Mitsubishi Tanabe Pharma Corporation
FY2012 Business Results

Development Pipeline

- Progress of the Development Pipeline

- Canagliflozin

May 9, 2013

Masayuki Mitsuka
Board Director , Managing Executive Officer
Development Division Manager

Mitsubishi Tanabe Pharma

Pipeline Development Status (In-house Development of New Molecular Entities)

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→: progress since Feb. 1, 2013

		Mechanisms (Indications)	Region	P1	P2	P3	NDA	Approval
New Molecular Entities in-house	TA-7284	SGLT2 inhibitor (Type 2 diabetes mellitus)	Japan	→	→	→	Application to be filed soon.	
	MT-1303	S1P receptor functional antagonist (Multiple sclerosis)	Europe	→	→			
	MT-3995	Selective mineralocorticoid receptor antagonist (Diabetic nephropathy)	Europe	→	→			
	MP-424	NS3-4A protease inhibitor (Chronic hepatitis C)	Korea	→				

Pipeline Development Status (LCM)

New Value Creation

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→: progress since Feb. 1, 2013

		Mechanisms (Indications)	Region	P1	P2	P3	NDA	Approval
LCM	Omeprazon	Proton pump inhibitor (Hericobacter pylori eradication by concomitant therapy for Hericobacter pylori gastritis)	Japan				→	
	Grtpa	Thrombolytic agent (Acute ischemic cerebrovascular disease [up to 4.5 hours after the onset of symptoms])	Japan				→	
	Tenelia	DPP-4 inhibitor (Type 2 diabetes mellitus, additional combination)	Japan	→	→	→	→	
	Imusera	S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)	Japan (Multinational study)			→		
	Talion	Selective histamine H1 receptor antagonist (Pediatric atopic dermatitis)	Japan			→		
	Telavic	NS3-4A protease inhibitor (Chronic hepatitis C, Pegasys/Feron combination)	Japan			→		

Pipeline Development Status (Out-licensed Product)

New Value Creation

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→: progress since Feb. 1, 2013

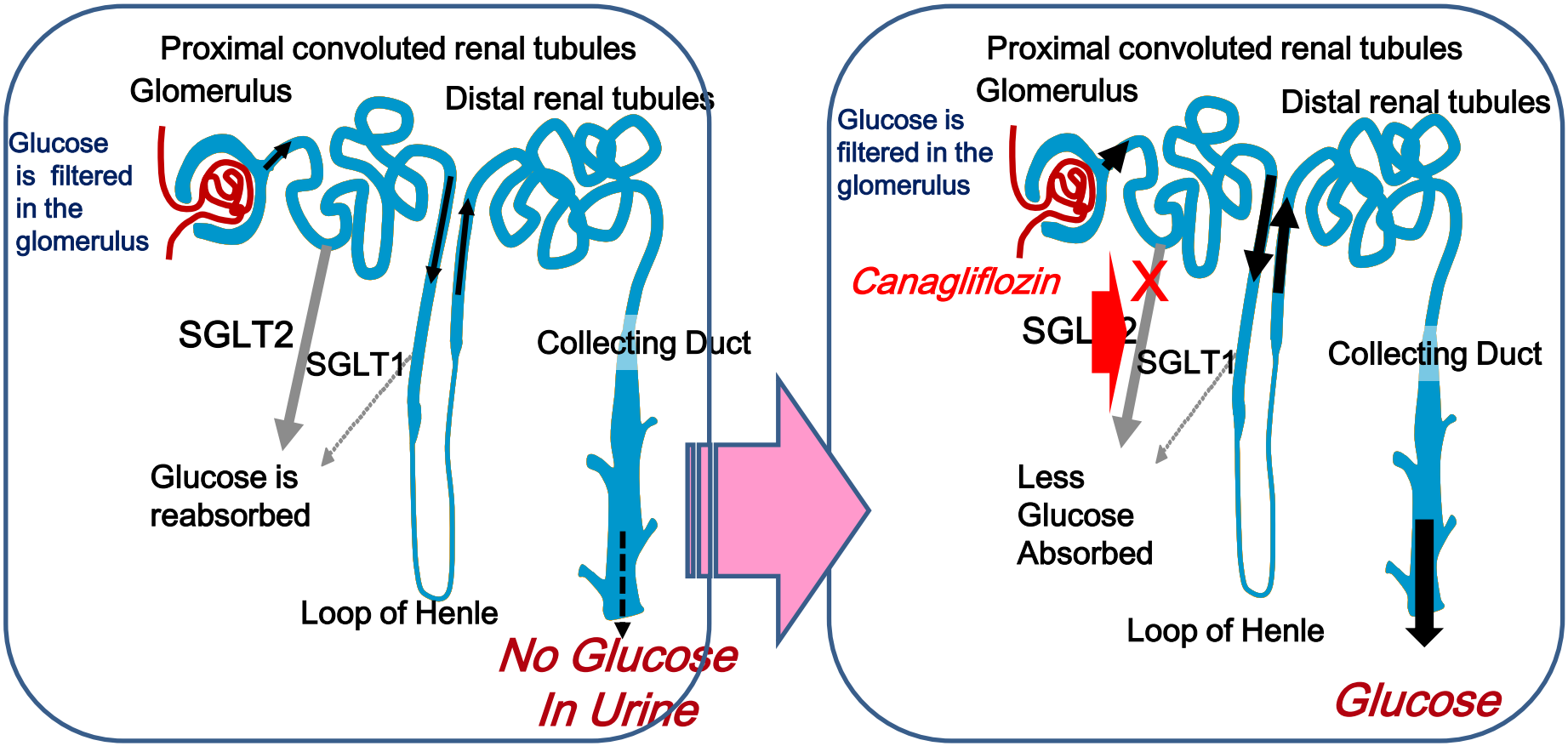
		Mechanisms (Indications)	Region	P1	P2	P3	NDA	Approval
Out-licensed product	TA-7284/ INVOKANA™	SGLT2 inhibitor (Type 2 diabetes mellitus)	U.S. (Janssen Pharmaceuticals)	→	→	→	→	
	TA-7284, FDC*1	SGLT2 inhibitor (Type 2 diabetes mellitus, metformin combination)	U.S. and Europe (Janssen Pharmaceuticals)				→	
	TA-1790	PDE5 inhibitor (ED)	Europe (Vivus)	→	→	→	Recommendation of approval	
	FTY720	S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)	Multinational study*2			→		

*1: Fixed dose combination
*2: Co-developed with Novartis Pharma in Japan

Canagliflozin and Strategy of Diabetic Therapy

- Approval of Canagliflozin in the US
- Future Developments Plan of Diabetes Treatment in Japan

SGLT Inhibitors and Glucose Absorption/Reabsorption



- Promotes excretion of glucose into the urine
- Loss of glucose = loss of calories
  ⇒ Reduction in body weight
  ⇒Greater improvement of blood glucose control

Phase III Studies Conducted in Japan and Abroad

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Initial Diagnosis	Mono Therapy	Dual Combination	Triple Combination	Insulin +/- Oral
Diet& Exercise	Cana vs. PBO 24 wks	Oral AHA + Cana 52 wks		
	Cana Open 52 wks			

Conducted by Mitsubishi Tanabe Pharma Corporation

N=1,472

Initial Diagnosis	Mono Therapy	Dual Combination	Triple Combination	Insulin +/- Oral
Diet& Exercise	Cana vs. PBO 26+26 wks	Met + Cana vs. Met + PBO 26+26 wks	Met + TZD + Cana vs. Met + TZD + PBO 26+26 wks	Insulin + Cana vs. Insulin + PBO 18 wks
		Met + Cana vs. Met + Glim 52+52 wks	Met + SU + Cana vs. Met + SU + PBO 26+26 wks	Body Composition Cana vs. PBO 26+78 wks
		SU + Cana vs. SU + PBO 18 wks	Met + SU + Cana vs. Met + SU + DPP4 52 wks	Renal Impairment Cana vs. PBO 26+26 wks
		Met + Cana vs. Met + DPP4 26+26 wks		

Cardiovascular Outcomes in High Risk Population (CANVAS)

Event-driven N=4330

Conducted by Janssen Research & Development

N=10,210

HbA1c Change from Baseline Over Time

Monotherapy Study

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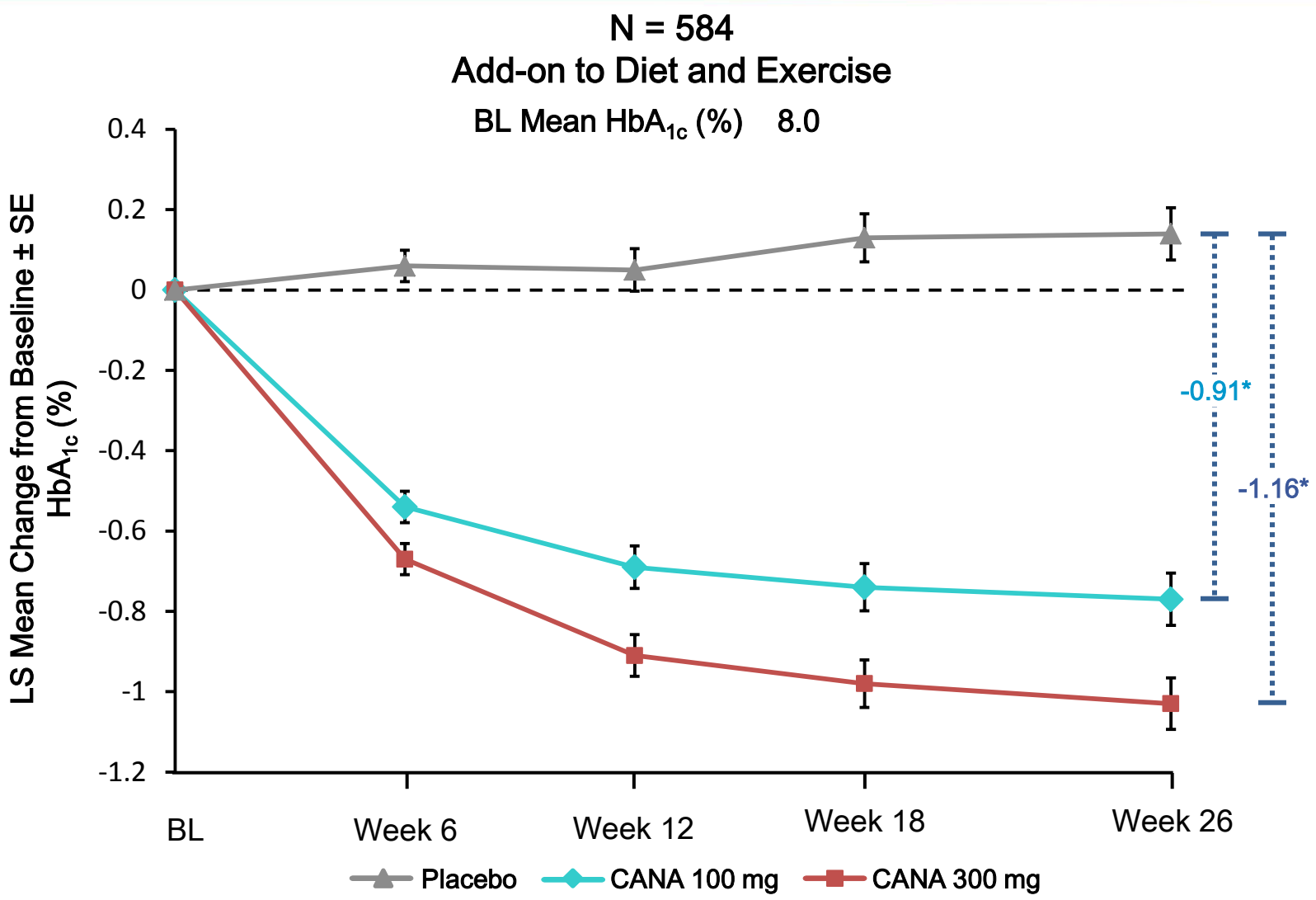

* p <0.001

Based on ANCOVA model, data prior to rescue (LOCF); N = mITT N

Stenlöf K et al Diabetes Obesity and Metabolism 2013; 15: 372-382

HbA1c Change from Baseline Over Time

Active (Sitagliptin)- controlled Add-on to Met + SU Study

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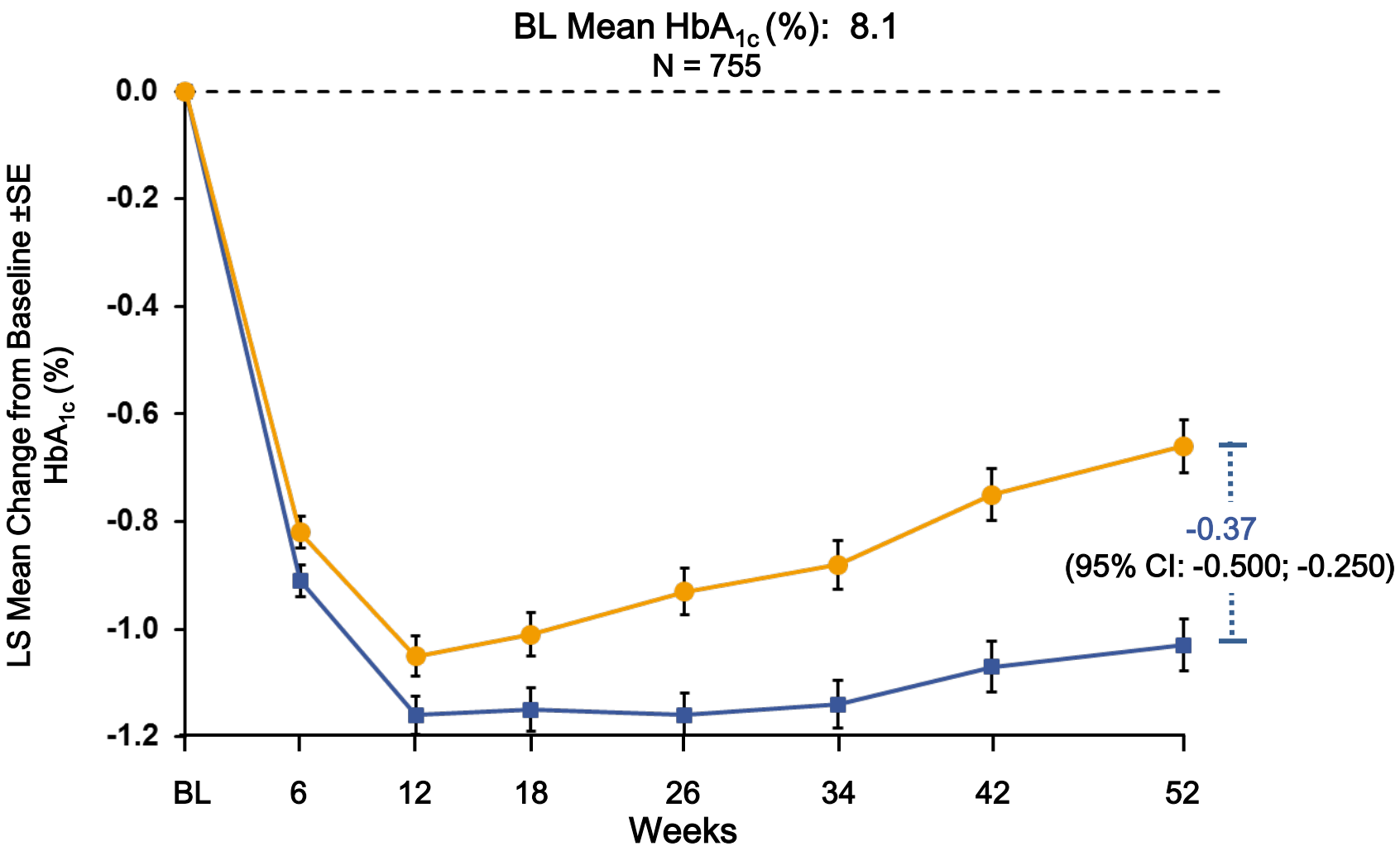


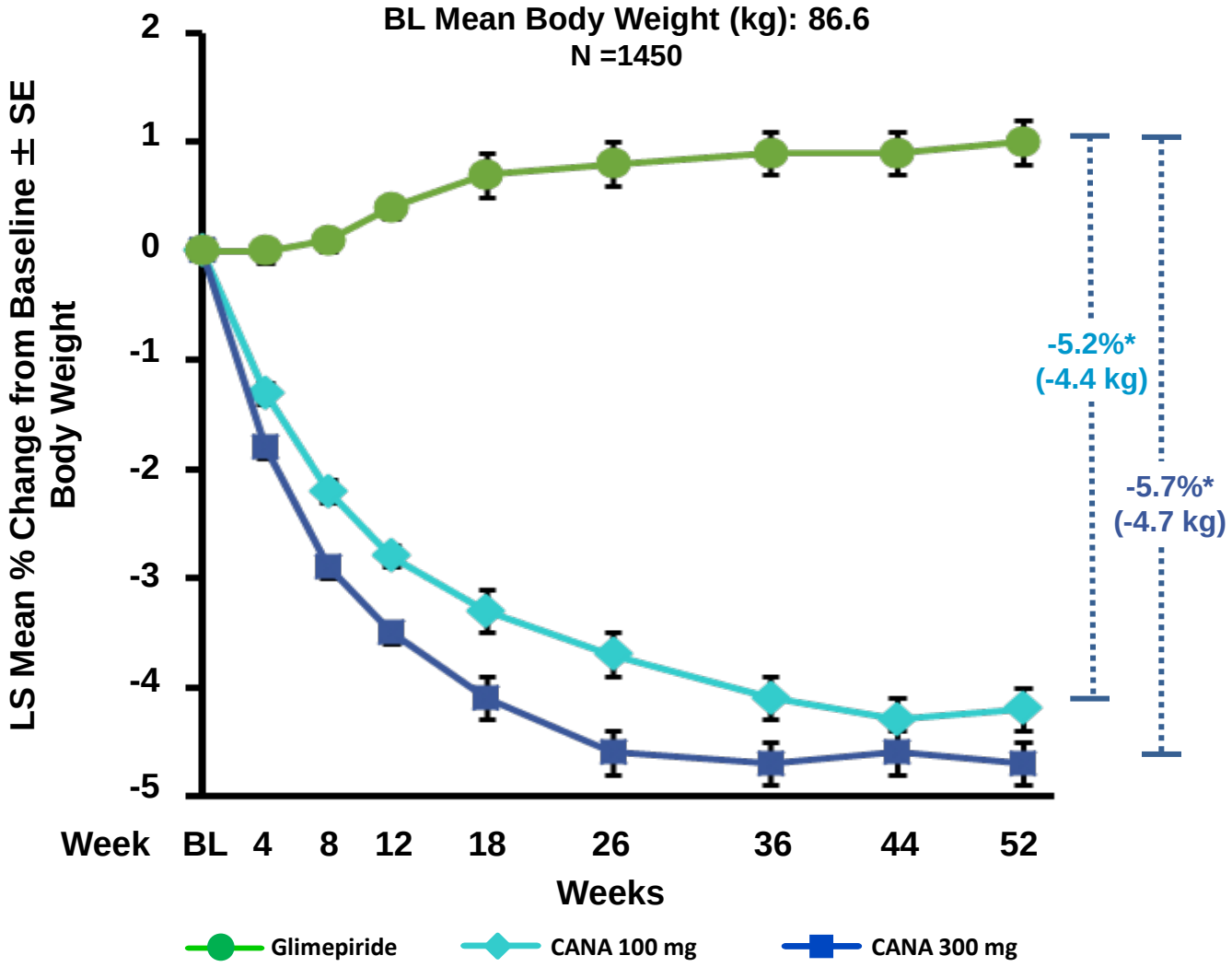
Based on ANCOVA model (LOCF)

Schernthamer G et al Diabetes Care published online April 5, 2013 DOI: 10.2337/dc12-2491

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM336236.pdf, CC-50

Body Weight Percent Change from Baseline Over Time

Active (Glimepiride)-controlled Add-on to Metformin Study



* p <0.001

Based on ANCOVA model, data prior to rescue (LOCF)

Toubro S., et al. Diabetologia. 2012; 55 (suppl1): S313

http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM336236.pdf, CC-47

Percent Change in fat distribution at week 52

LOCF

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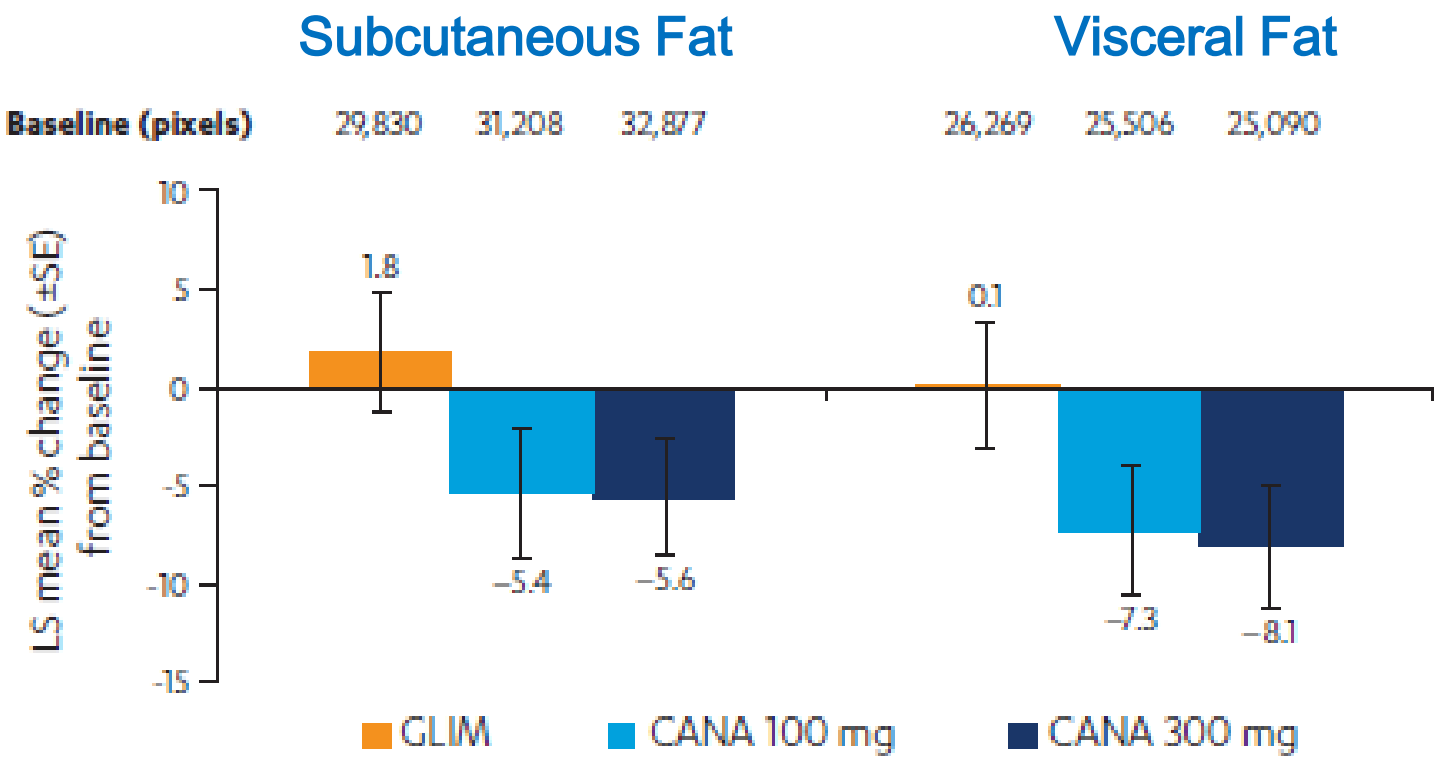

Toubro S., et al. Diabetologia. 2012; 55 (suppl1): S313

Prescribing Information in the US

Canagliflozin/ INVOKANA™

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< Indications and Usage >

- INVOKANA™ is a SGLT2 inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

< Dosage and Administration >

Recommended dosage

- Starting dosage: 100mg once daily
- Dose can be increased to 300mg once daily in patients tolerating INVOKANA™ 100mg once daily who have an eGFR of 60ml/min./1.73m^2 or greater and require additional glycemic control.

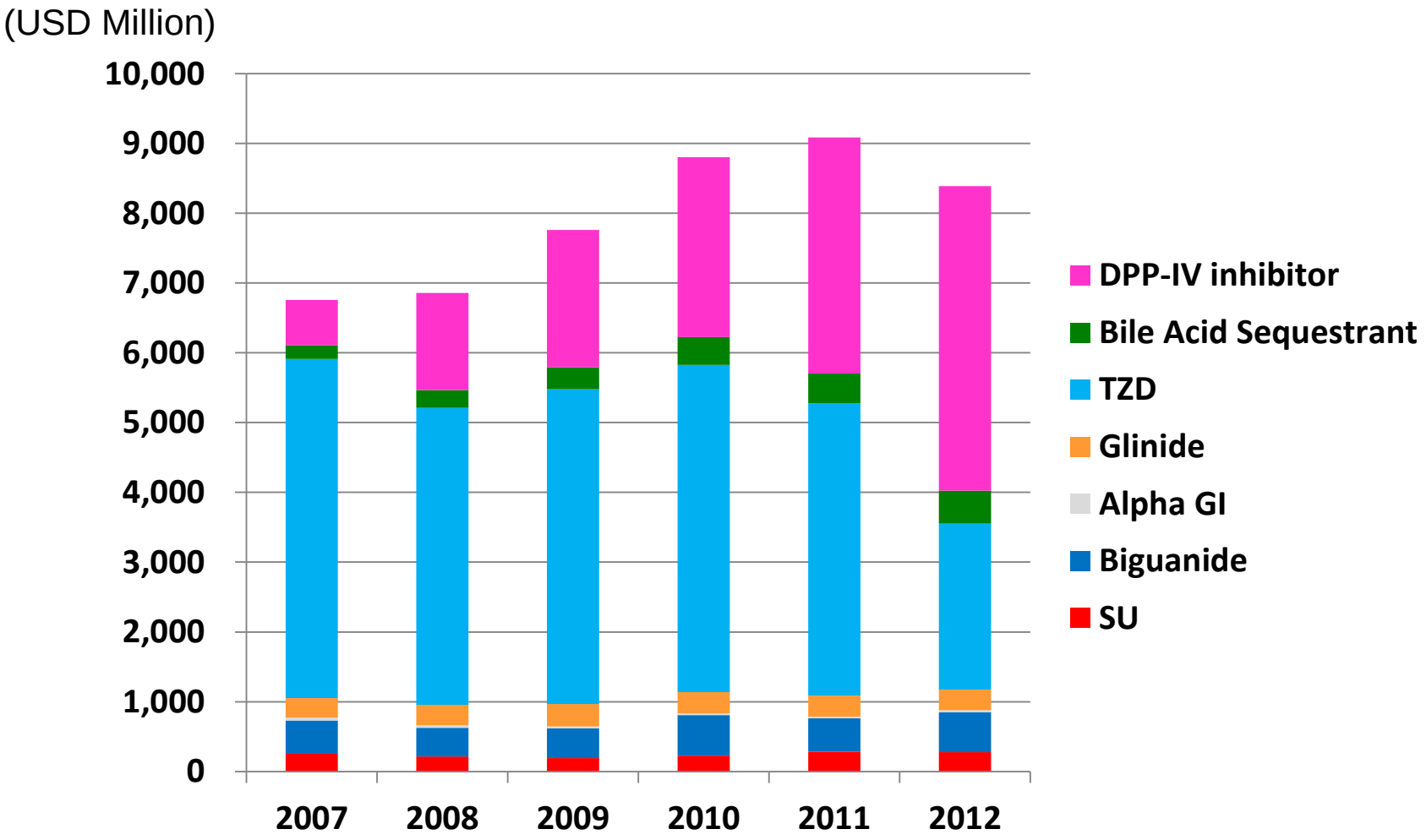
Patients with Renal Impairment

- Mild renal impairment (eGFR of 60mL/min./1.73 m^2 or greater): no dose adjustment
- eGFR of 45 to less than 60 mL/min/1.73 m^2 : limited to 100 mg once daily
- eGFR less than 45 mL/min/1.73 $m^{2:}$: should not be initiated
- eGFR persistently less than 45 mL/min/1.73 $m^{2:}$: should be discontinued

Required Assessments from FDA

1. Clinical pharmacology study in pediatric patients （ ages 10 to < 18 ）
2. Double-blind study in pediatric patients （ ages 10 to < 18 ）
   - 26-week + 26-week study, placebo-controlled, add-on to metformin and monotherapy
3. Assessment and analysis of spontaneous reports
   - Malignancy (pheochromocytoma, Leydig cell tumor and renal cell carcinoma) ; to continue for 10 years
   - Serious pancreatitis, severe hypersensitivity reactions, photosensitivity reactions, serious hepatic abnormalities and pregnancy; to continue for 5 years
4. DIA3010 study
   - Completion and submission of the final report for the 78-week double-blind extension phase
5. CV risk assessment
   - Assess the incidence of MACE

T2DM Market (Oral Agents) Snapshot in the US



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SGLT Inhibitor Development Environment

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Compound	Company (Development)	Overseas	Japan
Canagliflozin TA-7284	MTPC, Janssen Pharmaceuticals	EU Application Jun. 2012 US approval Mar. 2013	P3
Dapagliflozin BMS-512148	Bristol-Myers, AstraZeneca	US CRL Jan. 2012 EU approval Nov. 2012	P3
Empagliflozin BI10773	Boehringer Ingelheim, Eli Lilly	EU/US Application Q1 2013	P2/3
Ipragliflozin ASP1941	Astellas, Kotobuki	EU/US P2b completed in May 2012 EU/US Development terminated in Nov. 2012	NDA submission (Mar. 2013)
Luseogliflozin TS-071	Taisho	-	NDA submission (Apr. 2013)
Tofogliflozin CSG421	Chugai	P2 completed (Roche development terminated)	P3
Ertugliflozin PF04971729	Pfizer, Merck	P2 completed (Jan. 2011)	P1 completed Feb. 2011
LX4211	Lexicon	P2 completed (Jun. 2012)	-

CRL: Complete Response Letter

The Field of Diabetes Treatment: Future Development in Japan

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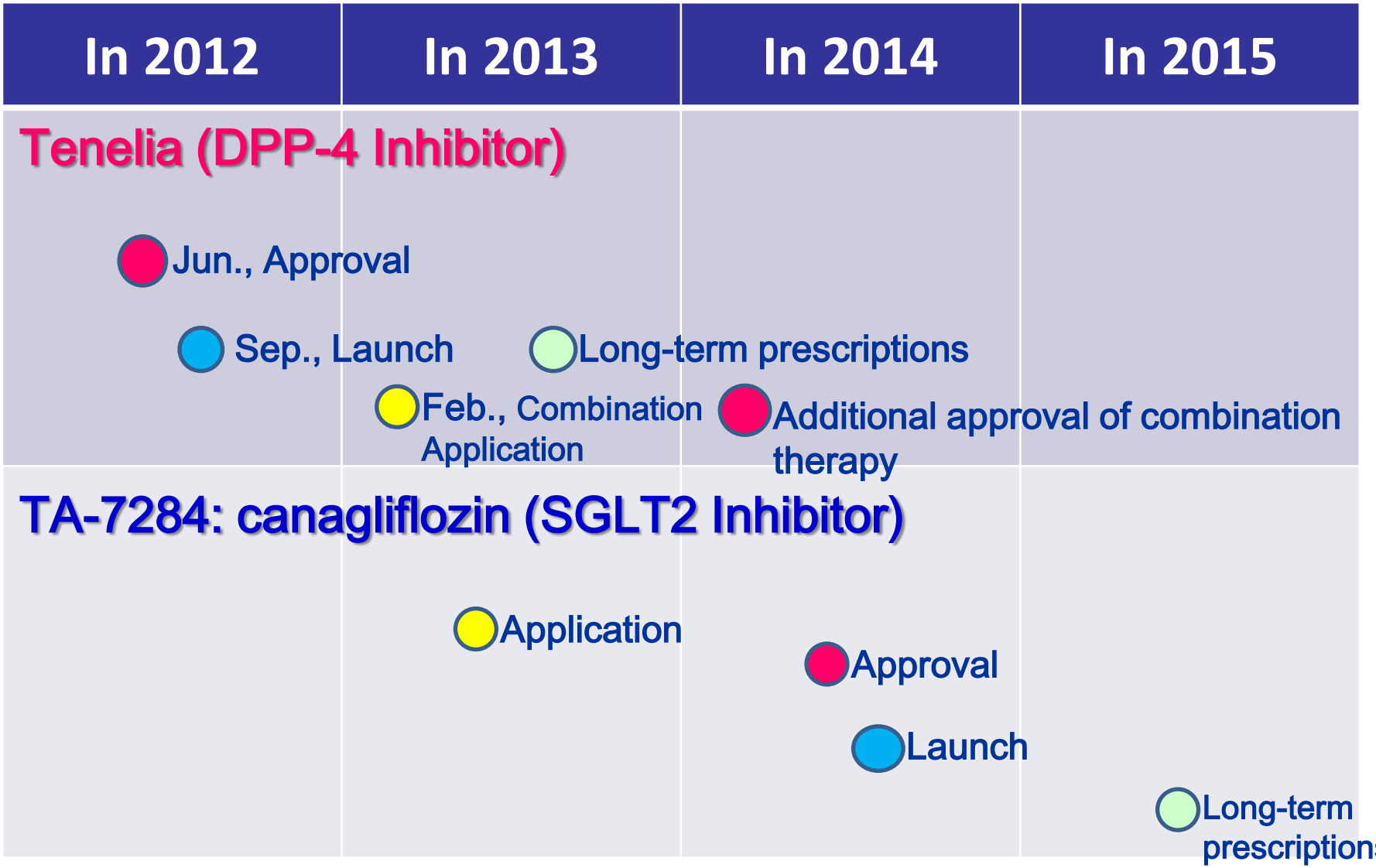
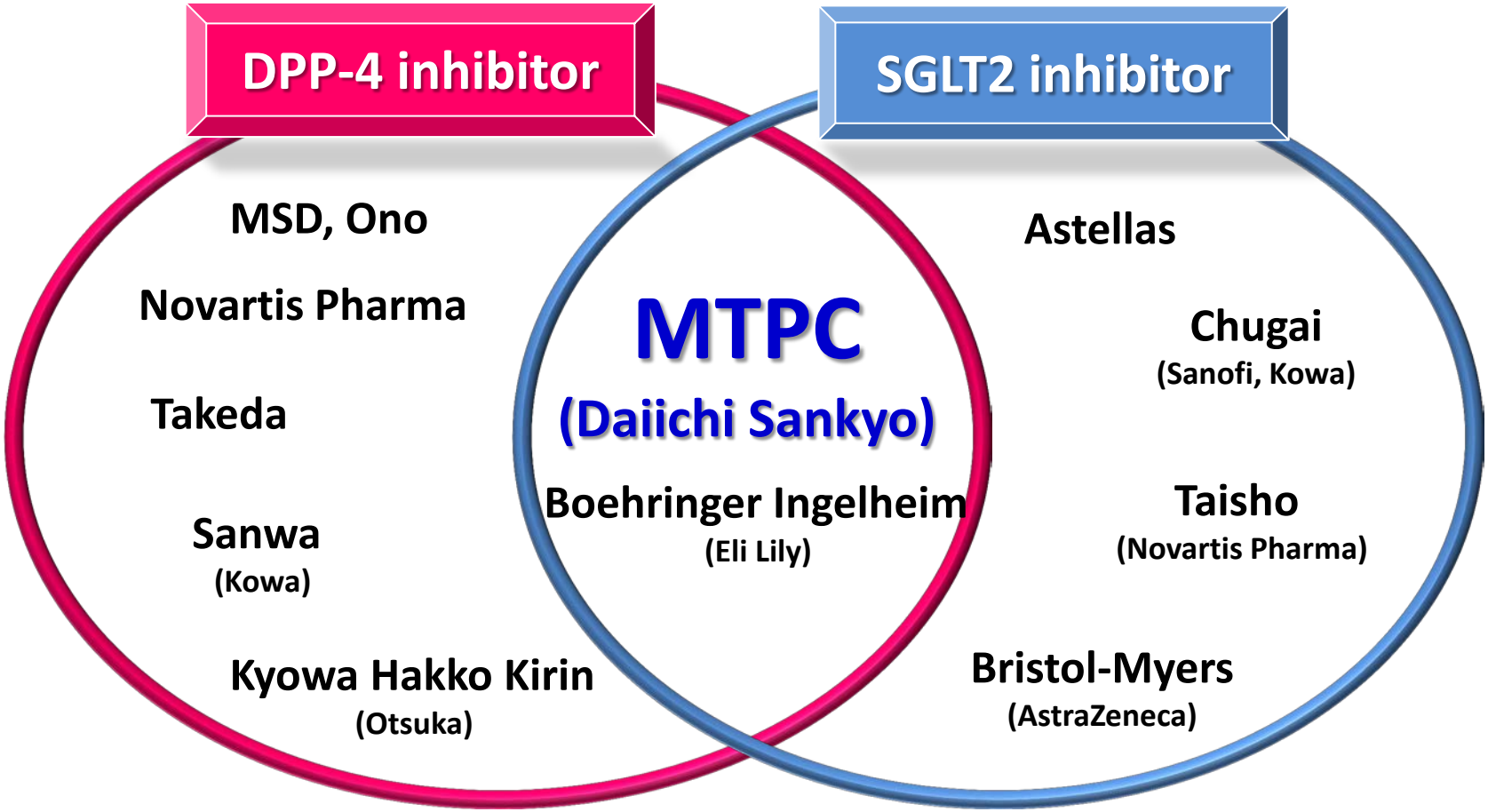


Advantage in Diabetic Area

■Major marketing authorization holders

( ): Co-marketing or co-promotion



MTPC and Boehringer Ingelheim are the originators having both drugs

New **Value** Creation

Becoming a “Company that Can Continue to Create New Value”

Cautionary Statement

The statements contained in this presentation is based on a number of assumptions and belief in light of the information currently available to management of the company and is subject to significant risks and uncertainties.