Annual Flash Report (unaudited)
Fiscal Year ended March 31, 2017

Supplemental Information

Status of Development Pipeline

as of May 8, 2017

I. Main Status of Development Pipelines (Oncology)

1. Development Status in Japan

< Approved >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Head and neck cancer *1	Injection	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*1: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo Intravenous Infusion was obtained in Japan for the treatment of recurrent or metastatic head and neck cancer.

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.

< Filed >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Gastric cancer	Injection	In-house (Co-development with Bristol-Myers Squibb)
Kyprolis for Intravenous Infusion	Additional dosage and administration	Multiple Myeloma / Proteasome inhibitor	Injection	In-license (Amgen Inc.)

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.

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Opdivo Intravenous Infusion	Additional indication	Hepatocellular carcinoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Glioblastoma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Ovarian cancer	Injection	III	In-house (Co-development with Bristol-Myers Squibb)
Kyprolis for Intravenous Infusion	Change of dosage and administration	Multiple Myeloma / Proteasome inhibitor	Injection	III	In-license (Amgen Inc.)
ONO-7643 / Anamorelin	New chemical entities	Cancer anorexia / cachexia / Ghrelin mimetic	Tablet	III	In-license (Helsinn Healthcare, S.A.)
Opdivo Intravenous Infusion	Additional indication	Solid tumor (Cervix carcinoma, Uterine body cancer, Soft tissue sarcoma)	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central Nervous System Lymphoma, Primary Testicular Lymphoma	Injection	II	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive/negative solid carcinoma	Injection	I / II	In-house (Co-development with Bristol-Myers Squibb)
ONO-5371 / Metyrosine	New chemical entities	Pheochromocytoma / Tyrosine hydroxylase inhibitor	Capsule	I / II	In-license (Valeant Pharmaceuticals North America LLC.)
ONO-4686 (BMS-986207)	New chemical entities	Solid tumor / Anti-TIGIT antibody	Injection	I / II	In-license (Co-development with Bristol-Myers Squibb)
Opdivo Intravenous Infusion	Additional indication	Biliary tract cancer	Injection	I	In-house (Co-development with Bristol-Myers Squibb)
ONO-7268 MX1	New chemical entities	Hepatocellular carcinoma / Therapeutic cancer peptide vaccines	Injection	I	In-license (OncoTherapy Science, Inc.)
ONO-7268 MX2	New chemical entities	Hepatocellular carcinoma / Therapeutic cancer peptide vaccines	Injection	I	In-license (OncoTherapy Science, Inc.)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-4481 (BMS-663513) / Urelumab	New chemical entities	Solid tumor / Anti-CD137 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4482 (BMS-986016)	New chemical entities	Solid tumor / Anti-LAG-3 antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4687 (BMS-986227) / Cabiralizumab	New chemical entities	Solid tumor and hematologic cancer *2 / Anti-CSF-1R antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-7701 (BMS-986205)	New chemical entities	Solid tumor and hematologic cancer *3 / IDO1 Inhibitor	Capsule	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4483 (BMS-986015) / Lirilumab	New chemical entities	Solid tumor *4 / Anti-KIR antibody	Injection	I	In-license (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Capsule	I	In-house
ONO-4578	New chemical entities	Solid tumor / PG receptor (EP4) antagonist	Tablet	I	In-house

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*2: Phase I of Anti-CSF-1R antibody (ONO-4687 / BMS-986227) was initiated for the treatment of solid tumor and hematologic cancer.
*3: Phase I of IDO1 inhibitor (ONO-7701 / BMS-986205) was initiated for the treatment of solid tumor and hematologic cancer.
*4: Phase I of Anti-KIR antibody (ONO-4483 / BMS-986015) was initiated for the treatment of solid tumor.

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.

2. Development Status in S. Korea and Taiwan

< Approved >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / Out-license
Opdivo Intravenous Infusion	Additional indication	Renal cell carcinoma *5	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*5: Approval for the partial change in approved items of the importing and marketing approval for Opdivo Intravenous Infusion was obtained in Taiwan for the treatment of advanced renal cell carcinoma who have received prior anti-angiogenic therapy.

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.

< Filed >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / Out-license
Opdivo Intravenous Infusion	Additional indication	Non-small cell lung cancer (Non- Squamous)	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer	Injection	Taiwan	In-house (Co-development with Bristol-Myers Squibb)

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.

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / Out-license
Opdivo Intravenous Infusion	Additional indication	Head and neck cancer	Injection	III	South Korea	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Urothelial cancer	Injection	III	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive/negative solid carcinoma	Injection	I / II	South Korea, Taiwan	In-house (Co-development with Bristol-Myers Squibb)

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.

3. Development Status in Europe and the United States

< Approved >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / Out-license
Opdivo Intravenous Infusion	Additional indication	Urothelial cancer *6	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Head and neck cancer *7	Injection	Europe	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*6: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo Intravenous Infusion was obtained in USA for the treatment of patients with locally advanced or metastatic urothelial carcinoma (mUC).

*7: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo Intravenous Infusion was obtained in Europe for the treatment of squamous cell cancer of the head and neck (SCCHN) in adults progressing on or after platinum-based therapy.

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.

< Filed >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Area	In-house*) / Out-license
Opdivo Intravenous Infusion	Additional indication	Urothelial cancer	Injection	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Colon cancer *8	Injection	USA	In-house (Co-development with Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*8: A supplemental application for the partial change in approved items of the manufacturing and marketing approval for Opdivo Intravenous Infusion was submitted in USA for the treatment of previously treated dMMR or MSI-H metastatic colorectal cancer.

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.

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / Out-license
Opdivo Intravenous Infusion	Additional indication	Glioblastoma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Small cell lung cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hepatocellular carcinoma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / Out-license
Opdivo Intravenous Infusion	Additional indication	Esophageal cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Multiple myeloma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastro-esophageal junction cancer and esophageal cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Gastric cancer	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Malignant pleural mesothelioma	Injection	III	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Diffuse large B cell lymphoma	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Follicular lymphoma	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Central Nervous System Lymphoma, Primary Testicular Lymphoma	Injection	II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-4059 / Tirabrutinib	New chemical entities	B cell lymphoma / Bruton's tyrosine kinase (Btk) inhibitor	Capsule	II	Europe USA	Out-license (Gilead Sciences, Inc.)
Opdivo Intravenous Infusion	Additional indication	Colon cancer	Injection	I / II	Europe	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer, ovarian cancer)	Injection	I / II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Virus positive/negative solid carcinoma	Injection	I / II	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Hematologic cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc.)	Injection	I	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Chronic myeloid leukemia	Injection	I	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-7475	New chemical entities	Acute leukemia / Axl / Mer inhibitor	Tablet	I	USA	In-house

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / Out-license
ONO-7579	New chemical entities	Solid tumor / Tropomyosin receptor kinase (Trk) inhibitor	Tablet	I	Europe USA	In-house

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.

I. Main Status of Development Pipelines (other than Oncology)

1. Development Status in Japan

< Filed >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	In-house*) / In-license
Orencia IV *9	Additional indication	Juvenile Idiopathic Arthritis / T-cell activation inhibitor	Injection	In-license (Bristol-Myers Squibb)

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*9: A supplemental application of Orencia intravenous infusion (rheumatoid arthritis treatment) was submitted for the treatment of active polyarticular juvenile idiopathic arthritis (JIA) for a partial change in approved items of manufacturing and marketing approval in Japan.

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

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
Orencia IV	Additional indication	Lupus nephritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
Orencia SC	Additional indication	Untreated rheumatoid arthritis / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
Orencia SC	Additional indication	Primary sjögren syndrome / T-cell activation inhibitor	Injection	III	In-license (Bristol-Myers Squibb)
ONO-1162 / Ivabradine	New chemical entities	Chronic heart failure / If channel inhibitor	Tablet	III	In-license (Les Laboratoires Servier)
Onoact for Intravenous Infusion 50 mg / 150 mg (ONO-1101)	Additional indication for pediatric use	Tachyarrhythmia in low cardiac function / Short acting beta 1 blocker	Injection	II / III	In-house
Onoact for Intravenous Infusion 50 mg / 150 mg (ONO-1101)	Additional indication	Ventricular arrhythmia / Short acting beta 1 blocker	Injection	II / III	In-house
ONO-2370 / Opicapone	New chemical entities	Parkinson’s disease / Long acting COMT inhibitor	Tablet	II	In-license (Bial)
ONO-8577 *10	New chemical entities	Overactive bladder / Bladder smooth muscle relaxant	Tablet	II	In-house

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	In-house*) / In-license
ONO-2160 / CD	New chemical entities	Parkinson's disease / Levodopa pro-drug	Tablet	I	In-house

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*10: Phase II of ONO-8577 (bladder smooth muscle relaxant) was initiated for overactive bladder.

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

2. Development Status in Overseas

< Clinical Trial Stage >

Product Name / Development Code / Generic Name	Classification	Target indication / Pharmacological Action	Dosage form	Phase	Area	In-house*) / Out-license
ONO-4474	New chemical entities	Osteoarthritis / Tropomyosin receptor kinase (Trk) inhibitor	Capsule	II	Europe	In-house
ONO-4059 / Tirabrutinib	New chemical entities	Sjögren syndrome *11 / Bruton's tyrosine kinase (Btk) inhibitor	Tablet	II	USA	Out-license (Gilead Sciences, Inc.)
Opdivo Intravenous Infusion	Additional indication	Hepatitis C	Injection	I	Europe USA	In-house (Co-development with Bristol-Myers Squibb)
	Additional indication	Sepsis	Injection	I	USA	In-house (Co-development with Bristol-Myers Squibb)
ONO-8055	New chemical entities	Underactive bladder / PG receptor (EP2 / EP3) agonist	Tablet	I	Europe	In-house

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2017

*11: Phase II of ONO-4059 (Bruton's tyrosine kinase (Btk) inhibitor) was initiated for Sjögren syndrome.

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