### **Annual Flash Report (unaudited)**

Fiscal Year ended March 31, 2018

**Supplemental Information** 

# **Profile for Main Development**

# KYPROLIS® for Intravenous Infusion (ONO-7057) / Carfilzomib (injection)

Kyprolis (ONO-7057) is a proteasome inhibitor, being developed for change in dosage and administration after launched for multiple myeloma. It is highly expected to be a new treatment option for multiple myeloma, which is a cancer of plasma cells (one of blood cells) and prognosis is considered poor.

# Orencia® IV (ONO-4164) / BMS-188667 (injection)

Orencia (ONO-4164) is marketed in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed, after that, additionally approved for the treatment of active polyarticular juvenile idiopathic arthritis (JIA). Also, in overseas, it is marketed for use in patients of rheumatoid arthritis for whom other therapies have failed and with juvenile idiopathic arthritis.

# Orencia® SC (ONO-4164) / BMS-188667 (injection)

Orencia (ONO-4164) is marketed for use in patients of rheumatoid arthritis for whom other therapies have failed.

# ONO-1162 / Ivabradine (tablet)

ONO-1162 is an If channel blocker and is approved for the indication of chronic heart failure in addition to stable angina in Europe. It is under development in Japan for the indication of chronic heart failure.

# Onoact® for Intravenous Infusion 50mg/150 mg (ONO-1101) (injection)

Onoact is being developed for ventricular arrhythmia, tachyarrhythmia upon sepsis, and tachyarrhythmia in low cardiac function in pediatric. It is designated as orphan drugs for rare diseases in August 2016.

# ONO-7643 / Anamorelin (tablet)

ONO-7643 is a small-molecule ghrelin mimetic being developed for cancer anorexia / cachexia. ONO-7643 has similar pharmacological actions to ghrelin, a circulating peptide hormone with multiple physiological actions, including appetite stimulation and muscle-building, and is therefore expected to be a breakthrough drug that improves quality of life (QOL) for patients impaired by a systemic wasting condition characterized by anorexia, lipolysis and muscle loss associated with the progression of cancer.

#### ONO-2370 / Opicapone (tablet)

ONO-2370 is a long acting COMT inhibitor being developed for the treatment of parkinson's disease. ONO-2370 is approved for the treatment of parkinson's disease in overseas by Bial and the compound has shown a long-lasting effect on COMT inhibition from once daily dosing in clinical studies so far and is expected to improve a dosing convenience.

### ONO-5371 / Metyrosine (capsule)

ONO-5371 is a tyrosine hydroxylase inhibitor against catecholamine biosynthesis, and is under clinical development for pheochromocytoma. ONO-5371 was approved and launched in the United States in 1979. In Japan, the Review Committee on Unapproved and Off-Label Drugs with High Medical Needs, set up by the Ministry of Health, Labour and Welfare (MHLW) regarded metyrosine as a drug with high medical needs and MHLW publicly sought pharmaceutical companies to develop metyrosine.

#### ONO-4059 (tablet)

ONO-4059 is a Btk inhibitor being developed for the treatment of B cell lymphoma and Sjögren syndrome.

#### ONO-4059 (capsule)

ONO-4059 is a Btk inhibitor being developed for the treatment of B cell lymphoma.

#### ONO-4578 (tablet)

ONO-4578 is a prostaglandin receptor (EP4) antagonist being developed for the treatment of solid tumor.

#### ONO-8055 (tablet)

ONO-8055 is a prostaglandin receptor (EP2/EP3) agonist being developed for the treatment of underactive bladder.

# ONO-7475 (tablet)

ONO-7475 is a Axl/Mer inhibitor being developed for the treatment of acute leukemia.

#### ONO-7579 (tablet)

ONO-7579 is a tropomyosin receptor kinase (Trk) inhibitor being developed for the treatment of solid tumor.

# Opdivo® Intravenous Infusion (ONO-4538) / BMS-936558 (injection)

Opdivo (ONO-4538), a human anti-human PD-1 monoclonal antibody, is being developed for the treatment of cancer etc. PD-1 is one of the receptors expressed on activated lymphocytes, and is involved in the negative regulatory system to suppress the activated lymphocytes. It has been reported that tumor cells utilize this system to escape from the host immune responses. It is anticipated that blockade of the negative regulatory signal mediated by PD-1 will promote the host's immune response, in which tumor cells and viruses are recognized as foreign and eliminated.

# Yervoy® Intravenous Infusion (ONO-4480) / Ipilimumab (injection)

Yervoy (ONO-4480), a human anti-human CTLA-4 monoclonal antibody, is being developed for the treatment of cancer.

In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

### ONO-4481 / Urelumab / BMS-663513 (injection)

ONO-4481, a human anti-human CD137 monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

# ONO-4482 / Relatimab / BMS-986016 (injection)

ONO-4482, a human anti-human LAG-3 monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

#### ONO-4686 / BMS-986207 (injection)

ONO-4686, a human anti-human TIGIT monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

#### ONO-4687 / Cabiralizumab / BMS-986227 (injection)

ONO-4687, a human anti-human CSF-1R monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

# ONO-7701 / BMS-986205 (capsule)

ONO-7701, IDO1 inhibitor, is being developed for the treatment of cancer.

In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

# ONO-4483 / Lirilumab / BMS-986015 (injection)

ONO-4483, a human anti-human KIR monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.

# ONO-7702 / Encorafenib (capsule)

ONO-7702, BRAF inhibitor, is being developed for the treatment of melanoma and colon cancer.

#### ONO-7703 / Binimetinib (tablet)

ONO-7703, MEK inhibitor, is being developed for the treatment of melanoma and colon cancer.

# *ONO-5704 / SI-613 (injection)*

ONO-5704, hyaluronic acid-NSAID, is being developed for the treatment of osteoarthritis and enthesopathy.

### ONO-7807 / BMS-986258 (injection)

ONO-7807, a human anti-human TIM-3 monoclonal antibody, is being developed for the treatment of cancer. In Japan, South Korea, and Taiwan, Ono is co-developing with Bristol-Myers Squibb Company. In the other areas, Bristol-Myers Squibb Company is developing.