

## Annual Flash Report (unaudited)

Fiscal Year ended March 31, 2014

### Supplemental Information

## Status of Development Pipeline

as of May 13, 2014

### Developments in Japan

#### *NDA filed (New Chemical Entities):*

- **ONO-4538 / BMS-936558 (injection)**  
Melanoma [human anti-human PD-1 monoclonal antibody]

#### *NDA filed (New Formulation):*

- **Opalmon® Tablets (Co-development with Dainippon Sumitomo Pharma Co., Ltd.)**  
Thromboangitis obliterans and lumbar spinal canal stenosis [Blood vessel dilation]

#### *NDA filed (Additional Formulation):*

- **Onoact® Intravenous Infusion 150 mg (ONO-1101) \*1**  
Post operative tachyarrhythmia under monitoring hemodynamics, Tachyarrhythmia in low cardiac function [Short acting beta 1 blocker]

#### *NDA filed (Additional Indication):*

- **Glactiv® Tablets (ONO-5435 / MK-0431) (Co-development with Merck & Co., Inc.)**  
Type 2 diabetes: combination therapy with a rapid-acting insulin secretagogue [DPP-4 inhibitor]

#### *Ongoing clinical studies (New Chemical Entities):*

- **ONO-4538 / BMS-936558 (injection)**  
Renal cell cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-7057 / Carfilzomib (injection) \*2 (In-licensed from Onyx Pharmaceuticals, Inc.)**  
Multiple Myeloma (Phase III) [Proteasome inhibitor]
- **ONO-2745 / CNS 7056 (injection) (In-licensed from PAION AG)**  
Short acting general anesthetic (Phase II / III) [GABA<sub>A</sub> receptor modulator]
- **ONO-7165 / EMD51144 (injection) (Co-development with Merck KGaA)**  
Non-small cell lung cancer (Phase II) [Therapeutic cancer peptide vaccine targeting the tumor antigen MUC-1]
- **ONO-4641 (tablet)**  
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-3849 / Methylalntrexone bromide (injection) (In-licensed from Progenics Pharmaceuticals, Inc.)**  
Opioid-induced constipation (Phase II) [Mu-opioid receptor antagonist]
- **ONO-7643 / RC-1291 (tablet) (In-licensed from Helsinn Therapeutics (U.S.), Inc.)**  
Cancer anorexia / cachexia (Phase II) [Ghrelin mimetic]
- **ONO-4538 / BMS-936558 (injection)**  
Esophageal cancer (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
Non-small cell lung cancer (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-1162 / Ivabradine (tablet) (In-licensed from Les Laboratoires Servier)**  
Chronic heart failure (Phase II) [If channel inhibitor]
- **ONO-5163 / AMG-416 (injection) (In-licensed from Amgen Inc.)**  
Secondary hyperparathyroidism (Phase I / II) [Calcium

sensing receptor agonist]

- **ONO-6950 (tablet)**  
Bronchial asthma (Phase I) [LT receptor antagonist]
- **ONO-7056 / Salirasib (tablet) (In-licensed from Kadmon Corporation LLC)**  
Solid tumor (Phase I) [Ras signal inhibitor]
- **ONO-7268 MX1 (injection) (In-licensed from OncoTherapy Science, Inc.)**  
Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-7268 MX2 (injection) (In-licensed from OncoTherapy Science, Inc.)**  
Hepatocellular carcinoma (Phase I) [Therapeutic cancer peptide vaccines]
- **ONO-2160/CD (tablet)**  
Parkinson's disease (Phase I) [levodopa pro-drug]
- **ONO-4053 (tablet) \*3**  
Allergic rhinitis (Phase I) [PGD2 receptor antagonist]

#### *Ongoing clinical studies (Additional Indications):*

- **Proemend® for i.v. infusion (ONO-7847 / MK-0517) (In-licensed from Merck & Co., Inc.)**  
Chemotherapy-induced nausea and vomiting in pediatric patients (Phase III) [NK1 receptor antagonist]
- **Orencia® IV (ONO-4164IV / BMS-188667IV) (Co-development with Bristol-Myers Squibb Company)**  
Juvenile Rheumatoid Arthritis (Phase III) [T-cell activation inhibitor]
- **Orencia® IV (ONO-4164IV / BMS-188667IV) (Co-development with Bristol-Myers Squibb Company)**  
Lupus nephritis (Phase III) [T-cell activation inhibitor]

#### *Ongoing clinical studies (Additional Dosing Regimen):*

- **Rivastach® Patch (ONO-2540 / ENA713D) (Co-development with Novartis Pharma AG)**  
Alzheimer's disease (Phase III) [dual inhibitor of AChE and BuChE]

*In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.*

### Developments abroad

#### *Ongoing clinical studies (New Chemical Entities):*

- **ONO-4538 / BMS-936558 (injection) (Out-licensed to Bristol-Myers Squibb Company)**  
Renal cell cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) (Out-licensed to Bristol-Myers Squibb Company)**  
Non-small cell lung cancer (Phase III) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) (Out-licensed to Bristol-Myers Squibb Company)**  
Melanoma (Phase III) [human anti-human PD-1 monoclonal antibody]

- **ONO-4538 / BMS-936558 (injection) \*4**  
(Out-licensed to Bristol-Myers Squibb Company)  
Glioblastoma (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) \*5**  
(Out-licensed to Bristol-Myers Squibb Company)  
Diffuse large B cell lymphoma (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection) \*6**  
(Out-licensed to Bristol-Myers Squibb Company)  
Follicular lymphoma (Phase II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4641 (tablet)**  
(Out-licensed to Merck KGaA)  
Multiple sclerosis (Phase II) [S1P receptor agonist]
- **ONO-6950 (tablet)**  
Bronchial asthma (Phase II) [LT receptor antagonist]
- **ONO-4053 (tablet)**  
Allergic rhinitis (Phase II) [PGD2 receptor antagonist]
- **ONO-2952 (tablet)**  
Irritable bowel syndrome (Phase II) [TSPO antagonist]
- **ONO-9054 (eye drop)**  
Glaucoma, ocular hypertension (Phase II) [PG receptor (FP / EP3) agonist]
- **ONO-4538 / BMS-936558 (injection) \*7**  
(Out-licensed to Bristol-Myers Squibb Company)  
Colon cancer (Phase I/II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Solid tumors (triple negative breast cancer, stomach cancer, pancreatic cancer, small cell lung cancer (Phase I/II) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Hepatocellular carcinoma (Phase I) [human anti-human PD-1 monoclonal antibody]
- **ONO-4538 / BMS-936558 (injection)**  
(Out-licensed to Bristol-Myers Squibb Company)  
Hepatitis C (Phase I) [human anti-human PD-1 monoclonal antibody]
- **ONO-4059 (capsule)**  
B cell lymphoma (Phase I) [Bruton's tyrosine kinase (Btk) inhibitor]
- **ONO-8055 (tablet)**  
Underactive bladder (Phase I) [PG receptor (EP2 / EP3) agonist]
- **ONO-8539 (tablet)**  
Gastroesophageal reflux disease (GERD) (Phase I) [PG receptor (EP1) antagonist]
- **ONO-1266 (capsule)**  
Portal hypertension (Phase I) [S1P receptor antagonist]
- **ONO-4232 (injection)**  
Acute heart failure (Phase I) [PG receptor (EP4) agonist]

*In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.*

#### Changes from Third Quarter Flash Report for the Fiscal Year ending March 2014 announced on February 4, 2014

- \*1: High content formulation of Onoact® **Intravenous Infusion 150 mg (ONO-1101)** was filed for the purpose of improvement in convenience.
- \*2: Phase III clinical study of ONO-7057 / Carfilzomib (proteasome inhibitor) was initiated for the treatment of multiple myeloma.
- \*3: Phase I clinical study of ONO-4053 (PGD2 receptor antagonist) was initiated for the treatment of allergic rhinitis.
- \*4: Phase II clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of glioblastoma.
- \*5: Phase II clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of diffuse large B cell lymphoma.
- \*6: Phase II clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of follicular lymphoma.
- \*7: Phase I/II clinical study of ONO-4538/BMS-936558 (human anti-human PD-1 monoclonal antibody) was initiated for the treatment of colon cancer.
- \*: Phase I clinical study of ONO-7746 (TPO receptor agonist) for the treatment of thrombocytopenia was terminated from strategic points of view and the license was returned to Nissan Chemical Industries, Ltd..