(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* | Phase 3 | 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 | Phase 2 | In-house |
| | | US | Phase 1 | |
| MT-3995 | Selective mineralocorticoid receptor antagonist (Diabetic nephropathy) | Europe | Phase 2 | In-house |
| | | Japan | Phase 2 | |
| | | US | Phase 1 | |
| MT-1303 | S1P receptor functional antagonist (Multiple sclerosis) | Europe | Phase 2 | In-house |
| | (Psoriasis) | Europe | Phase 2 | |
| | (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 |

*: Co-developed with FORUM Pharmaceuticals.

## ii. Additional Indications

| Product name (Generic name) | Category (Indications) | Region | Stage | Origin | Notes |
|---|---|---|---|---|---|
| Telavic (Telaprevir) | NS3-4A protease inhibitor (Chronic hepatitis C, [combination with Pegasys] ) | Japan | Phase 3 | US:Vertex Pharmaceuticals | |
| | (Chronic hepatitis C, [combination with Feron] ) | | Phase 3 | | |
| Talion (Bepotastine) | Selective histamine H1 receptor antagonist, anti-allergic agent (Pediatric allergic rhinitis) | Japan | sNDA filed (May, 2014) | Japan: Ube Industries | |
| | (Pediatric atopic dermatitis) | | sNDA filed (May, 2014) | | |
| Radicut (Edaravone) | Free radical scavenger (Amyotrophic lateral sclerosis*) | Japan | sNDA filed (Oct., 2014) | In-house | |
| Remicade (Infliximab [recombinant]) | Anti-human TNFα monoclonal antibody (Behcet's disease with special lesions*) | Japan | sNDA filed (Oct., 2014) | US:Janssen Biotech | |
| | (Refractory Kawasaki disease*) | | Phase 3 | | |
| | (Pediatric Crohn's disease) | | Phase 3 | | |
| | (Pediatric ulcerative colitis) | | Phase 3 | | |
| | (Psoriasis: increased dose) | | Phase 3 | | |
| 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 | Co-developed with The Research Foundation for Microbial Diseases of Osaka University |
| Canaglu (Canagliflozin) | SGLT2 inhibitor (Diabetic nephropathy) | Global clinical trial | Phase 3 | In-house | Sponsor: Janssen Research & Development, LLC |
| BindRen (Colestilan[INN]) | Non-absorbed phosphate binder (Pediatric hyperphosphatemia) | Europe | Phase 3 | In-house | |
| Cholebine (Colestimide[JAN]) | Bile acid signal regulation (Type 2 diabetes mellitus) | Japan | Phase 2 | In-house | |
| | Non-absorbed phosphate binder (Hyperphosphatemia) | | Phase 1 | | |

* 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 |
| | (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*1 | 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*2 (Development code: OTX015) |
| | (Solid cancer) | Europe, Canada | Phase 1 | |

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

*2 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*1) | Japan | Phase 3 | sNDA filed (Oct., 2014) |
| Remicade (Infliximab [recombinant]) | Anti-human TNFα monoclonal antibody (Behcet's disease with special lesions*1) | Japan | Phase 3 | sNDA filed (Oct., 2014) |

*1 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*2 |
| Y-803 | Bromodomain inhibitor (Solid cancer) | Europe, Canada | None | Phase 1 |

*2 20mg/1000mg(teneligliptin/metformin), 10mg/750mg and 10mg/500mg were submitted in Oct., Nov., and Dec. 2014, respectively.