Annual Flash Report (unaudited)
Fiscal Year ended March 31, 2015

Supplemental Information

Status of Development Pipeline
as of May 12, 2015

I. Main Pipelines Other than ONO-4538

ⅰ. Developments Status in Japan

Approved

- **Onoact® Intravenous Infusion 150 mg (ONO-1101)*1**
  - **Additional formulation**
  - Intraoperative tachyarrhythmia, Post operative tachyarrhythmia under monitoring hemodynamics, tachyarrhythmia in low cardiac function [Short acting beta 1 blocker]
  - Injection
  - ***In-house***

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- **Rivastach® Patch (ONO-2540 / ENA713D)**
  - **Additional Dosing Regimen**
  - Alzheimer's disease [dual inhibitor of AChE and BuChE]
  - Transdermal patch
  - ***In-license (Novartis Pharma AG)***

Ongoing clinical studies

- **Proemend® for i.v. infusion (ONO-7847 / MK-0517)**
  - **Additional indication for pediatric use**
  - Chemotherapy-induced nausea and vomiting in pediatric patients [NK_1 receptor antagonist] / Phase III
  - Injection
  - ***In-license (Merck & Co., Inc.)***
- **Orencia® IV (ONO-4164 / BMS-188667)**
  - **Additional indication**
  - Juvenile Rheumatoid Arthritis [T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **Orencia® IV (ONO-4164 / BMS-188667)**
  - **Additional indication**
  - Lupus nephritis[T-cell activation inhibitor] / Phase III
  - Injection
  - ***In-license (Bristol-Myers Squibb Company)***
- **ONO-7057 / Carfilzomib**
  - **New chemical entities**
  - Multiple Myeloma [Proteasome inhibitor] / Phase III
  - Injection
  - ***In-license (Onyx Pharmaceuticals, Inc.)***
- **ONO-5163 / AMG-416**
  - **New chemical entities**
  - Secondary hyperparathyroidism [Calcium sensing receptor agonist] / Phase III
  - Injection
  - ***In-license (Amgen Inc.)***
- **Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)*2**
  - **Additional indication for pediatric use**
  - Tachyarrhythmia in low cardiac function [Short acting beta 1 blocker] / Phase II/III
  - Injection
  - ***In-house***
- **ONO-7643 / RC-1291**
  - **New chemical entities**
  - Cancer anorexia/cachexia [Ghrelin mimetic] / Phase II
  - Tablet
  - ***In-license (Helsinn Healthcare, S.A.)***
- **ONO-1162 / Ivabradine**
  - **New chemical entities**
  - Chronic heart failure [If channel inhibitor] / Phase II
  - Tablet
  - ***In-license (Les Laboratoires Servier)***

Ongoing clinical studies

- **ONO-6950**
  - **New chemical entities**
  - Bronchial asthma [LT receptor antagonist] / Phase II
  - Tablet
  - ***In-house***
- **ONO-4053**
  - **New chemical entities**
  - Allergic rhinitis [PGD2 receptor antagonist] / Phase II
  - Tablet
  - ***In-house***
- **ONO-7056 / Salirasib**
  - **New chemical entities**
  - Solid tumor [Ras signal inhibitor] / Phase I
  - Tablet
  - ***In-license (Kadmon Corporation LLC)***
- **ONO-7268 MX1**
  - **New chemical entities**
  - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines] / Phase I
  - Injection
  - ***In-license (OncoTherapy Science, Inc.)***
- **ONO-7268 MX2**
  - **New chemical entities**
  - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines] / Phase I
  - Injection
  - ***In-license (OncoTherapy Science, Inc.)***
- **ONO-2160/CD**
  - **New chemical entities**
  - Parkinson's disease [levodopa pro-drug] / Phase I
  - Tablet
  - ***In-house***
- **ONO-2370 / Opicapone**
  - **New chemical entities**
  - Parkinson's disease [Long acting COMT inhibitor] / Phase I
  - Tablet
  - ***In-license (Bial)***
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - Capsule
  - ***In-house***
- **ONO-5371 / Metyrosine**
  - **New chemical entities**
  - Pheochromocytoma [Tyrosine hydroxylase inhibitor] / Phase I
  - Capsule
  - ***In-license (Valeant Pharmaceuticals North America LLC.)***

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*1: Marketing authorization of Onoact® Intravenous Infusion 150 mg (Short acting beta 1 blocker) (high content formulation) was obtained in Japan for the purpose of improvement in convenience.
*2: Phase II/III of Onoact® Intravenous Infusion 50 mg/150 mg (Short acting beta 1 blocker) was initiated for tachyarrhythmia in pediatric low cardiac function.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

ⅱ. Developments Status outside Japan

Ongoing clinical studies

- **ONO-6950**
  - **New chemical entities**
  - Bronchial asthma [LT receptor antagonist] / Phase II
  - Tablet
  - USA
  - ***In-house***
- **ONO-4053**
  - **New chemical entities**
  - Allergic rhinitis [PGD2 receptor antagonist] / Phase II
  - Tablet
  - Europe
  - ***In-house***
- **ONO-2952**
  - **New chemical entities**
  - Irritable bowel syndrome [TSPO antagonist] / Phase II
  - Tablet
  - USA
  - ***In-house***
- **ONO-9054**
  - **New chemical entities**
  - Glaucoma, ocular hypertension [PG receptor (FP / EP3) agonist] / Phase II
  - Eye drop
  - USA
  - ***In-house***
- **ONO-4059**
  - **New chemical entities**
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - Capsule
  - Europe
  - ***In-house***
- **ONO-8055**
  - **New chemical entities**
  - Underactive bladder [PG receptor (EP2 / EP3) agonist] / Phase I
  - Tablet
  - Europe
  - ***In-house***
- **ONO-1266**
  - **New chemical entities**
  - Portal hypertension [S1P receptor antagonist] / Phase I
  - Capsule
  - USA
  - ***In-house***
- **ONO-4232**
  - **New chemical entities**
  - Acute heart failure [PG receptor (EP4) agonist] / Phase I
  - Injection
  - USA
  - ***In-house***
- **ONO-4474 *1**
  - **New chemical entities**
  - Osteoarthritis [Tropomyosin receptor kinase (Trk) inhibitor] / Phase I
  - Capsule
  - Europe
  - ***In-house***

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*1: Phase I of ONO-4474 / Osteoarthritis (Tropomyosin receptor kinase (Trk) inhibitor) was initiated in healthy adult volunteers.
*2: Development of ONO-8539 (PG receptor (EP1) antagonist) was discontinued due to no expected treatment effect.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

II. Main Pipelines ONO-4538 etc

ⅰ. Developments Status in Japan, South Korea, and Taiwan

Approved

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558 *1	Melanoma	South Korea	In-house (Co-development with Bristol-Myers Squibb Company)
Ipilimumab	Melanoma	Taiwan	In-license (Bristol-Myers Squibb Company)
	Melanoma	South Korea	In-license (Bristol-Myers Squibb Company)

Change from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*1: Marketing authorization of Opdivo® Intravenous Infusion was obtained in South Korea for the treatment of unresectable or metastatic melanoma with disease progression.

Note: "In-house" compounds include a compound generated from collaborative research.

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Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558	Melanoma	Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer *2	Japan Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
Ipilimumab	Melanoma	Japan	In-license (Bristol-Myers Squibb Company)

Change from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*2: Opdivo® Intravenous Infusion was filed in Japan and Taiwan for the treatment of non-small cell lung cancer (except non-squamous cell carcinoma).

Note: "In-house" compounds include a compound generated from collaborative research.

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Renal cell cancer	Phase III	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer	Phase III	South Korea	In-house (Co-development with Bristol-Myers Squibb Company)
	Head and neck cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Gastric cancer	Phase III	Japan South Korea Taiwan	In-house (Co-development with Bristol-Myers Squibb Company)
	Esophageal cancer	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hodgkin's lymphoma	Phase II	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma*3	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumor (combination with Mogamulizumab) *4	Phase I	Japan	In-house (Co-development with Bristol-Myers Squibb Company and Kyowa Hakko Kirin)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*3: Phase I of Opdivo Intravenous Infusion was initiated for the treatment of hepatocellular carcinoma.
*4: Phase I was initiated for the treatment of Solid tumor (combination with Mogamulizumab) by Kyowa Hakko Kirin.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.

ⅱ. Developments Status in Europe and the United States

Approved

Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Melanoma	USA	In-house (Co-development with Bristol-Myers Squibb Company)
	Non-small cell lung cancer *1	USA	In-house (Co-development with Bristol-Myers Squibb Company)

Change from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*1: Marketing authorization of Opdivo® Intravenous Infusion was obtained in USA for the treatment of squamous non-small cell lung cancer.

Note: "In-house" compounds include a compound generated from collaborative research.

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Product Name / Development Code	Development Indications	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-9365588	Non-small cell lung cancer	Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Melanoma	Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Note: "In-house" compounds include a compound generated from collaborative research.

Ongoing clinical studies

Product Name / Development Code	Development Indications	Clinical Stage	Area	In-house / In-license
Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558	Renal cell cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Head and neck cancer	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Glioblastoma	Phase III	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Diffuse large B cell lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Follicular lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hodgkin's lymphoma	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Bladder cancer *2	Phase II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Colon cancer	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, bladder cancer)	Phase I/II	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatocellular carcinoma	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hematologic cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc.)	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Chronic myeloid leukemia	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)
	Hepatitis C	Phase I	USA Europe	In-house (Co-development with Bristol-Myers Squibb Company)

Change from Third Quarter Flash Report for the Fiscal Year ending March 2015 announced on February 3, 2015
*2: Phase II was initiated for the treatment of bladder cancer by Bristol-Myers Squibb Company.

Note: "In-house" compounds include a compound generated from collaborative research.
In the case of clinical development of the anticancer compound in the same indication, the most advanced clinical phase is described.