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Nikko Hotel, San Francisco January 8, 2013

Takeda Pharmaceutical Company Limited

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Takeda R&D Value

Takeda is a pharmaceutical company committed to the discovery and development of innovative solutions addressing unmet medical needs of patients through R&D investment

Takeda R&D Mission



Takeda Pharmaceutical Company Limited



Meet the future promise of Takeda as a leader in the pharmaceutical industry by providing solutions to patients with unmet medical needs

Transform the R&D organization to be an engine of growth that is an industry leader in R&D productivity

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Takeda R&D Principles						
PARTNERSHIP						
Takeda	Takeda Syrrx Cakeda MARCA NOCOLOGY COMPANY					
Discovery	Takeda California (formerly Syrrx)	Millennium	Nycomed	Affymax, Lundbeck, Orexigen, Novartis, Seattle Genetics, etc.		
 Advinus Envoy LigoCyte Intracellular Therapies 	• NESINA • SYR-472	• MLN0002 • MLN9708 • MLN8237 • MLN0264	 DAXAS REVESTIVE Veltuzumab Namilumab Alvesco Omnaris 	 REVESTIVE ADCETRIS OMONTYS RIENSO CONTRAVE LOTRIGA BRINTELLIX* Lurasidone ATL-962 AMG 386 AMG 706 TAK-816 TAK-361S ITI-214 		
*Proposed brand name of Lu AA21004						
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Cardiovascular Respiratory &	entral Nervous System General Medicine Vaccine	Oncology					
& Metabolic Inflammatory							
Program Status							
 The US NDA includes data from 6 demonstrated significant efficacy is Potential for favorable short and lo depression Lower incidence of treatment emerge No impact on sleep and weight neutr Absence of discontinuation symptom 	obal Phase 3 trials (including a study in elderly patients) th lose range of 5 to 20mg/day g term safety and tolerability and improvement of cognitive sexual dysfunction	at dysfunction of					
US NDA filed by Takeda in October 2012, & Japan NDA filing expected in mid-FY2013 Detrearship with U. Lundheele A/C							
*p<0.05; **p<0.01 <i>versus placebo.</i> DSST: Digit Symbol Substitution Tes RAVLT: Rey Auditory Verbal Learnin	Acute Major Depression in Elderly Patier Acute Major Depression in Elderly Patier Acute Major Depression in Elderly Patier 0.5 0.5 0.5 0.2 0.2 0.2 0.2 0.7 0.2 0.2 0.7 0.2 0.7 0.2 0.2 0.7 0.2 0.7 0.2 0.7 0.2 0.7 0.2 0.7 0.2 0.2 0.7 0.2 0.7 0.2 0.2 0.7 0.2 0.7 0.2 0.7 0.2 0.7 0.2 0.7 0.2 0.7 0.2 0.7 0.2 0.7 0.2 0.7 0.7 0.2 0.7 0.7 0.7 0.7 0.7 0.7 0.7 0.7	nts Vortioxetin Duloxetine					
*Proposed brand name of Lu AA21004	-0.1 - Recall	-					
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DEVELOPING

new standards of care by pursuing experimental combinations

SPEEDING

time to market by matching our drugs to patients most likely to respond















ADCETRIS (brentuximab vedotin) Building the foundation of care for CD30+ malignancies

Mechanism of Action

- First-in-class CD30-directed antibodydrug conjugate for relapsed/refractory HL and sALCL
- Unique, highly effective targeted therapy with clear patient selection opportunities.
- Commercially, ADCETRIS is a "gamechanger." Physicians have been deeply unsatisfied with existing therapy options.
- ADCETRIS binds to CD30 and is internalized, resulting in MMAE release.
- MMAE disrupts the microtubulin network, inducing cell cycle arrest and apoptosis.

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Program Status

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- Partnered with Seattle Genetics
- EMA approved MAA submission in October 2012, activities underway for ROW submissions
 - FDA approved BLA submission from Seattle Genetics in August 2011
- Lifecycle Activities
 - AETHERA Phase 3 study fully enrolled
 - ✓ 3 Phase 3's underway: FL CD30+ MTCL; CD30+ CTCL; FL HL
 - Enrollment completed ahead of schedule in the Ph1/2 r/r HL and sALCL study in Japan
- Diagnostic development underway for CD30+ MTCL and CD30+ CTCL

ADCETRIS (brentuximab vedotin)



First-in-class CD30 antibody-drug conjugate



Key Data – Phase 2

 Data from pivotal Phase 2 studies in relapsed/ refractory Hodgkin lymphoma (HL) and relapsed/refractory systemic anaplastic large cell lymphoma (sALCL) show high overall response rates and complete response rates.

	ORR	CR
R/R HL*	76%	35%
R/R sALCL [†]	86%	57%

* Relapsed/Refractory Hodgkin lymphoma

[†]Systemic anaplastic large cell lymphoma



TAK-700 (orteronel) Continuing to build our prostate cancer leadership



Mechanism of Action

- Selective, non-steroidal, small-molecule inhibitor of 17,20-lyase¹, a key enzyme in the androgen synthesis pathway²
- Orteronel inhibits 17,20-lyase activity and steroid production in the human NCI-H295R adrenocortical carcinoma cell line³



1. Yamaoka M, et al. AACR 2010 (oral presentation)

- Mostaghel EA, et al. Best Pract Res Clin Endocrinol Metab 2008;22:243–58
 Yamaoka M, et al. EORTC-NCI-AACR 2010 (Abstract #163)
- 4. ClinicalTrials.gov. Available at: www.clinicaltrials.gov

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Program Status

Updated Phase 2 data reported at ASCO 2012

resistant prostate cancer (mCRPC) began in

C21004: global Phase 3 in chemotherapy naïve

Initiated RTOG steroid-free dosing study (July

OS . Enrollment completed in June 2012 C21005: global Phase 3 in docetaxel relapsed mCRPC patients, primary endpoint of OS. Enrollment completed in November 2012 Following PMDA discussions, bridging study to enable Japan participation in global Phase 3

trials initiated in September 2012

 Successful FDA and EMA interactions regarding non-metastatic CRPC plan ROW submission strategy in development

mCRPC patients, co-primary endpoints of PFS and

Two Phase 3 trials in metastatic castration-

2010⁴

2012)



MLN8237 (alisertib)

First-in-class oral Aurora A inhibitor with potential in solid tumor and hematological malignancies



Mechanism of Action



- Aurora A inhibition results in mitotic defects and/or delay in mitotic progression
 - High incidence of abnormal mitotic spindles often with unseparated centrosomes
 - Chromosome alignment defects in metaphase, lagging chromosomes in anaphase and chromatin bridges in telophase

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Program Status

- Global Phase 3 program initiated in relapsed/refractory PTCL
- Single-agent clinical activity observed in aggressive lymphomas (ORR=32%)
 - Phase 1/2 combination with rituximab + vincristine ongoing in relapsed/refractory DLBCL and TFL (Transformed Follicular Lymphoma)
- Early single-agent clinical activity observed in solid tumor malignancies (n=5)
 - Randomized Phase 2 combination w/weekly paclitaxel in ovarian cancer ongoing: 38% ORR (RECIST and/or Ca¹²⁵) in Phase I escalation



Top 10 Companies by Pipeline Size 2012

Position 2012 (2011)	Company	No. of R&D products 2012 (2011)	No. of originated products
1 (2)	GlaxoSmithKline	257 (269)	147
2 (1)	Pfizer	225 (284)	152
3 (3)	Merck & Co	223 (236)	150
4 (4)	Novartis	218 (200)	151
5 (5)	Hoffmann-La Roche	198 (183)	147
6 (6)	Sanofi	178 (182)	91
7 (12)	Takeda	149 (103)	80
8 (9)	Bristol-Myers Squibb	146 (149)	113
9 (8)	AstraZeneca	144 (167)	85
10 (7)	Johnson & Johnson	142 (171)	85

Citeline: Pharma R&D Annual Review 2012

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Top 10 Companies by Ph-3 Ratio in total Clinical Pipeline (Nov 2012)

	Company	% of Ph-3		
1	Takeda	31%		
2	Merck & Co	28%		
3	Bayer	28%		
4	Boehringer Ingelheim	22%		
5	Novartis	20%		
6	Sanofi	20%		
7	Eli Lilly	19%		
8	Glaxo SmithKline	19%		
9	Johnson & Johnson	15%		
10	Bristol-Meyers Squibb	15%		
	Industrial average	19.9%		

EvaluatePharma® (as of November 2012)



I	Ensuring Steady Pipeline Approval						
	FY12	FY	13	FY	14	FY15-F	Y16
	Lotriga (TAK-085)	ATL-962		SYR-472	Lu AA21004	TAK-875	MLN0002
JP				TAK-536/CCB ² SGN-35	TAK-438	MLN9708 TAK-700	TAK-385 TAK-816
US	SYR-322 SYR-322/MET ³ SYR-322/PIO ⁴	Lu AA21004		TAK-700 MLN0002		TAK-875 MLN9708 MLN8237	
EU	ADCETRIS (SGN-35) Revestive (teduglutide) Rienso (ferumoxytol)	SYR-322 SYR-322/MET ³ SYR-322/PIO ⁴	Lurasidone Peginesatide TAK-390MR	TAK-491/CLD ⁵ MLN0002		TAK-875 MLN9708 TAK-700	
EM ¹	In emerging markets, compounds including SYR-322, TAK-491, SGN-35, MEPACT, TAK-375, TAK-390MR, DAXAS will be launched consecutively.						
	¹ Emerging Market, ² Calcium Channel Blocker, ³ Metformin, ⁴ Pioglitazone (ACTOS), ⁵ Chlorthalidone Note: Some in-licensed pipelines (including Amgen products) are not publicly disclosed based upon the disclosure policies of the originator companies.						In-license
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All forward-looking statements are based on judgments derived from the information available to the Company at this time. Forward looking statements can sometimes be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "continue," "seek," "pro forma," "potential," "target, " "forecast," or "intend" or other similar words or expressions of the negative thereof.

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