAS®	azilsartan/CCB	Hypertension (fixed dose combination of azilsartan and amlodipine besilate)	JP		
TAKELDA®	lansoprazole/LDA	Peptic ulcers (fixed dose combination of lansoprazole and low-dose aspirin)	JP		
BLB-750	-	Prevention of pandemic influenza (H5N1 strain & prototype)	JP		
VIPIDIA®	alogliptin	Diabetes mellitus	EU		
VIPDOMET®	alogliptin/metformin	Diabetes mellitus (fixed-dose combination of alogliptin and metformin)			
INCRESYNC®	alogliptin/pioglitazone	Diabetes mellitus (fixed-dose combination of alogliptin and pioglitazone)			
TAK-390MR	dexlansoprazole	Erosive esophagitis, Non-erosive gastro-esophageal reflux disease	EU*		
LATUDA®	lurasidone	Schizophrenia	EU		
ENTYVIO™	vedolizumab	Ulcerative colitis Crohn's disease	US		
CONTRACE®	naltrexone SR/ bupropion SR	Obesity	US		
SYR-472	trelagliptin	Diabetes mellitus	JP		
TAK-438	vonoprazan	Acid related diseases (GERD, peptic ulcer, etc)	JP		
-	fomepizole	Ethylene glycol and methanol poisonings	JP		
TAK-816	-	Prevention of infectious disease caused by Haemophilus influenza Type b	JP		
RIENSO®	ferumoxytol	Iron deficiency anemia from all causes in patients who have a history of unsatisfactory oral iron therapy or in whom oral iron cannot be used	EU		

R&D Productivity: Achieving all FY13 R&D Value Creation Goals



- Building on FY12 achievements, continued to realize dramatic improvement in our research productivity
- Initiated efforts to conduct early clinical studies through Experimental Medicine
- Established critical biomarkers and other basic tools useful for predicting or following clinical outcomes through Translational Medicine
- Committed to Project Summit goal and took bold and transformative steps to make every area of our R&D more efficient and competitive

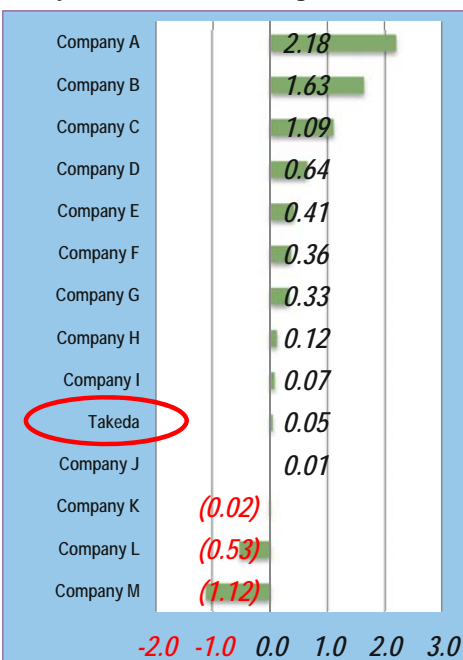


Productivity Improvement Takeda has consistent improvement in R&D productivity



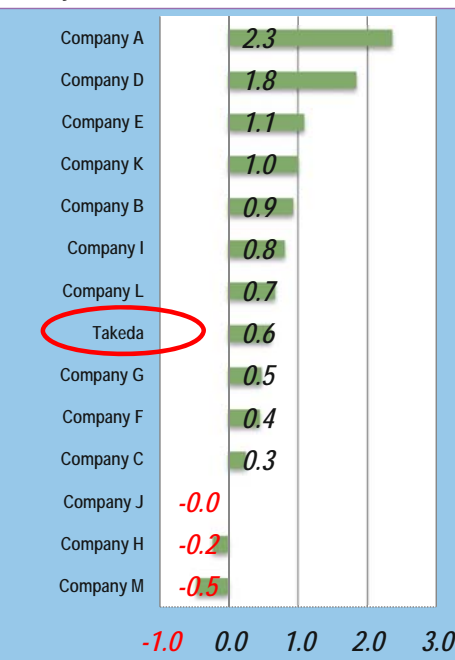
2008-2010

Based on 3-year period from '07 year end - '10 year end data as of August 16th, 2011



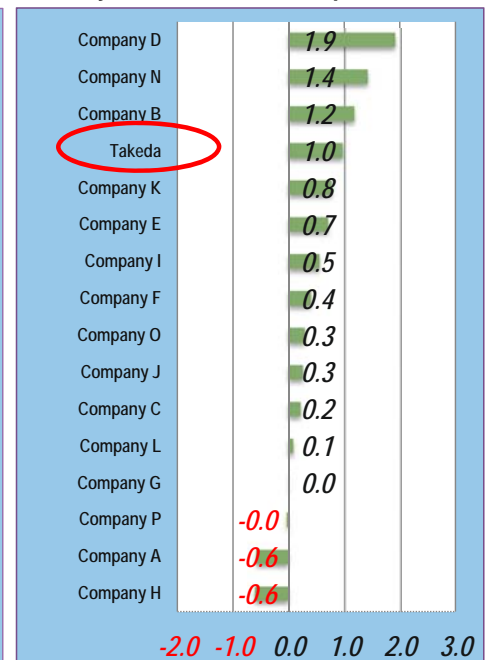
2009-2011

Based on 3-year period from '08 year end - '11 year end data as of Nov. 14th, 2012



2010-2012

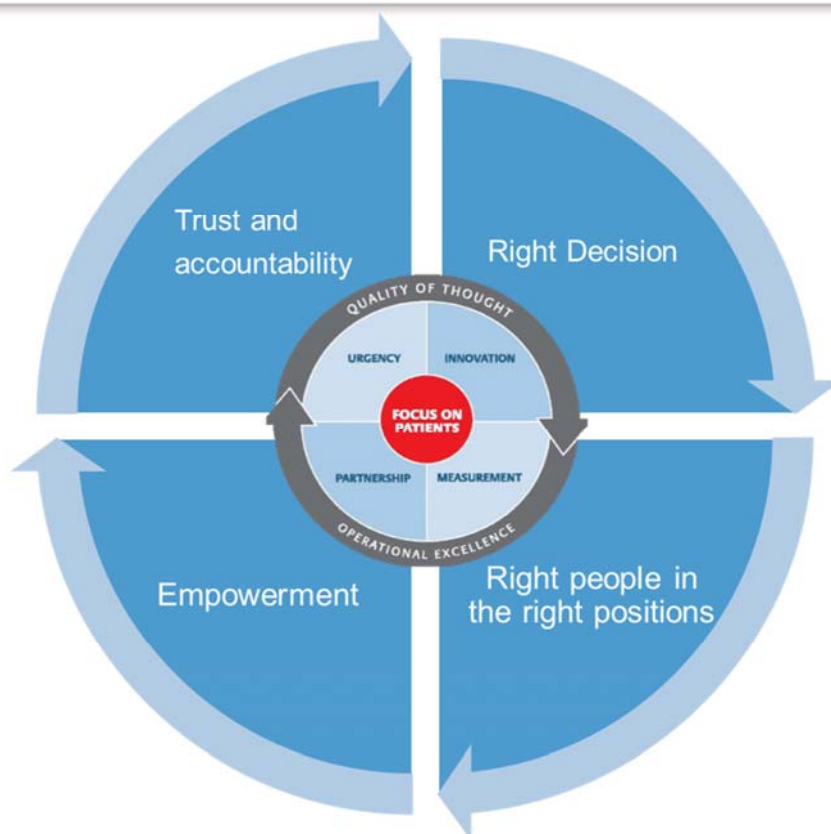
Based on 3-year period from '09 year end - '12 year end data as of Sep. 3rd, 2013



• Expected NPV (eNPV) of products at clinical stage (Phase 1 or later) is used. eNPV at the end of year 2007 is subtracted from eNPV at the end of 2010, followed by addition of NPV of products launched in 2008, 2009 & 2010. The delta eNPV is then divided by the total R&D expenditure in years 2008, 2009 & 2010. The same applies for 2009-2011 and 2010-2012.
 • This slide compares Takeda's R&D productivity with that of other major global pharmaceutical companies.
 • Sources: Parexel Biopharmaceutical R&D Statistical Sourcebook, Evaluate Pharma data (values used are pre-adjusted for M&A activity)

R&D Initiatives in the Mid-Range Growth Strategy

Strategies for Enhanced Productivity



Deliver the Late Stage Portfolio

Short-term key deliverables



Make Steady Progress Toward Approval

ENTYVIO
(MLN0002)

vonoprazan
(TAK-438)

trelagliptin
(SYR-472)

CONTRAVE
(naltrexone/bupropion)

Focus on Key Late-stage Assets

ixazomib
(MLN9708)

norovirus
vaccine

TAK-375SL

AD-4833/TOMM40

Advance Mid-stage Assets

alisertib
(MLN8237)

TAK-003
dengue vaccine

MLN0264

MLN4924

Enhance Effort on Life Cycle Management

ENTYVIO
subcutaneous formulation

ADCETRIS
CD-30 positive cancers

ULORIC XR
Extended release

VELCADE
Front Line Mantle Cell
Lymphoma

Fill the Gap in the Middle Portfolio

Medium-term key deliverables



Progress Our Early Stage Portfolio As Quickly As Possible

namilumab
GM-CSF antagonist

TAK-137
AMPA receptor potentiator

MLN0128
mTORC 1/2 inhibitor

TAK-058
5-HT₃ antagonist

TAK-114
(Natura-alpha)
STAT-3 inhibitor

RSLV-132
Fc fusion protein platform

TAK-063
PDE10A inhibitor

TAK-648
PDE4 inhibitor

Business Development

- Focus on business development/in-licensing activity on promising assets that are ready for a POC&C experiment

Mono-oki Projects (Repositioning)

- Explore additional or other uses for existing compounds

Invest in Cutting-edge Science and Technology

Maximize Drug Discovery Potential

Advance Experimental/Translational Medicine Capability

Events Expected in FY2014

Approvals

US	ENTYVIO/vedolizumab (ulcerative colitis, Crohn's disease), CONTRAVE/naltrexone SR-bupropion SR (obesity)
JP	SYR-472/trelagliptin (type 2 diabetes), TAK-438/vonoprazan (acid-related diseases), TAK-816 (Hib vaccine), fomepizole (ethylene glycol and methanol poisonings)
EU	ENTYVIO/vedolizumab (ulcerative colitis, Crohn's disease), RIENSO (all cause iron deficiency anemia)

Submissions

US	VELCADE (front line mantle cell lymphoma), MLN9708/ixazomib (R/R multiple myeloma), MLN8237/alisertib (R/R peripheral T-cell lymphoma), TAK-390MR OD/dexlansoprazole (orally disintegrating tablet)
JP	TAP-144-SR/leuprorelin 6 month formulation (prostate cancer, breast cancer)
EU	MLN9708/ixazomib (R/R multiple myeloma), ADCETRIS (post-autologous stem cell transplant Hodgkin's lymphoma), ADCETRIS (refractory cutaneous T-cell lymphoma)

R/R = Relapsed/Refractory

Ensuring Steady Pipeline Approval



	FY14	FY15	FY16	FY17 - FY18
JP	SYR-472/trelagliptin (type 2 diabetes) TAK-438/vonoprazan (acid related diseases) Lu AA21004/vortioxetine (major depressive disorder) TAK-816 (Hib vaccine) fomepizole (ethylene glycol / methanol poisoning)	TAP-144-SR/leuprorelin (6 month formulation) TAK-700/orterone! (prostate cancer)	MLN9708/ixazomib (R/R multiple myeloma)	TAK-385/relugolix (uterine fibroids) TAK-385/relugolix (endometriosis) MLN0002/vedolizumab (ulcerative colitis) MLN0002/vedolizumab (Crohn's disease) MLN8237/alisertib (R/R peripheral T-cell lymphoma) Norovirus vaccine TAK-850 (seasonal influenza) motesanib (non small-cell lung cancer) ADCETRIS (FL mature T-cell lymphoma)
US	ENTYVIO/vedolizumab (ulcerative colitis) ENTYVIO/vedolizumab (Crohn's disease) CONTRAVE /naltrexoneSR-bupropionSR (obesity) TAK-700/orterone! (prostate cancer)	MLN9708/ixazomib (R/R multiple myeloma) MLN8237/alisertib (R/R peripheral T-cell lymphoma) VELCADE (FL mantle cell lymphoma) TAK-390MROD/dexlansoprazole (orally disintegrating tablet)	MLN9708/ixazomib (AL amyloidosis)	TAK-375SL/ramelteon (bipolar disorder) MLN9708/ixazomib (FL multiple myeloma) MLN8237/alisertib (ovarian cancer) Norovirus vaccine TAK-003 (Dengue vaccine) ENTYVIO/vedolizumab (subQ formulation) TMX-67XR/febuxostat (extended release)
EU	ENTYVIO/vedolizumab (ulcerative colitis) ENTYVIO/vedolizumab (Crohn's disease) RIENSO (all cause iron deficiency anemia)	MLN9708/ixazomib (R/R multiple myeloma) TAK-700/orterone! (prostate cancer) ADCETRIS (relapsed cutaneous T-cell lymphoma) ADCETRIS (post-ASCT Hodgkin's lymphoma)		MLN9708/ixazomib (FL multiple myeloma) MLN9708/ixazomib (AL amyloidosis) MLN8237/alisertib (R/R peripheral T-cell lymphoma) Norovirus vaccine TAK-003 (Dengue vaccine) LATUDA (bipolar disorder) ADCETRIS (FL mature T-cell lymphoma) ADCETRIS (FL Hodgkin's lymphoma)
EMG N.Asia	In Emerging Markets and North Asia, compounds including alogliptin, azilsartan medoxomil, brentuximab vedotin, mifamurtide, ramelteon, dexlansoprazole, ixazomib, vedolizumab will be launched consecutively.			Projected timeline is currently under evaluation In-house In-license

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R/R: Relapsed / Refractory; FL: Front Line

Please note that approval timing of several products, including certain in-licensed items, are not disclosed

Takeda Pharmaceutical Company Limited

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