# (2) State of New Product Development (As of February 2, 2015)

i. New Drugs

Development code (Generic name)	Category (Indications)	Region	Stage	Origin	
MT-4666	α7nACh receptor agonist (Dementia of Alzheimer's type)	Global clinical trial*		US: FORUM Pharmaceuticals	
MT-2412 (Teneligliptin, Canagliflozin)	Fixed-dose combination of DPP-4 inhibitor and SGLT2 inhibitor (Type 2 diabetes mellitus)	Japan Phase 3		In-house	
MP-214 (Cariprazine)	Dopamine D3/D2 receptor partial agonist (Schizophrenia)	Japan	Phase 2b/3	Hungary: Gedeon Richter	
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type 2 diabetes mellitus)	Europe US	Phase 2 Phase 1	- In-house	
		Europe	Phase 2		
MT-3995	Selective mineralocorticoid receptor antagonist (Diabetic nephropathy)	Japan	Phase 2	In-house	
	(Blasette Hephropathy)	US	Phase 1		
	S1P receptor functional antagonist (Multiple sclerosis)	Europe	Phase 2		
MT-1303	(Psoriasis)	Europe	Phase 2	In-house	
	(Inflammatory diseases, Autoimmune diseases)	Japan,Europe, US	Phase1		
MT-2301	Haemophilus influenza type b (Hib) vaccine (Prophylaxis of Pediatric Hib infection)	Japan	Phase 2	US: Nuron Biotech	
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of H5N1 influenza)	Canada	Phase 2	In-house	
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of seasonal influenza)	US, Canada	Phase 2	In-house	
Influenza vaccine	Plant-based VLP vaccine (Prophylaxis of H7N9 influenza)	Canada	Phase 1	In-house	
MP-424 (Telaprevir)	NS3-4A protease inhibitor (Chronic hepatitis C)	Korea	Phase 1	US:Vertex Pharmaceuticals	
GB-1057 (Recombinant human serum albumin)	Recombinant human serum albumin (Stabilizing agent)	US	Phase 1	In-house	
MP-124	PARP inhibitor (Acute ischemic stroke)	US	Phase 1	In-house	
MP-157	Angiotensin type 2 receptor agonist (Hypertension)	Europe	Phase 1	In-house	
MT-0814	CC chemokine receptor 3 antagonist (Age-related macular degeneration)	Japan	Phase 1	In-house	

<sup>\*:</sup> Co-developed with FORUM Pharmaceuticals.

# ii. Additional Indications

Telavic (Telaprevir)   (Chronic hepatitis C, [combination with Pegasys])   (Palas 3   Selective histamine H1 receptor antagonist, antiallergic agent (Pediatric allergic rejnititis)   (Pediatric allergic agent (Amyotrophic lateral sclerosis*)   (Pediatric allergic assert)   (Amyotrophic lateral sclerosis*)   (Pediatric Crohn's disease)   (Pediatric Crohn's disease)   (Pediatric Crohn's disease)   (Pediatric Crohn's disease)   (Pediatric Ucerative colitis)   (Peoriasis: increased dose)   (Perinasis: increased dose)   (Perinasis: increased dose)   (Perinasis: increased dose)   (Perinasis: etelanus combined vaccine)   (Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)   (Peophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)   (Palas de University)   (Phase 3   In-house   Phase 3   In-house   (Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)   (Palastic unephropathy)   (Phase 3   In-house   Phase 3   In-house   (Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)   (Palastic unephropathy)   (Phase 3   In-house   Phase 3   In-house   (Phase)	Product name (Generic name)	Category (Indications)	Region	Stage	Origin	Notes
Selective histamine H1 receptor antagonist, antiallergic agent (Pediatric allergic rhinitis)  (Pediatric atopic dermatitis)  (Pediatric atopic dermatitis)  (Pediatric atopic dermatitis)  (Radicut (Edaravone)  (Edaravone)  (Anti-human TNFc monoclonal antibody (Behcet's disease with special lesions*)  (Pediatric crohn's disease)  (Pediatric Crohn's disease)  (Pediatric Crohn's disease)  (Pediatric Ucreative colitis)  (Pooriasis: increased dose)  Imusera (Fingolimod)  (Fingolimod)  Tribik (Adsorbed diphtheria-purified pertussis-tetanus combined vaccine)  Tribik (Adsorbed (Prophylaxis of pertussis, diphtheria, and tetanus: Stage 2 vaccination)  Canaglu (Canagliflozin)  Soll-12 inhibitor (Diabetic nephropathy)  Selective histamine H1 receptor antagonist, antial (May, 2014)  Japan: The louse (May, 2014)  Japan: No. No. Absorbed phosphate binder  SNDA filed (May, 2014)  SNDA filed (No. (Co., 2014)  Phase 3  US. Janssen  Biotech  US. Janssen  Biotech  Phase 3  Phase 3  In-house  Co-developed with Novartis Phasma in Japan (Incincal trial)  Phase 3  In-house  Co-developed with the Research Foundation for Microbial Diseases of Osaka University  Stage 2 vaccination)  Canaglu (Canagliflozin)  SGLT2 inhibitor (Diabetic nephropathy)  Figuring Phase 3  In-house  Sponsor: Janssen Research & Development, LLC  BindRen  Non-absorbed phosphate binder		(Chronic hepatitis C, [combination with Pegasys])	Japan		Pharmaceutic	
Redicut (Edaravone)   Free radical scavenger (Edaravone)   Anti-human TNFa monoclonal antibody (Behcet's disease with special lesions*)   Anti-human TNFa monoclonal antibody (Behcet's disease with special lesions*)   Anti-human TNFa monoclonal antibody (Behcet's disease with special lesions*)   Phase 3   US:Janssen (Pediatric Crohn's disease)   Phase 3		Selective histamine H1 receptor antagonist, anti- allergic agent	Japan	sNDA filed	'	
(Edaravone) (Amyotrophic lateral sclerosis*)  Anti-human TNFα monoclonal antibody (Behcet's disease with special lesions*)  (Refractory Kawasaki disease*) (Pediatric Crohn's disease) (Pediatric ulcerative colitis) (Psoriasis: increased dose)  Imusera (Fingolimod)  Tribik (Adsorbed diphtheria-purified pertussis-tetanus combined vaccine)  Tribik (Adsorbed Vaccine) (Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)  Canagliu (Canagliflozin)  Elin-house  In-house  In-house  In-house  In-house  In-house  Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas  In-house  Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas  In-house  Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas  In-house  Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas  In-house  Co-developed with Phase 3  Japan: The Research Foundation for Microbial Diseases of Osaka University  Osaka University  Osaka University  In-house  Research & Development, LLC  BindRen  Non-absorbed phosphate binder		(Pediatric atopic dermatitis)			madelines	
Remicade (Infliximab [recombinant])  Remicade (Infliximab [recombination])  Remicade (Infliximab [recombination])  Remicade (Infliximab [recombination])  Remicade (Infliximab [recombination])  Rephase 3  Remicade (Infliximab [recombination])  Rephase 3  Inhouse   Co-developed with Novartis Pharma in Japan, Ilcensed to Novartis overseas  Research Research Research Research Scholar [recombination]]  Remicade (Infliximab [recombination])  Rephase 3  Inhouse   Co-developed with Novartis overseas  Research Res		-	Japan		In-house	
(Infliximab [recombinant])  (Pediatric Crohn's disease) (Pediatric ulcerative colitis) (Psoriasis: increased dose)  Imusera (Fingolimod) (Chronic inflammatory demyelinating polyradiculoneuropathy)  Tribik (Adsorbed diphtheria-purified pertussis-tetanus combined vaccine)  Canaglu (Canagliflozin)  SGLT2 inhibitor (Diabetic nephropathy)  Japan  Phase 3  In-house  Sistants  Phase 3  In-house  Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas  In-house  Japan  Phase 3  In-house  Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas  Foundation for Microbial Diseases of Osaka University  Osaka University  Sponsor: Janssen Research & Development, LLC  Phase 3  In-house  Phase 3  In-house  In-house  Phase 3  In-house		•				
[recombinant])  [recombinant]  [recombinant])  [recombinant]  [recomb		(Refractory Kawasaki disease*)	.lanan	Phase 3	US:Janssen	
Imusera (Fingolimod)   S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)   Global clinical trial   Phase 3   In-house   Co-developed with Novartis Pharma in Japan, licensed to Novartis overseas    Tribik (Adsorbed diphtheria-purified pertussis-tetanus combined vaccine)   Vaccine (Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)   Japan   Phase 3   Japan: The Research Foundation for Microbial Diseases of Osaka University   Osaka University   Osaka University    Canaglu (Canagliflozin)   SGLT2 inhibitor (Diabetic nephropathy)   Global clinical trial   Phase 3   In-house   Sponsor: Janssen Research & Development, LLC	,	(Pediatric Crohn's disease)	Japan	Phase 3	Biotech	
Imusera (Fingolimod)  S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)  Tribik (Adsorbed diphtheria-purified pertussis-tetanus combined vaccine)  Canaglu (Canagliflozin)  SGLT2 inhibitor (Diabetic nephropathy)  S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)  Phase 3  Japan: The Research Foundation for Microbial Diseases of Osaka University  Canaglu (Canagliflozin)  SGLT2 inhibitor (Diabetic nephropathy)  S1P receptor functional antagonist (Co-developed with Novartis overseas  A Japan: The Research Foundation for Microbial Diseases of Osaka University  Sage 2 vaccination)  SGLT2 inhibitor (Diabetic nephropathy)  SIP receptor functional antagonist (Co-developed with Novartis overseas  In-house  Sponsor: Janseen Research & Development, LLC		(Pediatric ulcerative colitis)		Phase 3		
Imusera (Fingolimod)  S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)  Tribik (Adsorbed diphtheria-purified pertussis-tetanus combined vaccine)  Canaglu (Canagliflozin)  SGLT2 inhibitor (Diabetic nephropathy)  In-house  S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)  Phase 3  In-house  Novartis Pharma in Japan, licensed to Novartis overseas  In-house  Novartis Pharma in Japan, licensed to Novartis overseas  In-house  Novartis Pharma in Japan, licensed to Novartis Pharma in Japan, licensed to Novartis overseas  In-house  Research Foundation for Microbial Diseases of Osaka University  Osaka University  Sponsor: Janssen Research & Development, LLC  BindRen  Non-absorbed phosphate binder		(Psoriasis: increased dose)		Phase 3		
(Adsorbed diphtheria-purified pertussis-tetanus combined vaccine)  Canaglu (Canagliflozin)  Significant pertussis, diphtheria, and tetanus; Stage 2 vaccination)  Vaccine (Prophylaxis of pertussis, diphtheria, and tetanus; Stage 2 vaccination)  Japan  Phase 3  Phase 3  Phase 3  Phase 3  In-house  Sponsor: Janssen Research & Development, LLC  BindRen  Non-absorbed phosphate binder  Non-absorbed phosphate binder  Furope  Phase 3  In-house		(Chronic inflammatory demyelinating		Phase 3	In-house	Novartis Pharma in Japan, licensed to
Canagli (Canagliflozin) (Diabetic nephropathy) Clinical trial Phase 3 In-house Research & Development, LLC  BindRen Non-absorbed phosphate binder Furope Phase 3 In-house	(Adsorbed diphtheria-purified pertussis-tetanus	(Prophylaxis of pertussis, diphtheria, and tetanus;	Japan	Phase 3	Research Foundation for Microbial Diseases	The Research Foundation for Microbial Diseases of
' ' Furope   Phase 3   In-house	-			Phase 3	In-house	Research &
			Europe	Phase 3	In-house	
Bile acid signal regulation Cholebine Cholebine Phase 2	Cholebine (Colestimide[JAN])		Japan	Phase 2	In-house	
(Colestimide[JAN]) Non-absorbed phosphate binder (Hyperphosphatemia)  Japan Phase 1				Phase 1		

<sup>\*</sup> Orphan drug designated

### iii. Licensing-out

Development code (Generic name)	Category (Indications)	Region	Stage	Licensee (Notes)	
TA-7284 (Canagliflozin)	SGLT2 inhibitor (Type2 diabetes mellitus / fixed dose combination with metformin, XR)	US	Phase 3	US: Janssen Pharmaceuticals, Inc	
(Canagiiiloziii)	(Diabetic nephropathy)	Global clinical trial	Phase 3		
FTY720 (Fingolimod)	S1P receptor functional antagonist (Chronic inflammatory demyelinating polyradiculoneuropathy)	Global clinical trial	Phase 3	Switzerland: Novartis (Co-developed with Novartis Pharma in Japan)	
	(Primary progressive multiple sclerosis)	Global clinical trial	Phase 3	Switzerland: Novartis	
Y-39983	ROCK (rho-kinase) inhibitor (Glaucoma)	Japan	Phase 2	Japan: Senju Pharmaceutical	
MT-210	5-HT2A/ Sigma 2 receptor antagonist (Schizophrenia)	Europe	Phase 2	US:Minerva Neuroscience	
TA-7906	PDE4 inhibitor (Atopic dermatitis)	Japan	Phase 2	Japan: Maruho	
MCC-847 (Masilukast)	Leukotriene D4 receptor antagonist (Asthma)	Korea	Phase 2	Korea: SAMA Pharma	
TA-8995	CETP inhibitor (Dyslipidemia)	Netherlands, Danmark	Phase 2	Netherlands: DEZIMA Pharma	
MT-4580	Ca sensing receptor agonist (Secondary hyperparathyroidism in hemodialysis patients)	Japan	Phase 2	Japan: Kyowa Hakko Kirin	
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type2 diabetes mellitus / fixed dose combination with metformin, XR)	Korea	NDA filed <sup>*1</sup>	Korea: Handok	
sTU-199 (Tenatoprazole)	Proton pump inhibitor (Gastroesophageal reflux disease)	Europe	Phase 1	France: Negma/Sidem	
Wf-516	SSRI / 5HT1A receptor antagonists (Depression)	Europe	Phase 1	US:Minerva Neuroscience	
Y-803	Bromodomain inhibitor (Hematological cancer)	Europe, Canada	Phase 1	US: Merck <sup>*2</sup>	
1-000	(Solid cancer)	Europe, Canada	Phase 1	(Development code: OTX015)	

<sup>\*1 20</sup>mg/1000mg(teneligliptin/metformin), 10mg/750mg and 10mg/500mg were submitted in Oct., Nov., and Dec. 2014, respectively.

<sup>\*2</sup> Merck acquired OncoEthix, the licensee, in December 2014.

## iv. Changes Since Previous Announcement on October 29, 2014

In-house Development

Product name (Generic name)	Category (Indications)	Region	As of October 29, 2014	As of February 2, 2015
Radicut (Edaravone)	Free radical scavenger (Amyotrophic lateral sclerosis <sup>*1</sup> )	Japan	Phase 3	sNDA filed (Oct., 2014)
Remicade (Infliximab [recombinant])	Anti-human TNFα monoclonal antibody (Behcet's disease with special lesions <sup>*1</sup> )	Japan	Phase 3	sNDA filed (Oct., 2014)

<sup>\*1</sup> Orphan drug designated

## Licensing-out

Development code (Generic name)	Category (Indications)	Region	As of October 29, 2014	As of February 2, 2015
MP-513 (Teneligliptin)	DPP-4 inhibitor (Type2 diabetes mellitus / fixed dose combination with metformin, XR)	Korea	Phase 1	NDA filed <sup>*2</sup>
Y-803	Bromodomain inhibitor (Solid cancer)	Europe, Canada	None	Phase 1

 $<sup>^{*}2</sup>$  20mg/1000mg(teneligliptin/metformin), 10mg/750mg and 10mg/500mg were submitted in Oct., Nov., and Dec. 2014, respectively.