Supplemental Information

Status of Development Pipeline
as of May 9, 2016

I. Main Pipelines Other than ONO-4538

1. Developments Status in Japan

Ongoing clinical studies

- **ONOact** Intravenous Infusion 50 mg / 150 mg (ONO-1101)
  - Additional indication
    - Ventricular arrhythmia [Short acting beta 1 blocker]
      - Phase II/III
    - Injection
    - In-house

- ONO-7643 / RC-1291
  - New chemical entities
    - Cancer anorexia/cachexia [Ghrelin mimetic]
      - Tablet
    - In-license (Helsinn Healthcare, S.A.)

- ONO-6950
  - New chemical entities
    - Bronchial asthma [LT receptor antagonist]
      - Injection
    - In-house

- ONO-2370 / Opicapone
  - New chemical entities
    - Parkinson’s disease [Long acting COMT inhibitor]
      - Tablet
    - In-license (Bial)

- ONO-5371 / Metyrosine
  - New chemical entities
    - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines]
      - Tablet
    - In-license (Valeant Pharmaceuticals North America LLC.)

- ONO-7268 MX1
  - New chemical entities
    - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines]
      - Injection
    - In-license (OncoTherapy Science, Inc.)

- ONO-7268 MX2
  - New chemical entities
    - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines]
      - Injection
    - In-license (OncoTherapy Science, Inc.)

- ONO-2160/CD
  - New chemical entities
    - Parkinson’s disease [levodopa pro-drug]
      - Tablet
    - In-house

- ONO-4059
  - New chemical entities
    - B cell lymphoma [Bruton’s tyrosine kinase (Btk) inhibitor]
      - Capsule
    - In-house

- ONO-8577*3
  - New chemical entities
    - Overactive bladder [bladder smooth muscle relaxant]
      - Injection
    - In-house

Approved

- Proemend® for i.v. infusion (ONO-7847 / MK-0517)*1
  - Additional indication for pediatric use
    - Injection
    - In-license (Merck & Co., Inc.)

- Orencia® SC (ONO-4164 / BMS-188667)*2
  - Additional formulation
    - Orencia® SC 125 mg Auto-injector 1 mL
      - Injection
    - In-license (Bristol-Myers Squibb Company)

Filed

- ONO-7057 / Carfilzomib
  - New chemical entities
    - Multiple Myeloma [Proteasome inhibitor]
      - Injection
    - In-license (Onyx Pharmaceuticals, Inc.)

- ONO-5163 / AMG-416 / Etecalcetide Hydrochloride
  - New chemical entities
    - Secondary hyperparathyroidism [Calcium sensing receptor agonist]
      - Injection
    - In-license (Amgen Inc.)

- ONO-2370 / Opicapone
  - New chemical entities
    - Parkinson’s disease [Long acting COMT inhibitor]
      - Injection
    - In-license (Bial)

- ONO-5371 / Metyrosine
  - New chemical entities
    - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines]
      - Tablet
    - In-license (Valeant Pharmaceuticals North America LLC.)

- ONO-7268 MX1
  - New chemical entities
    - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines]
      - Injection
    - In-license (OncoTherapy Science, Inc.)

- ONO-7268 MX2
  - New chemical entities
    - Hepatocellular carcinoma [Therapeutic cancer peptide vaccines]
      - Injection
    - In-license (OncoTherapy Science, Inc.)

- ONO-2160/CD
  - New chemical entities
    - Parkinson’s disease [levodopa pro-drug]
      - Tablet
    - In-house

- ONO-4059
  - New chemical entities
    - B cell lymphoma [Bruton’s tyrosine kinase (Btk) inhibitor]
      - Capsule
    - In-house

- ONO-8577*3
  - New chemical entities
    - Overactive bladder [bladder smooth muscle relaxant]
      - Injection
    - In-house

- ONO-8577*3
  - New chemical entities
    - Overactive bladder [bladder smooth muscle relaxant]
      - Injection
    - In-house

- Onoact® Intravenous Infusion 50 mg / 150 mg (ONO-1101)
  - Additional indication
    - Tachycardia in low cardiac function [Short acting beta 1 blocker]
      - Phase II/III
    - Injection
    - In-house
Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016

*1: Approval for a partial change in approved items of the manufacturing and marketing authorization of Proemend® for intravenous infusion was obtained in Japan for the treatment of chemotherapy-induced nausea and vomiting for pediatric patients.

*2: Orencia® SC was obtained in Japan for the manufacturing and marketing approval of subcutaneous injection 125 mg Auto-injector 1 mL.

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

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.

\[ \text{ii. Developments Status outside Japan} \]

**Ongoing clinical studies**

- **ONO-6950**
  - New chemical entities
  - Bronchial asthma [LT receptor antagonist] / Phase II
  - Tablet
  - USA
  - In-house

- **ONO-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
  - Out-license (Santen Pharmaceutical Co., Ltd.)

- **ONO-4059**
  - New chemical entities
  - B cell lymphoma [Bruton's tyrosine kinase (Btk) inhibitor] / Phase I
  - Capsule
  - USA & Europe
  - Out-license (Gilead Sciences, Inc.)

- **ONO-8055**
  - New chemical entities
  - Tablet
  - Europe
  - In-house

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016

*4: A licensing agreement was entered with Santen Pharmaceutical Co., Ltd. to grant Santen exclusive right to manufacture, develop and commercialize globally ONO-9054, an FP and EP3 dual receptor agonist.

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

<table>
<thead>
<tr>
<th>Product Name / Development Code</th>
<th>Development Indications</th>
<th>Area</th>
<th>In-house / In-license</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558</td>
<td>Non-small cell lung cancer*1</td>
<td>South Korea</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Melanoma*2</td>
<td>Taiwan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Non-small cell lung cancer (Squamous)*2</td>
<td>Taiwan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
</tbody>
</table>

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016

*1: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in South Korea for the additional indication of locally advanced or metastatic non-small cell lung cancer refractory to existing chemotherapy.

*2: The manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in Taiwan for the treatment of unresectable or metastatic melanoma and metastatic squamous non-small cell lung 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.

<table>
<thead>
<tr>
<th>Product Name / Development Code</th>
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<th>Area</th>
<th>In-house / In-license</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558</td>
<td>Non-small cell lung cancer (Non-Squamous)</td>
<td>Taiwan*3</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Renal cell carcinoma</td>
<td>Japan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Hodgkin’s lymphoma*4</td>
<td>Japan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
</tbody>
</table>

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016

*3: A supplemental application for approval for the additional indication of Opdivo® Intravenous Infusion was filed in Taiwan for the treatment of unresectable or metastatic renal cell carcinoma and previously treated non-squamous non-small cell lung cancer.

*4: A supplemental application for approval for the additional indication of Opdivo® Intravenous Infusion was filed in Japan for the treatment of relapsed or refractory Hodgkin’s lymphoma.

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.

### Ongoing clinical studies

<table>
<thead>
<tr>
<th>Product Name / Development Code</th>
<th>Development Indications</th>
<th>Clinical Stage</th>
<th>Area</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Opdivo® Intravenous Infusion (ONO-4538) /BMS-936558</td>
<td>Head and neck cancer</td>
<td>Phase III</td>
<td>Japan South Korea Taiwan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Gastric cancer</td>
<td>Phase III</td>
<td>Japan South Korea Taiwan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td>Product Name / Development Code</td>
<td>Development Indications</td>
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</tr>
<tr>
<td>Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558</td>
<td>Esophageal cancer</td>
<td>Phase III</td>
<td>Japan, South Korea, Taiwan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Small cell lung cancer</td>
<td>Phase III</td>
<td>Japan, South Korea, Taiwan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Hepatocellular carcinoma</td>
<td>Phase III</td>
<td>Japan, South Korea, Taiwan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Glioblastoma</td>
<td>Phase III</td>
<td>Japan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Urothelial cancer*5</td>
<td>Phase III</td>
<td>Japan, South Korea, Taiwan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Ovarian cancer</td>
<td>Phase II</td>
<td>Japan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Solid tumor*6</td>
<td>Phase II</td>
<td>Japan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>(Cervical cancer, Endometrial cancer, Soft tissue sarcoma)</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Malignant pleural mesothelioma*7</td>
<td>Phase II</td>
<td>Japan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Virus-positive/negative solid tumor</td>
<td>Phase I/II</td>
<td>Japan, South Korea, Taiwan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Biliary tract cancer</td>
<td>Phase I</td>
<td>Japan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td>Urelumab (ONO-4481) / BMS-663513</td>
<td>Solid tumor</td>
<td>Phase I</td>
<td>Japan</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
</tbody>
</table>

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.

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016

*5: Phase III of Opdivo® Intravenous Infusion was initiated for the treatment of Urothelial cancer.
*6: Phase II of Opdivo® Intravenous Infusion was initiated for the treatment of Solid tumor (Cervical cancer, Endometrial cancer, and Soft tissue sarcoma).
*7: Phase II of Opdivo® Intravenous Infusion was initiated for the treatment of Malignant pleural mesothelioma.
### Developments Status in Europe and the United States

#### Approved

<table>
<thead>
<tr>
<th>Product Name / Development Code</th>
<th>Development Indications</th>
<th>Area</th>
<th>In-house / In-license</th>
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</thead>
<tbody>
<tr>
<td>Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558</td>
<td>Renal cell carcinoma *8</td>
<td>Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
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<tr>
<td></td>
<td>Non-small cell lung cancer (Non-squamous) *9</td>
<td>Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
</tbody>
</table>

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016

*8: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in Europe for the additional indication of previously treated advanced renal cell carcinoma.

*9: Approval for the partial change in approved items of the manufacturing and marketing approval for Opdivo® Intravenous Infusion was obtained in Europe for the additional indication of locally advanced or metastatic non-squamous non-small cell lung cancer after prior chemotherapy.

**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

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<thead>
<tr>
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<th>Development Indications</th>
<th>Area</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558</td>
<td>Hodgkin’s lymphoma*10</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
</tbody>
</table>

Changes from Third Quarter Flash Report for the Fiscal Year ending March 2016 announced on February 2, 2016

*10: A supplemental application for approval for the additional indication of Opdivo® Intravenous Infusion was filed in USA and Europe for the treatment of previously treated classical Hodgkin lymphoma.

**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.

#### Ongoing clinical studies

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<tr>
<td>Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558</td>
<td>Head and neck cancer</td>
<td>Phase III</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Glioblastoma</td>
<td>Phase III</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Small cell lung cancer</td>
<td>Phase III</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Urothelial cancer</td>
<td>Phase III</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Hepatocellular carcinoma</td>
<td>Phase III</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Esophageal cancer</td>
<td>Phase III</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
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</tr>
<tr>
<td>Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558</td>
<td>Diffuse large B cell lymphoma</td>
<td>Phase II</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
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<td>Follicular lymphoma</td>
<td>Phase II</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
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<tr>
<td></td>
<td>Colon cancer</td>
<td>Phase I/II</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Solid tumors (triple negative breast cancer, gastric cancer, pancreatic cancer, small cell lung cancer, urothelial cancer, ovarian cancer)</td>
<td>Phase I/II</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Virus-positive/negative solid tumor</td>
<td>Phase I/II</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Hematologic cancer (T-cell lymphoma, multiple myeloma, chronic leukemia, etc.)</td>
<td>Phase I</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Chronic myeloid leukemia</td>
<td>Phase I</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C</td>
<td>Phase I</td>
<td>USA Europe</td>
<td>In-house (Co-development with Bristol-Myers Squibb Company)</td>
</tr>
</tbody>
</table>

**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.