Better Health, Brighter Future

Second Quarter of Fiscal 2013 Updates Related to R&D Activities

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Takeda Pharmaceutical Company Limited

Focus for Mid-Range Growth Strategy

Special Initiatives

Initiatives for Improving R&D Productivity

Improving R&D Productivity

Quality of Thought

Operational Excellence

Optimized Global R&D Activities

Reduced R&D Cycle time

- ✓Fast to Candidate
- ✓Fast to IND
- ✓Fast to POC&C

Reduced R&D Cost

- ✓40% reduced cost per candidate

Built Optimized R&D Structures

- ✓Integration of Millennium R&D functions
- ✓Global Target Marketplace
- ✓Consolidated European R&D activities

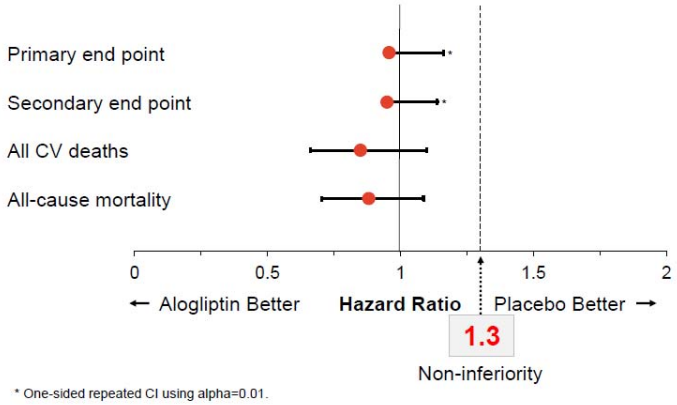
R&D Pipeline Stage-ups (since July 31, 2013)

			Ph-1	Ph-2	Ph-3	Filing	Approval
BRINTELLIX® (vortioxetine)	Major depressive disorder	US					
OBLEAN® (cetilistat)	Obesity with both type 2 diabetes mellitus and dyslipidemia	JP					
VIPIDIA™ (alogliptin)	Diabetes mellitus	EU					
VIPDOMET™ (alogliptin/metformin)	Diabetes mellitus (fixed-dose combination with metformin)	EU					
INCRESYNC™ (alogliptin/pioglitazone)	Diabetes mellitus (fixed-dose combination with pioglitazone)	EU					
TAK-390MR (dexlansoprazole)	Erosive esophagitis (healing and maintenance), Non-erosive gastro-esophageal reflux disease	EU*					
TAK-816	Prevention of infectious disease caused by Haemophilus influenzae type b (Hib)	JP					
AMITIZA® (lubiprostone)	Liquid formulation	US					
AD-4833/TOMM40	Delay of onset of mild cognitive impairment due to Alzheimer's disease	US/EU					
TAK-137	Psychiatric disorders and neurological diseases	-					

*Dexlansoprazole has been approved in 16 countries in the EU by the decentralized procedure

NESINA® / VIPIDIA™ (alogliptin)
EXAMINE Study Demonstrated Affirmative CV Safety Profile

Major EXAMINE study findings



Primary end point: composite of death from CV causes, nonfatal myocardial infarction, or non-fatal stroke
Secondary end point: primary composite with the addition of urgent revascularization due to angina within 24 hours after hospital admission

- Non-inferiority vs. placebo met for all endpoints
- HbA1c levels were significantly lower in patients on alogliptin than on placebo in addition to standard of care
- No differences between alogliptin and placebo group in hypoglycemia incidence, reported malignancies (including pancreatic cancer), and renal function
- Low and similar frequencies of acute and chronic pancreatitis
- Trend of decrease in mortality observed
- No increased incidence of hospitalization for heart failure

EXAMINE

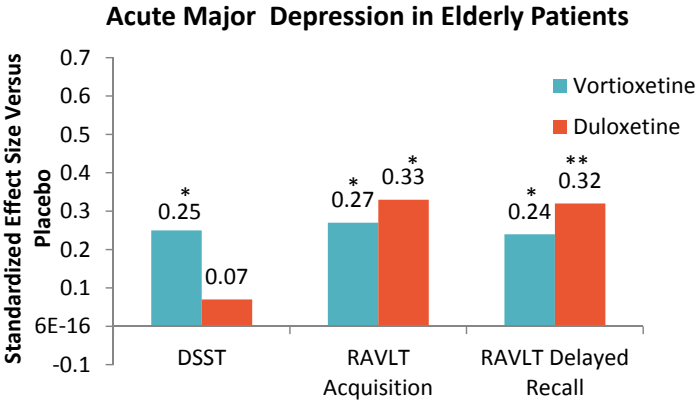
Brintellix® (vortioxetine)
Approved in the US for Major Depressive Disorder

Program Status

- Novel multimodal anti-depressant, in-licensed from Lundbeck of Denmark
- Approved in the US on September 30th, 2013 for the treatment of adults with Major Depressive Disorder
- Efficacy and safety established across a global clinical trial program including six positive short term studies and one long-term maintenance trial
- Incidence of treatment emergent sexual dysfunction with Brintellix across doses 5-20mg in female patients was ≤34%; for male patients incidence was ≤29% (ASEX scale)
- Potential for favorable profile related to cognitive dysfunction

Brintellix™
vortioxetine
5mg•10mg•20mg tablets

Key Data – Phase 3



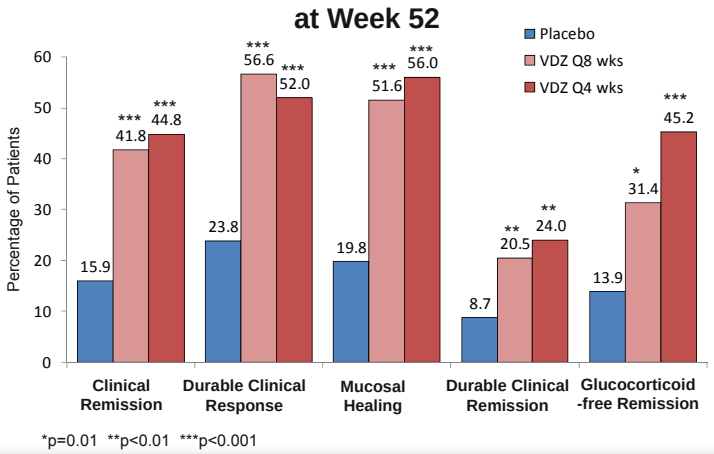
*p<0.05; **p<0.01 *versus placebo.*
DSST: Digit Symbol Substitution Test
RAVLT: Rey Auditory Verbal Learning Test

MLN0002 (vedolizumab)
Priority Review for US BLA of UC Granted

Program Status

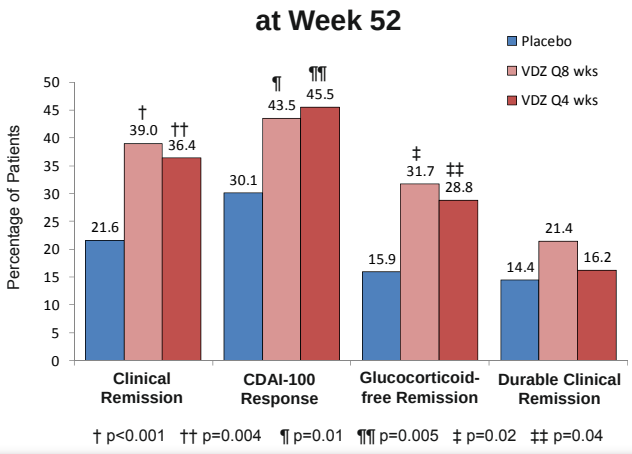
- A novel class of gut-selective monoclonal antibody targets α4β7 integrin on leukocytes involved in ulcerative colitis (UC) and Crohn's disease (CD)
- Filed in the EU (Mar 2013) and US (Jun 2013)
- Priority review for UC has been granted in the US, PDUFA date: February 18, 2014
- Has demonstrated efficacy in patients who are anti-TNF naïve and those with prior anti-TNF failure
- Two Phase 3 results were published in the August 22, 2013 issue of *the New England Journal of Medicine.*

GEMINI I : Ulcerative Colitis



*p=0.01 **p<0.01 ***p<0.001

GEMINI II : Crohn's Disease



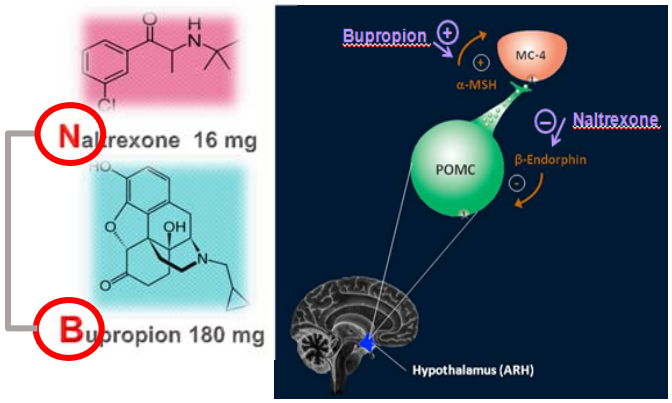
† p<0.001 †† p=0.004 ¶ p=0.01 ¶¶ p=0.005 ‡ p=0.02 ‡‡ p=0.04

Contrave®(bupropion SR / naltrexone SR)
Potential NDA Resubmission in 2013

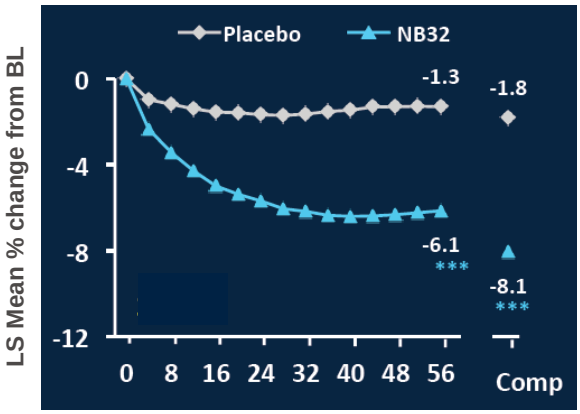
Program Status

- Fixed-dose, sustained-release combination of naltrexone-HCl and bupropion-HCl
- CV outcome "LIGHT STUDY" underway to meet FDA requirement
- Interim analysis of the "LIGHT STUDY" expected to be conducted by early December, with the potential resubmission of the New Drug Application by year end 2013; six month review expected
- The first obesity agent to be supported by prospective cardiovascular outcome (MACE) data

Mechanism of Action



Key Data – Phase 3



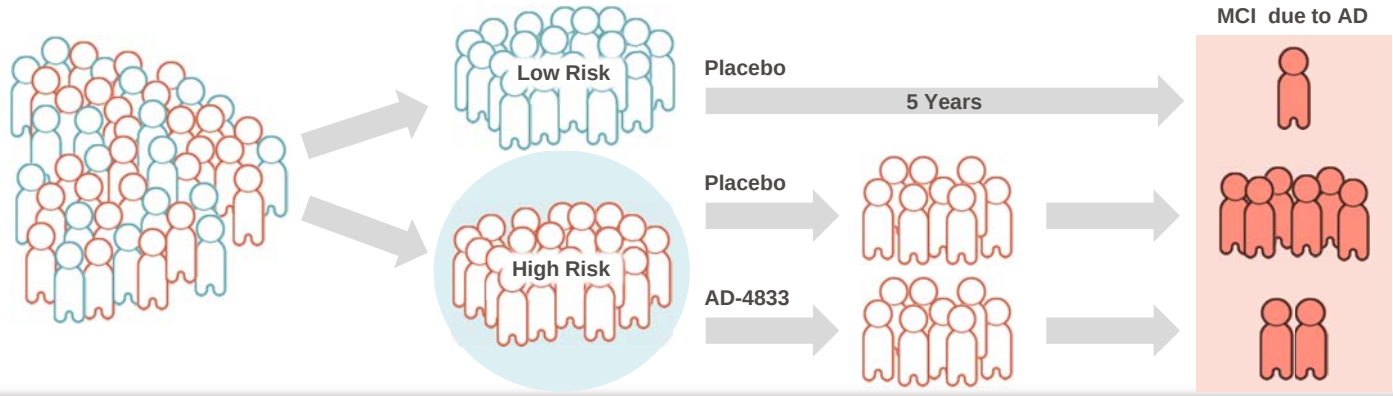
***p<0.001 vs placebo; completers at endpoint

AD-4833/TOMM40
Groundbreaking TOMMORROW Phase 3 Trial Initiated

AD-4833/TOMM40

- Landmark clinical program with the potential to change the treatment paradigm in the Alzheimer's Disease (AD) continuum, essentially delaying disease progression to Mild Cognitive Impairment (MCI) and AD in cognitively normal individuals
- Risk Assessment Algorithm: TOMM40 biomarker + APOE + age has the potential to identify cognitively normal individuals at high risk of developing MCI due to AD in 97% of the population
- Low dose AD-4833 (pioglitazone) as a novel and safe treatment to delay MCI due to AD
- Trial objectives: (1) Qualify the biomarker algorithm (comprised of APOE + TOMM40 genotypes + age)
  (2) Assess efficacy of low dose AD-4833 to delay MCI due to AD

The TOMMORROW Phase 3 Study



TAK-875 (fasiglifam)
High Potential Late-stage Pipeline

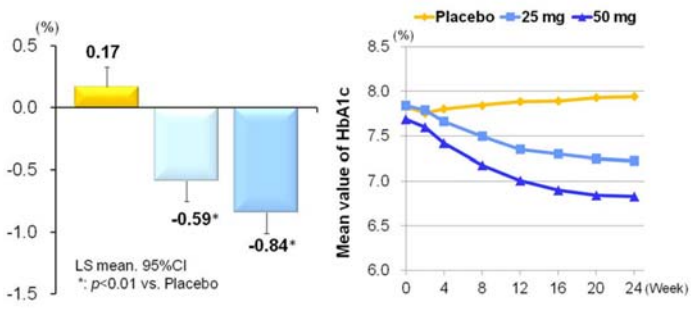
Program Status

- GPR40 agonist for type 2 diabetes
- Reduces glucose levels with low risk of hypoglycemia (2% for fasiglifam versus 19% for glimepiride in Phase 2 trial)
- Well tolerated, no dose adjustment in patients with renal impairment
- Projected approvals in FY2015 (Japan), FY2016 (US & EU)

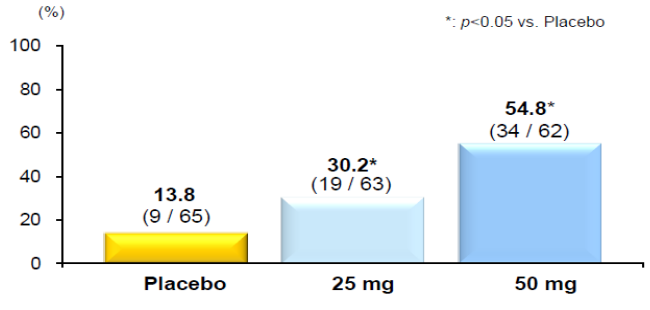
Phase 3 Data (Japanese study CCT-003)

- Significant HbA1c reduction at 24 weeks compared to placebo
- Significant reduction in percentage of patients whose HbA1c levels reached the glycemic target (less than 6.9%)
- Incidence of hypoglycemia was similar to placebo for both TAK-875 25mg & 50mg, with no weight gain

Mean HbA1c Change from Baseline at Week 24



Percent of Subjects with HbA1c <6.9% at Week 24



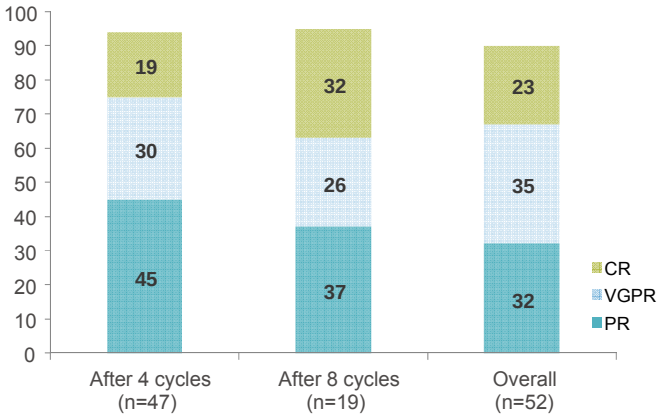
MLN9708 (ixazomib citrate)
High Potential Late-stage Pipeline

Program Status

- First oral proteasome inhibitor in Phase 3
- Developing the all-oral regimen in Multiple Myeloma (MM)
- Single oral weekly dose
- On-going registration supportive clinical trials include ongoing Phase 3 trials in front line MM, R/R MM and R/R AL Amyloidosis
- Potential in a broad range of hematological and solid tumors
- Takeda has global marketing rights
- Projected approval in FY2015 (US/EU/Japan)

Phase 1/2 Data in Front Line MM

Preliminary responses with MLN9708, lenalidomide and dexamethasone



- Of 3 response-evaluable patients who have completed 12 cycles, 2 achieved CR and 1 VGPR

Promising Pipelines in Early to Mid Stages

MLN8237: alisertib (Relapsed or refractory peripheral T-cell lymphomas, others)
Phase 3 (US, EU), Phase 1 (Japan)
- First-in-class, oral, highly selective inhibitor of Aurora A kinase
- Preclinical results show high-level activity in hematologic and solid tumors

DENVax (Prevention of dengue fever)
Phase 2
- Live virus vaccine including the four serotypes of the dengue virus that cause dengue fever

MT203: namilumab (Rheumatoid arthritis)
Phase 1
- Fully human monoclonal antibody neutralizing GM-CSF (Granulocyte macrophage colony-stimulating factor)
- Phase 1 study in RA is ongoing

Norovirus vaccine
Phase 1/2
- The first-in-class vaccine against norovirus in the world
- Phase 1/2 data presented at Infectious Disease (ID) Week 2013

TAK-137 (Psychiatric disorders and neurological diseases)
Phase 1
- AMPA receptor potentiator, potential to be first-in-class to treat various conditions due to its high potency and safety/tolerability profile
- Phase 1 study in healthy subjects is ongoing

MLN0264 (Advanced GI malignancies)
Phase 1
- Antibody-Drug Conjugate targeting GCC
- Phase 1 study in patients with GCC expressing advanced GI malignancies ongoing

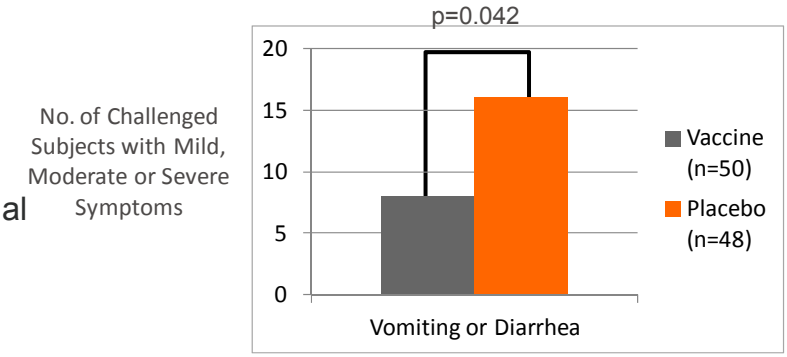
Norovirus Vaccine
Data presented at Infectious Disease (ID) Week 2013

Phase 1/2 Data presented at Infectious Disease (ID) Week 2013

- The candidate vaccine had a clinically relevant impact on the incidence of norovirus illness after challenge, as well as the severity in breakthrough cases
- In addition, a positive trend toward reduction in viral shedding in stool was observed
- The study also provided important information toward optimization of confirmatory lab testing for norovirus disease and infection in a future field trial

Mild, Moderate or Severe AGE* Symptoms

52% reduction observed in mild, moderate or severe vomiting and/or diarrhea in subjects receiving vaccine vs placebo



*: Acute Gastroenteritis

Ensuring Steady Pipeline Approval

	FY13	FY14	FY15	FY16 - FY17
JP	azilsartan (TAK-536) CCB [1] lansoprazole (AG-1749) LDA [2] cetilistat (ATL-962) influenza vaccine (BLB-750) brentuximab vedotin (SGN-35)	trelagliptin (SYR-472) vonoprazan (TAK-438) vortioxetine (Lu AA21004) Hib vaccine (TAK-816)	fasiglifam (TAK-875) ixazomib (MLN9708) orteronel (TAK-700) [5] leuprorelin 6M (TAP-144-SR)	relugolix (TAK-385) motesanib
US	vortioxetine (Lu AA21004) vedolizumab (MLN0002)	orteronel (TAK-700) [5]	ixazomib (MLN9708) alisertib (MLN8237)	fasiglifam (TAK-875) ramelteon (TAK-375) SL
EU	alogliptin (SYR-322) alogliptin MET [3] alogliptin PIO [4] dexlansoprazole (TAK-390MR) lurasidone	vedolizumab (MLN0002)	ixazomib (MLN9708) orteronel (TAK-700) [5]	fasiglifam (TAK-875) alisertib (MLN8237)
EM NA[6]	In emerging markets and North Asia, compounds including alogliptin, azilsartan medoxomil, brentuximab vedotin, MEPACT, ramelteon, dexlansoprazole and DAXAS will be launched consecutively.			

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

[1] Calcium Channel Blocker (amlodipine), [2] Low Dose Aspirin, [3] Metformin, [4] Pioglitazone (ACTOS),
[5] Projected timeline is currently under review, [6] Emerging Markets + North Asia

In-house | In-license

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