Agenda

1. Development Pipeline Status

2. Major Development Projects
   - Overseas Development Status
   - Diabetes
   - Autoimmune disease
   - Others
1. Development Pipeline Status
1. Development Pipeline Status
< Japan >

Changes from October 29, 2009 to 12 May, 2010

**Japan**

- Metabolism/Cardiovascular
  - Immunology
  - CNS
  - Others

**Phase 1**
- Cholebine (Hyperphosphatemia)
- MP-435 (Rheumatoid Arthritis)
- MT-4666 (Alzheimer's disease)
- TA-7284 (Diabetes Mellitus)

**Phase 2**
- Cholebine (Type 2 Diabetes Mellitus)
- FTY720 (Multiple Sclerosis)
- MP-214 (Schizophrenia)

**Phase 3**
- MP-513 (Type 2 Diabetes Mellitus)
- CNT0148 (Rheumatoid Arthritis)
- Remicade (Crohn's disease)
- APTA-2217 (COPD)
- APTA-2217 (Asthma)
- VG-IH (Myasthenia Gravis)
- VG-IH (Systemic Sclerosis)
- Modiodal (OSAS)
- Radicut (ALS)
- MP-424 (Chronic Hepatitis C)

**Filed**
- BK-4SP (vaccine) *1
- TA-8317/ACREF (Breakthrough Cancer Pain)
- Omeprazone * (additional 3 indications)

**Discontinued**
- TA-6666 (Type 2 Diabetes Mellitus)
- MCC-847 (Allergic Rhinitis) (Asthma)

**Approved (Japan)**
- Radicut (add. Form. BAG)
- Remicade (Psoriasis)
- Remicade (Ankylosing Spondylitis)
- Pazucross (Additional dose, Sepsis/Pneumococcus)
- Remicade (Ulcetative Colitis)
- VG-IH (Hypo-, Agammaglobulinemia)
- VG-IH (IgG2 deficiency)
- VG-IH (Polymyositis, Dermatomyositis)
- TA-8317/ACREF (Breakthrough Cancer Pain)

**Stage Up**
- Remicade (Psoriasis)
- Remicade (Ankylosing Spondylitis)
1. Development Pipeline Status

<Overseas> In-house developments, licensed products

Changes from October 29, 2009 to 12 May, 2010

Overseas (in-house development products)

- MP-124 (Stroke)
- MP-136 (Dyslipidemia)
- TA-8995 (Dyslipidemia)
- TA-5493 (Rheumatoid Arthritis, Psoriasis)
- GB-1057 (Stabilizing Agent)

Overseas (main licensed products)

- TA-7284 (Obesity)
- T-0047 (Multiple Sclerosis)
- TA-6666 (Type 2 Diabetes Mellitus)
- TA-5538 (Overactive Bladder)
- MCC-135 (Myocardial Infarction)

Phase 1

- Phase Up

Phase 2

- TA-7284 (Diabetes Mellitus)
- T-0047 (Multiple Sclerosis)

Phase 3

- TA-7284 (Diabetes Mellitus)
- TA-1790 (US) (Erectile Dysfunction)
- TA-1790 (Korea) (Erectile Dysfunction)

Filed

- FTY720 (Multiple Sclerosis)

Discontinued

- Argatroban* (HIT) (EU)
- Discontinued

Others

- MCI-186 (Stroke)
- MCI-186 (Diabetes Mellitus)
- MT-2832 (Secondary Hyperparathyroidism)
- MCC-257 (Diabetic Neuropathy)
- MB-1 (Dyslipidemia)
- MP-136 (Stroke)
- MP-136 (Dyslipidemia)
- MP-136 (Type 2 Diabetes Mellitus)
- MCC-257 (Diabetic Neuropathy)
- MCI-196 (Hyperphosphatemia)
- MP-146 (Chronic Kidney Disease)
- MP-136 (Type 2 Diabetes Mellitus)
- TA-5538 (Overactive Bladder)
- MCC-135 (Myocardial Infarction)
2. Major Development Products

Overseas Development Status
Major Development Projects [Overseas]

In-house Developments
- MCI-196 (Hyperphosphatemia)
- MP-146 (CKD)
- MT-2832 (Secondary hyperparathyroidism)

Licensing-Out
- FTY720 (MS)
- TA-7284 (Diabetes)

Objective: NDA in FY2010
- Steady progress in P3
- Steady progress in P2

Novartis Pharma
 Filed in Dec. 2009
- Johnson & Johnson Pharmaceutical Research & Development, LLC

File
Approval
Oral Antidiabetic Agent Market

Increasing sales forecasts in major countries

Data Source; Data Monitor
“Commercial Insight: Antidiabetics Forecast Data Summary, IMHC0297, 09/2009”
**MP-513  (Teneligliptin)**

### Status of Development
- **Japan:** Phase 3
- **US/Europe:** Phase 2
  - Under negotiation for licensing

### Competitors in Japan

<table>
<thead>
<tr>
<th>Phase</th>
<th>Launched</th>
<th>Approved</th>
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<tbody>
<tr>
<td></td>
<td>Sitagliptin, Vildagliptin</td>
<td>Alogliptin</td>
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<tr>
<td>Phase 3</td>
<td>Linagliptin</td>
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<td>Teneligliptin (MTPC)</td>
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<td>SK0403</td>
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<td>Saxagliptin</td>
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### Characteristics
- May improve hyperglycemia with an oral once daily low dose
- Low excretion rate from kidneys (possible potential no dosage adjustment is required on the patients with low kidney functions)

### Results of Clinical Trials
- **Japan Diabetes Society (May)**
- **American Diabetes Association (June)**
TA-7284 (Canagliflozin)

**Status of Development**
- Japan: Phase 2 by MTPC
- US/Europe: Phase 3, licensed out
  - Development by Johnson & Johnson Pharmaceutical Research & Development, LLC (Planned filing 2012)

■ SGLT2 inhibitors under development

<table>
<thead>
<tr>
<th>(Japan)</th>
<th>(Overseas)</th>
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<tbody>
<tr>
<td>Phase 3</td>
<td>Dapagliflozin TA-7284/Canagliflozin</td>
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<tr>
<td>Phase 2</td>
<td>Dapagliflozin TA-7284/Canagliflozin</td>
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<td>RG7201/CSG452</td>
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<td>Canagliflozin (MTPC)</td>
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<td>BI10773</td>
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<td>RG7201/CSG452</td>
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<td>ASP1941</td>
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</table>

■ Characteristics
- Potent blood glucose lowering + weight reduction
- Insulin-independent mechanism

■ Results of Clinical Trials
  - Japan Diabetes Society (May)
  - American Diabetes Association (June)
Autoimmune disease
**FTY720 (Multiple Sclerosis)**

**[Status of Development]**
- Overseas: Licensing-out to Novartis, NDA filed last December in US and Europe
- Japan: Co-development with Novartis K.K, NDA filing to be planned at the end of 2010*1

**[Competitors]**
- Current treatment (injection only)

<table>
<thead>
<tr>
<th>Drug name</th>
<th>Avonex</th>
<th>Rebif</th>
<th>Betaferon</th>
<th>Copaxone (glatiramer acetate)</th>
<th>Tysabri (natalizumab)</th>
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</thead>
<tbody>
<tr>
<td>Dosage, Administration</td>
<td>IM 1/wk</td>
<td>SC 3/wk</td>
<td>SC Alternate-day</td>
<td>SC 1/day</td>
<td>IV 1/month</td>
</tr>
</tbody>
</table>

**[AAN, Apr. 2010]**

**TRANSFORMS extension study**

*ARR*:
- IFN 1y: 0.31
- IFN 1y → FTY720 0.5mg 1y: 0.22

*Cumulative number *2:
- IFN 1y: 2.1
- IFN 1y → FTY720 0.5mg 1y: 0.7

*2: Cumulative number of new/newly enlarged T2 lesions

*1: when results of Phase 2 studies yield expected outcomes
Remicade (Life Cycle Management)

RA (July, 2003)
RA (dose escalation) (July, 2009)

BD (eyes) (Jan. 2007)

RA (dose escalation) (July, 2009)

CD (Jan. 2002)

CD (maintenance) (Nov. 2007)

CD (dose escalation): Phase 3

AS: approved in April 2010

Psoriasis: approved in January 2010

UC: sNDA, June 2009

CD: Crohn’s disease
RA: Rheumatoid arthritis
BD: Behcet’s disease (uveoretinitis)
AS: Ankylosing spondylitis
UC: Ulcerative colitis

Approved
NDA on file
Under clinical trial
Under review
Results of P3 clinical trial in Japan

PASI score improvement ratio of each PS subtype
(Results of a Long term trial)

- ●: Overall
- ○: Plaque psoriasis (n=37)
- △: Psoriasis arthropathica (n=12)
- □: Pustular psoriasis (n=7)
- ◇: Erythrodermic psoriasis (n=8)

Approved in January 2010

Remicade (Psoriasis)
Indication for Ankylosing Spondylitis was approved in May, 2003 in Europe and December, 2004 in the US
Remicade (Ankylosing Spondylitis)
Results of Phase 3 clinical trial in Japan

ASAS components: global patient assessment, spinal pain, physical function, morning stiffness/inflammation

Japan College of Rheumatology, April 2010
Remicade (Ulcerative Colitis)  
Results of Phase 3 clinical trial Overseas

【Filed】 June, 2009

ACT1

Clinical response(%)

8 30 54 week

Primary Endpoint

*: p<0.001  
**: p=0.002

placebo  5mg of infliximab  10mg of infliximab

Primary Endpoint

ACT2

8 30 week

Results of Phase 3 clinical trial Overseas

Modified from “Rutgeerts P et al., NEJM. 2005:323(23):2462-2476”
## Competitor's of Remicade in Japan

<table>
<thead>
<tr>
<th>Product name</th>
<th>Remicade</th>
<th>Enbrel</th>
<th>Humira</th>
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<tbody>
<tr>
<td>Development</td>
<td>MTPC</td>
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<td>Eisai/Abbott</td>
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<tr>
<td>Indications</td>
<td>- CD</td>
<td>RA</td>
<td>RA</td>
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<tr>
<td></td>
<td>- RA</td>
<td>JIA</td>
<td>PS</td>
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<tr>
<td></td>
<td>- BD</td>
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<tr>
<td></td>
<td>- PS</td>
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<tr>
<td></td>
<td>- AS</td>
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<td>Filed/</td>
<td>Filed: UC</td>
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<td>Filed: CD, AS</td>
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<tr>
<td>Development</td>
<td>P3: CD (dose escalation)</td>
<td></td>
<td>P2/3: UC, JIA</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Product name</th>
<th>Actemra</th>
<th>Orenchia</th>
<th>Cimzia</th>
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</thead>
<tbody>
<tr>
<td>Development</td>
<td>Chugai</td>
<td>BMS</td>
<td>UCB/Otsuka</td>
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<tr>
<td>Indications</td>
<td>RA</td>
<td>JIA</td>
<td>—</td>
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<tr>
<td></td>
<td>Castleman's disease</td>
<td>—</td>
<td>—</td>
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<tr>
<td>Filed/</td>
<td>P1/2: RA (SC administration)</td>
<td>Filed: RA (April 2010: Division deliberation)</td>
<td>P3: CD, RA</td>
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<tr>
<td>Development</td>
<td></td>
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</tbody>
</table>

**Abbreviations:**
- CD: Crohn’s disease
- RA: Rheumatoid arthritis
- BD: Behcet’s disease (uveoretinitis)
- AS: Ankylosing spondylitis
- UC: Ulcerative colitis
- PS: Psoriasis
- JIA: Juvenile idiopathic arthritis

**Notes:**
- Enbrel is from Wyeth (Pfizer) / Takeda.
- Actemra is from Chugai.
- Orenchia is from BMS.
- Cimzia is from UCB/Otsuka.
CNTO148 (Rheumatoid Arthritis)

【Development Status】
・Japan: Co-development (Janssen Pharma)
  Phase 2/3, preparations for NDA filing
・Overseas: Launched in Europe and US
  (by Johnson and Johnson/MSD)

【Mechanism・Product profile】
・Anti-TNF α monoclonal antibody
・Injection solution for subcutaneous use
・Once per month
Primary endpoint:
ACR20 response at week 14
CNTO148 + MTX: 55%
Placebo + MTX: 33%
(p=0.001)

Partly modified from:
MP-435 (Rheumatoid Arthritis)

**[Status of Development]**
- Japan: Own development, will stage up to Phase 2 soon
- Overseas: Licensing-out to Jansen Pharmaceutica

**[Mechanism of Action]**
Anti immunosuppression and anti inflammatory action by C5a receptor antagonism

![Diagram](attachment:image.png)
Others
MP-424 (Chronic Hepatitis C)

< Phase 3 schedule >

<table>
<thead>
<tr>
<th>Year</th>
<th>Subjects</th>
<th>Treatment</th>
<th>Follow up</th>
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<tbody>
<tr>
<td>2008Y</td>
<td>Naïve</td>
<td>424/PEG/RBV 12W</td>
<td>PEG/RBV 12W</td>
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<td>Relapsers</td>
<td>424/PEG/RBV 12W</td>
<td>PEG/RBV 12W</td>
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<tr>
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<td>Non responders</td>
<td>424/PEG/RBV 12W</td>
<td>PEG/RBV 12W</td>
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<tr>
<td>2009Y</td>
<td>Naïve</td>
<td>PEG/RBV 48W</td>
<td>Follow up</td>
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<td>Relapsers</td>
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<td>Non responders</td>
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<td>2010Y</td>
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<td>Non responders</td>
<td>424/PEG/RBV 12W</td>
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<tr>
<td>2011Y</td>
<td>Naïve</td>
<td>PEG/RBV 12W</td>
<td>Follow up</td>
</tr>
</tbody>
</table>

PEG: PEG–Interferon Alfa– 2b
RBV: Ribavirin

Japan: Priority advice designated product (February 2008)

SVR*: Sustained Viral Response
**BK-4SP (Combined Vaccine)**

- **Present**
  - Diphtheria
  - Pertussis
  - Tetanus
  - Poliovirus (oral/live vaccine)

- **New Development**
  - Diphtheria
  - Pertussis
  - Tetanus
  - Poliovirus (Inactivated vaccine)

- Use inactivated poliovirus
  - Possible prevention of side reactions (paralysis) and secondary infection
- Reduce patients burden by simultaneous inoculation

**Development Status**
Started Phase 3 co-development with The Research Foundation for Microbial Diseases of Osaka University
Cautionary Statement

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